KAISER PERMANENTE®

Kaiser Permanente Washington Pre-Authorization requirements:

Kaiser Permanente Washington requires pre-authorization for most services to be covered. The information below outlines pre-authorization requirements at a high level. Some requests for pre-authorization will be reviewed by a clinician for medical necessity. The criteria used to determine medical necessity is also outlined below.

For questions regarding pre-authorization requirements for specific services, please consult your Certificate of Coverage or contact Member Services at 1-888-901-4636.

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Transplants –organ and stem cell transplants	Yes	Your physician will request authorization for all stages including pre-transplant care, transplant, and post-transplant care		Please check your Certificate of Coverage for benefit and cost share information.	

Date Sent: 6/28/23

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Facility admissions: ❖ Skilled Nursing facility ❖ Mental Health facility ❖ Chemical Dependency facility ❖ Long-term Care facility ❖ Rehabilitation facility ❖ Scheduled inpatient admissions to a hospital ❖ Emergency admission to a hospital	<u>Planned/Scheduled Admissions =</u> Yes	<u>Planned/Scheduled Admissions =</u> Your ordering physician will obtain pre-authorization.		Please check your Certificate of Coverage for benefit information and/or limitations for these admissions.	
	<u>Urgent/Emergent Admissions =</u> Notification of the admission to Kaiser Permanente Washington is required	<u>Urgent/Emergent Admissions =</u> The hospital should notify Kaiser Permanente Washington and you should also notify Kaiser Permanente Washington by calling the Hospital Notification line provided on the back of your Kaiser Permanente Washington ID card			

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Surgery – inpatient and outpatient	Yes	Your surgeon's office will coordinate authorization for procedures, including notification of the facility where the procedure will be performed.	Many different procedures may require medical necessity review. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information including what may not be covered.	
Durable Medical Equipment Prosthetics Orthotics	Yes	Your physician and DME vendor will work with Kaiser Permanente Washington to obtain authorization for needed equipment.	Some equipment requires medical necessity review. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information including what may not be covered.	

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Home Health Care	Yes	Your physician and home health care agency will work with Kaiser Permanente Washington to obtain authorization.	Home care services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Hospice	Yes	Your hospice agency will notify Kaiser Permanente Washington when hospice is elected.	None	Please check your Certificate of Coverage for benefit information.	
Radiology – MRI, CT, MRA, PET Scans, Dexa Scans (High End Imaging)	Yes	Your ordering physician will work with Kaiser Permanente Washington to obtain pre-authorization.	None		
Radiology – Diagnostic Radiology i.e. x-rays, ultrasounds	No	N/A	None		
Genetic Testing	Yes	Your ordering physician will work with Kaiser Permanente	Genetic Tests must be medically necessary to be covered. Please consult the Kaiser Permanente		

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
		Washington to obtain pre-authorization.	Washington Clinical Review Criteria for more information.		
Laboratory/Pathology Services (excluding genetic testing)	No	N/A	Some lab/pathology must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.		
Specialty care and specialists inside the network	Yes* *See Women's Health care, and Alternative Health care for specific authorization requirements for these services	Your Primary Care Physician will refer you and obtain pre-authorization for specialty care.		Some specialty care provided at a Kaiser Permanente Washington facility may not need pre-authorization and are allowed as a self-referred service. Please check your Certificate of Coverage for benefit information. Specialty care	

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
				outside of the network is not covered unless emergent or approved in advance by Kaiser Permanente Washington.	
Women's Health care	No – outpatient services do not require authorization	N/A	None	Please check your Certificate of Coverage for benefit information.	
Alternative Health Care - Spinal Manipulations	No	N/A	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	The number of visits is limited. Please check your Certificate of Coverage for limits.	
Alternative Health Care - Acupuncture	No	If required, your provider will submit the request for additional visits.	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	*Your plan may allow additional visits with pre-authorization. Please check your Certificate of Coverage for limits.	

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Alternative Health Care - Naturopathy	No	If required, your provider will submit the request for additional visits.	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	*Your plan may allow additional visits with pre-authorization. Please check your Certificate of Coverage for limits.	
Alternative Health Care - Massage Therapy	No	N/A	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	The number of visits for rehabilitative therapy, which includes massage, speech, physical, and occupational therapy, is limited. Please check your Certificate of Coverage for visit limits.	
Physical Therapy, Occupational Therapy, and Speech Therapy	No	N/A		The number of visits for rehabilitative therapy, which includes massage, speech, physical, and occupational therapy, is limited. Please check your	

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
				Certificate of Coverage for visit limits.	
Mental Health	Yes	Contact Kaiser Permanente Washington Behavioral Health Services	Mental health services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Chemical Dependency	Yes	Contact Kaiser Permanente Washington Behavioral Health Services	Chemical dependency services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Applied Behavioral Analysis (ABA) Therapy	Yes	Your ordering physician will obtain authorization from Kaiser Permanente Washington.	ABA Therapy must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Clinical Trials	Yes	Your ordering physician and trial	Services must be medically necessary to be	Please check your Certificate of	

Public Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
		provider will work with Kaiser Permanente Washington to obtain authorization for covered services.	covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Coverage for benefit information.	
Outpatient Emergency Care	No	N/A		Please see "Facility Admissions" above for authorization requirements if you are admitted to the hospital. Please check your Certificate of Coverage for benefit information.	You can see any provider for emergent care.
Primary Care (PCP)	No	N/A	None	Please check your Certificate of Coverage for benefit information.	

For questions regarding pre-authorization requirements for specific services, please consult your Certificate of Coverage or contact Member Services at 1-888-901-4636.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

4Kscore® Test: Predicting the Risk of Aggressive Prostate Cancer

- 4KRK
- Four Kallikrein Markers
- Kallikrein Panel

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “4Kscore® Test: Predicting the Risk of Aggressive Prostate Cancer” for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Prostate Specific Antigen (PSA) is the most widespread test for prostate cancer (PSA) screening. However, it is associated with a high risk of over detection and overtreatment. Since its introduction into practice in the late 1980s, PSA testing has led to a significant increase in the incidence of prostate cancer and migration to an earlier stage at diagnosis. Most men with an elevated PSA either do not have prostate cancer or have a low-risk disease that is unlikely to affect the quality or length of life if left untreated. Between 17% and 50% of men with prostate cancer detected by PSA test have indolent tumors that would not have led to clinical disease. In addition, PSA levels may be elevated by conditions other than cancer such as benign prostatic hyperplasia, and prostatitis. The specificity and sensitivity of the PSA test used alone in detecting prostate cancer range from 20-40% and 70-90% respectively, with an AUC (area under the receiver operating characteristic [ROC]) curve of 0.55-0.71 (depending on the cutoff value used), and a positive predictive value (PPV) of only 25-40%. The low specificity of the PSA

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test, results in performance of a large number of unnecessary biopsy procedures with the associated anxiety and complications. It is estimated that more than one million men undergo prostate biopsy every year in the USA, the majority of which are potentially avoidable (Vickers 2010, Bratt 2012, Voigt 2014, Parekh 2015).

Continuous efforts are being made to improve the accuracy of the PSA test and/or develop new biomarkers for prostate cancer screening. PSA density and PSA velocity have been used but were found to only slightly improve the predictive value of PSA, to a level that is insufficient to distinguish between aggressive and indolent forms of prostate cancer. PCA3 and TMPRSS2-ERG fusion biomarkers measured in the urine immediately after a vigorous prostate massage, were also evaluated, but each has its limitations (Punnen 2015, Ferro 2016).

Currently the prediction tools used to preoperatively distinguish between an aggressive and a pathologically insignificant disease incorporate PSA level, clinical stage, as well as biopsy variables such as transrectal ultrasound prostate volume, Gleason grade, number of positive biopsy cores, percentage of cancer in any core sample, total cancer length, and noncancer tissue in biopsy cores. The AUC for the accuracy of these prediction tools ranges from 0.70-0.80 (Carlsson 2013).

The 4Kscore® (4KRK) test (OPKO Lab, Nashville, TN) is a new blood test that has been introduced and evaluated for its ability to accurately predict the risk of aggressive prostate cancer. The test incorporates a panel of four kallikrein protein biomarkers (total PSA [tPSA], free PSA [fPSA], intact PSA [iPSA], and human kallikrein-related peptide 2 [hK2]), together with clinical information (age, and optionally the results of a DRE), in an algorithm that, according to some investigators, provides a percent risk for a high grade cancer (Gleason score ≥7). Tissue kallikrein or kallikrein-related enzymes are a family of 15 secreted serine proteases, the regulatory functions of which are linked to the development of malignancy, neurodegeneration, inflammation and other disorders. Messenger RNA expression of all kallikreins can be detected in the prostate tissue, but KLK2 (also known as human kallikrein2 [hK2]), and KLK3 (also known as PSA) are the most dominant. Some researchers found that in prostate cancer there is a dysregulation and overexpression of both PSA and hK2 and that their levels increase as the prostate cancer becomes more undifferentiated. They also indicate that these kallikreins directly and indirectly contribute to prostate cancer progression and metastasis (Konety 2015, Punnen 2015, McDonald 2016).

Several European studies evaluated the ability of the 4Kscore to distinguish between a pathologically insignificant and an aggressive disease. Based on their analyses, several investigators suggest that 4Kscore test would play an important clinical role as a reflex test before performing an initial prostate biopsy in men with elevated PSA, abnormal DRE results, or after a negative biopsy and persistently higher PSA levels (Punnen 2015). According to the manufacturer, the 4Kscore Test does not provide a diagnosis of prostate cancer; it is designed to help clarify the decision on whether or not to perform a biopsy based on the probability of a patient having aggressive prostate cancer. The test should not be used in isolation to make the decision on the need for biopsy. Other factors such as health status, PSA history medical history, family history of prostate cancer, etc., should all be considered with the 4Kscore risk level into a shared decision-making with the patient.

Medical Technology Assessment Committee (MTAC)

4Kscore Test for Prostate Cancer

03/21/2016: MTAC REVIEW

Evidence Conclusion: *Clinical validity (Predictive accuracy) of the 4Kscore test* The four kallikrein markers were initially validated in Europe using retrospective data from multiple European cohorts that participated in European Randomized Study of Prostate Cancer Screening (ERSPC). These were followed by a study in the UK using retrospective data from ProtecT study cohort, and a prospective study conducted in the USA. All 4Kscore validation studies compared its predictive accuracy versus the base model using total PSA and reported the results in the area under the receiver operating characteristic curve (AUC). AUC only focuses on the predictive accuracy of a model. It does not account for potential harms, benefits or cost, and may not capture the tradeoffs that the physician and patient face in making a decision about interventions that can carry both benefits and harms (Baker, 2012). Voigt and colleagues' meta-analysis (Evidence Table 1) pooled data from seven separate trials participating in the ERSPC. The results of the meta-analysis as well as the results of the individual studies it included, suggest that an algorithm using a panel of tPSA, fPSA, iPSA, and hK2 measured in the serum, together with age and optional DRE, is more accurate than measuring total PSA (tPSA) alone in predicting high grade cancer among men with a PSA levels ≥ 3 ng/mL. The pooled mean difference in AUC between the Kallikrein clinical model vs. base clinical model was 0.10 (95% CI, 0.08- 0.12), p<0.00001, for predicting any cancer and 0.08 (95% CI, 0.05-0.11), p<0.00001 for predicting high-grade cancer. Bryant and colleagues (2015, Evidence Table 2) validated a statistical model based the four kallikrein markers using retrospective data from the Prostate

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Testing for Caner and Treatment (ProtecT study) conducted in the UK. In that study, men with PSA ≥3 ng/mL underwent an extended 10-core biopsy (sextant biopsy in ERSPC). The kallikrein markers were retrospectively measured in cryopreserved blood, mainly plasma rather than serum. Because of these differences from the ERSPC, the investigators generated new prediction models modified from those developed from the ERSPC cohorts. Similar to the other European studies, the results of the UK study showed that the statistical model including the panel of four kallikrein markers significantly improved the prediction of high-grade cancer vs. the use of total PSA plus age. The incremental increase in the AUC with using age + a panel of 4K markers versus age + tPSA was 0.085 for any grade prostate cancer and 0.082 for high-grade cancer. It is to be noted however, that these studies used retrospective data form earlier cohorts from European studies conducted among Caucasian men 50 years of age or older. Plasma or serum samples have been stored for several years and may have been previously thawed and refrozen, which would degrade the kallikrein markers. The trials participating in the ERSPC used sextant biopsy and the ProtecT study used 10-core biopsy. Parekh et al, 2015 (Evidence Table 3) prospectively validated the 4Kscore test in the USA. The study enrolled 1,300 men referred to biopsy (regardless of their PSA level or clinical findings) in 26 urology centers in the USA. 300 men were used for calibrating the algorithm and 1,012 for its validation. The primary outcome was Gleason score ≥ 7 prostate cancer (PCa) on prostate biopsy. Accuracy of the 4Kscore test was assessed by the AUC, calibration plots, and decision curve analysis. The great majority of the participants (86%) were white men, which may limit generalization of the results. The authors compared the predictive accuracy of the 4Kscore vs. a modified Prostate Cancer Prevention Trial Risk Calculator (PCPTRC) 2.0. The results showed that the 4Kscore had a significantly higher discrimination in detecting Gleason ≥7 cancer compared to modified PCPTRC 2.0 (AUC 0.82 versus 0.74, p<0.0001).

The results of validation studies on the predictive accuracy of the 4Kscore may be summarized in the following table: *The AUC for discriminating /predicting Gleason ≥7 cancer using the full panel 4Kscore**

	N participants	**AUC (95% CI)**
USA validation study (Parekh, 2015) *	1,012	0.82 (95% CI, 0.79 to 0.85)
UK study (Bryant, 2015) **	6,129	0.82 (95% CI, 0.80 to 0.84)
European trials participating in ERSPC study		
Unscreened cohorts	262	0.87
France (Benchikh, 2010)	740	0.83-0.84
Goteborg (Vickers, 2008)	2,914	0.76-0.78
Rotterdam (Vickers, 2010)		
Screened cohorts	1.241	0.83
Goteborg (Vickers, 2008)	1,501	0.80
Rotterdam (Vickers, 2010)		

*Compared to AUC 0.74 with modified Prostate Cancer Prevention Trial Risk Calculator (PCPTRC) 2.0 (P<0.0001)
** Compared to AUC of 0.63 (95% CI, 0.62-0.65), for total PSA +age (p <0.001).

- AUC for total PSA models ranged between the European studies from 0.51 to 0.77.
- Mean difference in AUC between 4K model and the base model (consisting of age total PSA, and DRE) in predicting high grade cancer varied between 0.10 (95% CI, 0.06-0.16) to 0.13 (95% CI, 0.11-0.15) depending on whether DRE results were or were not included with the 4K panel and age.

Clinical utility of the 4Kscore test Clinical utility of a test implies that high-level evidence shows that the use of the marker improves patient outcome sufficiently to justify its incorporation into routine clinical care (NCCN Task Force [Febbo 2011]).There are no published RCTs or prospective controlled studies, to date, that examined the clinical utility of the 4Ksore test or its therapeutic impact, i.e. whether its results would have an effect on the treatment decision-making and improve patient outcomes. The published studies examined and validated the predictive ability of the 4Kscore test but did not directly examine its impact on the clinical outcomes. In order to investigate the potential clinical effect of the four kallikrein markers in the blood, the investigators used decision analyses to simulate outcomes if biopsy decisions have been based on various cut-points from the models. Decision analyses methods are based on simulations using estimates of the probability and sequelae of events in a hypothetical cohort of patients (Vickers, 2006). Bryant and colleagues' 2015 (Evidence Table 2), decision curve analysis based on various cutpoints showed that a model using a threshold representing a 6% risk of Gleason score ≥7 in men with PSA ≥3 ng/ml, would reduce the biopsy rate by 42.8%, but at the expense of missing 14 of 133 (10.5%) high grade cancers. The analysis of the US prospective study (Parekh et al, 2015, Evidence Table 3) suggests that the use 4Kscore test among men with PSA ≥3 ng/ml, may potentially reduce the number of prostate biopsies, but may also fail to detect a small number of significant cancers depending on the cutoff value used. Using 6% risk as a cutoff would reduce 30% of the biopsies and delay the diagnosis of 1.3% of high-grade cancers. A ≥9% cutoff would reduce 43% biopsies and delay diagnosis of 2.4% Gleason ≥7 cancers.

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Konety and colleagues, 2015 (Evidence Table 4), retrospectively examined the impact of the 4Kscore Test on the urologist-patient decisions about performing a biopsy in men with abnormal PSA and/or DRE results. The study retrospectively collected data from participating urologists who ordered the 4Kscore Test as part of their assessment of men referred their practice for abnormal PSA and or DRE. The results of the analysis suggest that performing the 4Kscore Test resulted in 64.6% reduction in prostate biopsies among the 611 patients seen by the participating urologists. Due to its design and limitations, the study does not provide sufficient evidence to determine the clinical utility of the test. Conclusion: There is fair evidence from a number of validation studies that 4Kscore test may improve the predictive accuracy of total PSA when used among mainly white men with PSA level ≥ 3ng/mL. As indicated earlier the predictive accuracy of a marker or test does not account for potential harms, and benefits, and may not capture the tradeoffs that the physician and patient face in making a decision about interventions that can carry both benefits and harms. There is insufficient evidence on the clinical utility of the 4Kscore test. There is insufficient evidence to determine the therapeutic impact of the 4Kscore test or the effect of the treatment decision based on the results of the test on the patient outcomes.
Articles: The search for studies on the accuracy of the 4Kallikrein panel in predicting high grade prostate cancer, revealed one study that prospectively evaluated the test among men in the USA, and a number of European studies that used retrospective data from several cohorts of screened and unscreened men participating in European Randomized Study of Prostate Cancer (ERSPC) and one cohort from the British ProtecT study. A meta-analysis that pooled the results of seven studies using the ERSPC cohorts was also identified. The search did not reveal any randomized controlled trial that examined the clinical utility of the 4Kscore test, only an observational study that analyzed retrospective data for men receiving the test. The following studies were selected for critical appraisal: Voigt JD, Zappala SM, Vaughan ED, et al. The Kallikrein Panel for prostate cancer screening: its economic impact. Prostate. 2014 Feb; 74(3):250-259 See Evidence Table 1. Bryant RJ, Sjoberg DD, Vickers AJ, et al. Predicting high-grade cancer at ten-core prostate. See Evidence Table 2. Parekh DJ, Punnen S, Sjoberg DD, et al. A multi-institutional prospective trial in the USA confirms that the 4Kscore accurately identifies men with high-grade prostate cancer. Eur Urol. 2015 Sep; 68(3):464-470. See Evidence Table 3. biopsy using four kallikrein markers measured in blood in the ProtecT study. J Natl Cancer Inst. 2015 Apr 11; 107. Konety B, Zappala SM, Parekh DJ, et al. The 4Kscore test reduces prostate biopsy rates in community and academic urology practices. Rev Urol. 2015; 17 (4):231-240. See Evidence Table 4.

The use of 4Kscore Test for Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
03/21/2016	04/05/2016[MPC], 02/07/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/16/2022

[MPC] Medical Policy Committee

Revision History	Description
04/05/2016	Created criteria; Added MTAC review

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02/07/2017	Medicare is silent; MPC approved to adopt GHC criteria for Medicare members
10/10/2017	Added Medicare instructions for 0010M and 81539
08/08/2018	Removed 0010M
09/01/2020	Added Medicare LCD L37122 and LCA A57337; Removed KPWA Medical Policy statement under Medicare section.
09/16/2022	Removed Medicare LCD L37122 (retired 6/12/22) and LCA A57337 (retired 6/12/22), added KPWA Medical Policy statement under Medicare section.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Applied Behavioral Analysis Therapy (ABA)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare Members

- **For patients with a Microsoft contract**, click here to view the criteria.
- **For all other plans where the contract includes coverage for ABA therapy, see below for criteria**
- **For plans without a benefit**, the service is not covered at this time.

For all Kaiser Permanente plans with a benefit (except Microsoft)
ABA requires preauthorization for initial and continued therapy. Specific coverage may be defined in the individual member contract. The following criteria must be met:

1. The member has a diagnosis of an Autism Spectrum Disorder (DSM-V code including severity levels) by a neurologist, pediatric neurologist, developmental pediatrician, psychologist, psychiatrist, or nurse practitioner experienced in the diagnosis and treatment of autism, or, has a developmental disability for which there is evidence that ABA therapy is effective.
2. The diagnostic assessment must include **All of the following** elements:
    a. Documentation of formal diagnostic procedures by an experienced clinician (e.g., Autism Diagnostic Interview-Revised, Autism Diagnostic Observation Schedule, diagnostic interview using DSM-V criteria)
    b. Description of how patient's behaviors are having an impact on development, communication or adjustment such that:
        i. The member cannot adequately participate in home, school, or community activities; and/ or the member presents a safety risk to self or others, and
        i. Less intrusive and/or less intensive behavioral interventions have been tried and have not been successful and/or there is no equally-effective alternative strategy available to address the member's behaviors
    c. Specific evaluations to determine developmental profile using **ONE or more of the following** standard tools:
        i. Adaptive/Functional skills: Vineland Adaptive Behavior Scales
        ii. Communication skills: Preschool Language Scale-5 (PLS-5), Clinical Evaluation of Language Fundamentals-5 (CELF-5), Verbal Behavior Milestones Assessment and Placement Program (VB-MAPP)

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iii. Cognitive Assessment (Wechsler scales, Kaufman scales)
iv. Social Skills Rating Scales (SSRS), Assessment of Basic Language and Learning Skills (ABLLS), Achenbach System of Empirically Based Assessment (ASEBA)
v. Behavior rating scales: ASEBA, Behavior Assessment System for Children, Third Ed. (BASC-3), Gilliam Autism Rating Scale

d. Expanded laboratory, documented routine developmental surveillance by providers at every well child visit, screening questionnaire, audiology assessment results, only if indicated.
e. There is evidence that the patient is capable of participating in ABA therapy

3. A documented individualized treatment plan (ITP) that includes:
   a. A time-limited ITP that has been developed based on a diagnostic assessment within no more than 12 months of initiating treatment
   b. ITP is multidisciplinary in nature, member-centered, family-focused, community-based, culturally-competent and least intrusive
   c. Treatment plans that are templates or generic to a particular program are not acceptable
   d. The ITP must address behaviors and symptoms that prevent the member from adequately participating in home, school, or community activities and/or present a safety risk to self or others, with a focus on parent training
   e. The ITP should consider all school or other community resources available to the patient and provide evidence that the requested services are not redundant to other services already being provided. The ITP should include a review of a school-based IEP (if present) and how the ITP does not duplicate what is on the IEP. The ITP should also include a review of other treatment if present (e.g., outpatient mental health, speech therapy) and how the ITP does not duplicate these community-based resources. Coordination between the ABA provider and school and/or other service providers must take place directly between the providers, and not through parents.
   f. Coverage of ABA therapy in public or private schools is only provided under the following circumstances:
      i. Observation and assessment of behavior may take place in the school as part of the ITP assessment with the permission of school personnel
      ii. ABA may be provided on school property before and after regular school hours with the permission of school personnel
      iii. ABA may be provided during regular school hours with permission of school, when medically necessary, and the ABA intervention does not duplicate services the school could be expected to provide.

4. The ITP must include **All of the following**:
   a. Description of autistic behaviors that are targets for treatment. The targets for treatment should be based on where there is the most significant gap in functioning as measured by developmental and behavioral assessment including **TWO or more of the following:**

      ONE Norm-Referenced assessment is required to be completed during the initial ABA assessment, and to be readministered every 12 months. The provider is to use an instrument that will be suitable for serial measurements over time, and thus to measure functional progress over treatment periods. Some options for norm-based assessment are:

      - Vineland3 Adaptive Behavior Scales
      - Adaptive Behavior Assessment System (ABAS)
      - Pervasive Developmental Disorder Behavior Inventory (PDDBI)
      - Social Skills Improvement System (SSIS)

      ONE Criterion-Reference assessment is required to be completed during the initial ABA assessment, and to be updated every 6 months. Some options for this assessment are:

      - The Carolina Curriculum
      - Verbal Behavior Milestones Assessment and Placement Program (VB MAPP)
      - Preschool Language Scale-5 (PLS-5),
      - Promoting Emergence of Advanced Knowledge (PEAK)
      - Accept-Identify-Move (AIM)
      - Assessment of Basic Language and Learning Skills (ABBLS)
      - Essentials for living (EFLs)
      - or similar standardized measure
   b. A comprehensive description of treatment interventions and techniques specific to each of the

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targeted behavioral/symptoms
   c. Establishment of baseline data, measurable treatment goals, and criteria for goal attainment and objective measures of progress for each intervention specified (including baseline and targeted goals)
   d. Strategies for generalizing learning skills across persons and situations. Generalization plans are monitored closely as they are key to the patient transitioning to a lower level of care.
   e. A description of parent education, including measurable parenting goals with baseline and criteria for goal attainment, and description of interventions. The parent goals are to include instruction in ABA principles in order to training and support generalization and maintenance of skills. Detailed description of interventions with parents to support their active participation in ABA treatment, including a plan for transferring interventions with the patient from the ABA provider to the parents. An ITP that does not adequately feature parental involvement may be subject to denial.
   f. Strategies for communication and coordinating treatment with other providers and agencies including school-based special education programs, day care, and other health care providers
   g. Hours requested are itemized for each treatment modality (e.g., parent training, certified behavior technician time, lead behavior therapist, supervision, social skills group, completion of six-month progress report)
   h. Measurable discharge criteria for completing treatment and plans for continued care after a discharge plan from ABA, which include **All of the following**:
      i. Plans for transition through a continuum of less intensive treatments such that patient's symptoms can be effectively managed at a lower level of care
      ii. Specific behavioral goals that, when reached, will indicate the patient is adequately participating in home, school, or community activities and/or is no longer presently a safety risk to self or others
5. Discharge Criteria - Typically individuals no longer need ABA services if **ONE of the following** is met:
   a. Patient behaviors and/or symptoms do not prevent them from adequately participating in home, school, or community activities and/or no longer present a safety risk to self or others
   b. Their behaviors and/or symptoms can be adequately addressed through alternative methods (i.e. school, developmental disability services, parent training)
   c. Functional and measurable progress toward treatment goals is not occurring as measured by (majority of goals are not being met, there is not significant progress on behaviors and/or symptoms that prevent them from adequately participating in home, school, or community activities, and/or no longer present a safety risk to self or others), improvement is not durable over time, and/or generalizable outside the treatment setting, and there is no reasonable expectation of further progress
   d. Parents have not been active participants in ABA treatment
6. Transition to a lower level of care. Discharge is often not a discrete event, but instead is a transitional process, to prevent relapse of skills. Transition to a lower level of care could include any of the following: lowered number of treatment hours (focused ABA), enhanced focus on training parents or other caregivers, or the use of other treatment modalities e.g., mental health counseling group treatments or other community support activities.
7. Coverage of development of the ITP does include time to do baseline assessments, review of past treatment (including IEPs) and development of a plan that includes parent training and coordination with other treatment providers. Six to 10 hours is usually sufficient for the development of the ITP. However, more complex cases, or cases in which a complete functional analysis is needed, may require up to 15-20 hours for the initial assessment and treatment planning.

8. The amount of treatment is based on medical necessity. As noted in the 2014 Agency for Healthcare Research and Quality update on A Review of Research of Therapies for Children with Autism Spectrum Disorder, early intervention programs (i.e., for children typically, under the age of six) are provided for up to 25 hours a week and can last as long as 12 weeks to 3 years. These services can include direct services to member/identified patient and/or parents by program manager/lead behavioral therapist and/or therapy assistants/behavioral technicians/paraprofessionals, supervision, and the development of a six-month progress report. In the unusual case of very acute and/or unsafe patient behavior, up to 40 hours/week of treatment may be authorized.
9. Fewer hours may be required (5-15 hours per week) for Focused ABA when the primary difficulty is in one targeted area (i.e., social skills deficits).

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10. Evaluation of progress: At least every six months, the provider completes the KP ABA Progress Report Form. This document is used to review progress in treatment including the following information:
    a. How patient is progressing towards goals (i.e., what percentage of goals patient has achieved and how these goals have led to functional progress as it pertains to increasing patient's ability to adequately participate in home, school, or community activities, and/or decrease safety risk to self or others
    b. Progress towards parent goals (how parents have been active participants in the treatment, what percentage of parent goals have been passed, and progress towards transferring interventions with the patient to the parents)
    c. For goals that have not been met, describe reason for not meeting goals, how goals are being adjusted, and how interventions are being revised to meet goals
    d. Any new goals that have been identified (if new goals are identified, include baseline and targeted performance). New goals should be geared towards progress or transition to less intensive interventions.
    e. A criterion referenced assessment is to be submitted every six months.
    f. How the patient is progressing towards discharge and/or plans for discharging from care and/or reducing intensity of intervention based on patient progress and/or the implementation of less intensive behavioral interventions. A discharge plan stating that ABA will be needed until he/she no longer meets criteria for ASD is not appropriate. A patient could still meet diagnostic criteria for ASD but be able to be successfully and safely treated at a lower level of care.
    g. A brief description of what was done during the past six months to coordinate treatment with school and/or health care providers (i.e., phone call was made to speech therapist to make sure there is common picture communication system; a conference was held with the school to coordinate behavioral interventions for self-injurious behavior). This coordination must take place directly between the ABA provider and any other service providers, and not through the parents
    h. If functional progress is not occurring (i.e., one or two consecutive ITP's where patient is not meeting majority of goals and not making functional progress towards increased participation in home, school, or community activities and/or is not less of a safety risk to self or others) and there is not a reasonable expectation of further progress, then continuation of ABA services is not considered to be medically necessary
11. Every 12 months standardized (norm-referenced) developmental assessment should be re-administered to assess whether patient continues to be making functional and measurable progress. The provider is to use the same instrument over time as much as possible so scores can be compared over time to measure progress.
12. The following are not considered to be medically necessary ABA services:
    a. More than one program manager/lead behavioral therapist for a member/identified patient at any one time.
    b. More than one agency/organization providing ABA services for a member/identified patient at any one time.
    c. If the school has determined that a child is eligible to receive services under an IEP which would overlap with ABA services and the school services are declined or discontinued by the parent.
    d. Activities and therapy modalities that do not constitute application of applied behavioral analysis techniques for treatment of autism. Examples include (but not limited to):
        i. Taking the member/identified patient to appointments or activities outside of the home (e.g., recreational activities, eating out, shopping, play activities, medical appointments), except when the member/identified patient has demonstrated a pattern of significant behavioral difficulties during such specific activities
        ii. Assisting the member/identified patient with academic work or functioning as a tutor, educational or other aide for the member/identified patient in school
        iii. Provision of services that are part of an IEP and therefore should be provided by school personnel, or other services that schools are obligated to provide
        iv. Doing housework or chores, or assisting the member/identified patient with housework or chores, except when the member has demonstrated a pattern of significant behavioral difficulties during specific housework or chores, or acquiring the skills to do specific housework or chores is part of the ABA treatment plan for the member/identified patient
        v. travel time
        vi. residing in the member's home and functioning as live-in help (e.g., in an au-pair role)
13. All ABA visits with the patient and/or family should be documented. Documentation should include:
    a. Who was present at the visit?

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b. Duration of the visit
c. What was the targeted behavior during the visit?
d. What was the procedure/activity/intervention during visit?
e. What was the response to procedure/activity/intervention?
f. Intervention format (individual, group, supervision, parent training)
g. Graphical or numerical data to track progress/participation
h. Signature title, credentials of person completing documentation
i. Include targeted behavior, interventions, response, modifications in techniques and plan for next visit with behavior tracking sheets that record and graph data collected for each visit

ABA Provider Qualifications and Procedure Codes

Providers delivering ABA must meet **ALL of the following** qualifications:

1. At a minimum, the lead behavioral therapist, providing treatment and clinical supervision of treatment program must demonstrate that she/he is a board-certified behavior analyst (BCBA) or must demonstrate that she/he has at least 240 hours of coursework related to behavior analysis and/or 750 hours of supervised experience or 2 years of practical experience in designing and implementing comprehensive behavioral analytic therapies for children with autism; ***and***
2. ***Either***:
   a. Individually satisfy **ALL of the following** requirements:
      i. Be a licensed health provider under Title 18, Revised Code of Washington, including but not limited to: speech therapist, occupational therapist, psychologist, pediatrician, neurologist, psychiatrist, mental health counselor, social worker; and
      ii. Be licensed to practice independently; and
      iii. Be credentialed and contracted by the Plan; ***or***
   b. Be employed by a Healthcare Delivery Organization that meets **All of the following** requirements:
      i. Be a hospital, mental health facility, home health agency or in-home agency licensed to provide home health services, or other mental health agency licensed by the Washington Department of Health; ***or*** a community mental health agency or home health agency licensed by the Washington Department of Social and Health Services; and
      ii. Be credentialed and contracted by the Plan.
   c. Clinical supervision for unlicensed staff providing services must be provided by a lead behavioral therapist as indicated above. Such supervision must:
      i. Include bimonthly (once every 60 days) approval and review of the ITP and case review of every member receiving clinical health services; and
      ii. Include at least one hour of on-site supervision, with on-site observation for at least one hour for every 40 hours of service to the member.

Effective March 1, 2023

ABA requires preauthorization for initial and continued therapy. Specific coverage may be defined in the individual member contract. The following criteria must be met:

1. The member has a diagnosis of an Autism Spectrum Disorder (DSM-V code including severity levels) by a neurologist, pediatric neurologist, developmental pediatrician, psychologist, psychiatrist, or nurse practitioner experienced in the diagnosis and treatment of autism, or, has a developmental disability for which there is evidence that ABA therapy is effective.
2. The diagnostic assessment must include **All of the following** elements:
   a. Documentation of formal diagnostic procedures by an experienced clinician (e.g., Autism Diagnostic Interview-Revised, Autism Diagnostic Observation Schedule, diagnostic interview using DSM-V criteria)
   b. Description of how patient's behaviors are having an impact on development, communication or adjustment such that:
      i. The member cannot adequately participate in home, school, or community activities; and/ or the member presents a safety risk to self or others, and
      ii. Less intrusive and/or less intensive behavioral interventions have been tried and have not been successful and/or there is no equally effective alternative strategy available to address the member's behaviors
   c. Specific evaluations to determine developmental profile using **ONE or more of the following** standard tools:

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i. Adaptive/Functional skills: Vineland Adaptive Behavior Scales
ii. Communication skills: Preschool Language Scale-5 (PLS-5), Clinical Evaluation of Language Fundamentals-5 (CELF-5), Verbal Behavior Milestones Assessment and Placement Program (VB-MAPP)
iii. Cognitive Assessment (Wechsler scales, Kaufman scales)
iv. Social Skills Rating Scales (SSRS), Assessment of Basic Language and Learning Skills (ABLLS), Achenbach System of Empirically Based Assessment (ASEBA)
v. Behavior rating scales: ASEBA, Behavior Assessment System for Children, Third Ed. (BASC-3), Gilliam Autism Rating Scale

d. Expanded laboratory, documented routine developmental surveillance by providers at every well child visit, screening questionnaire, audiology assessment results, only if indicated.
e. There is evidence that the patient can participate in ABA therapy

3. A documented individualized treatment plan (ITP) that includes:
   a. A time-limited ITP that has been developed based on a diagnostic assessment within no more than 12 months of initiating treatment
   b. ITP is multidisciplinary in nature, member-centered, family-focused, community-based, culturally-competent and least intrusive
   c. Treatment plans that are templates or generic to a particular program are not acceptable ITP must address behaviors and symptoms that prevent the member from adequately participating in home, school, or community activities and/or present a safety risk to self or others, with a focus on parent training
   d. The ITP must address behaviors and symptoms that prevent the member from adequately participating in home, school, or community activities and/or present a safety risk to self or others, with a focus on parent training
   e. The ITP should take into account all school or other community resources available to the patient and provide evidence that the requested services are not redundant to other services already being provided. The ITP should include a review of a school-based IEP (if present) and how the ITP does not duplicate what is on the IEP. The ITP should also include a review of other treatment if present (e.g., outpatient mental health, speech therapy) and how the ITP does not duplicate these community-based resources. Coordination between the ABA provider and school and/or other service providers must take place directly between the providers, and not through parents.
   f. Coverage of ABA therapy in public or private schools is only provided under the following circumstances:
      i. Observation and assessment of behavior may take place in the school as part of the ITP assessment with the permission of school personnel
      ii. ABA may be provided on school property before and after regular school hours with the permission of school personnel
      iii. ABA may be provided during regular school hours with permission of school, when medically necessary, and the ABA intervention does not duplicate services the school could be expected to provide.
   g. ABA services do not eliminate the requirement that the school district to provide appropriate mandatory services
   h. ABA services are not to be used for custodial caregiving services, including respite for caregivers

4. The ITP must include **All of the following**:
   a. The provider must use KP WA required report templates, available at Applied Behavioral Analysis Treatment for Autism | Kaiser Permanente Washington; updates will be posted on the provider site.
   b. Description of autistic behaviors that are targets for treatment. The targets for treatment should be based on where there is the most significant gap in functioning as measured by developmental and behavioral assessment including **TWO or more of the following:**

      a. ONE Norm-Referenced assessment is required to be completed during the initial ABA assessment, and to be readministered every 12 months. The provider is to use an instrument that will be suitable for serial measurements over time, and thus to measure functional progress over treatment periods. Some options for norm-based assessment are:
         - Vineland3 Adaptive Behavior Scales
         - Adaptive Behavior Assessment System (ABAS)

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- Pervasive Developmental Disorder Behavior Inventory (PDDBI)
- Social Skills Improvement System (SSIS)

b. ONE Criterion-Reference assessment is required to be completed during the initial ABA assessment, and to be updated every 6 months. Some options for this assessment are:
- The Carolina Curriculum
- Verbal Behavior Milestones Assessment and Placement Program (VB MAPP)
- Preschool Language Scale-5 (PLS-5),
- Promoting Emergence of Advanced Knowledge (PEAK)
- Accept-Identify-Move (AIM)
- Assessment of Basic Language and Learning Skills (ABBLS)
- Essentials for living (EFLs)
- The Assessment of Functional Living Skills (AFLS) or similar empirically based assessment tool.

c. A comprehensive description of treatment interventions and techniques specific to each of the targeted behavioral/symptoms
d. Establishment of baseline data, measurable treatment goals, and criteria for goal attainment and objective measures of progress for each intervention specified (including baseline and targeted goals)
e. Strategies for generalizing learning skills across persons and situations. Generalization plans are monitored closely as they are key to the patient transitioning to a lower level of care.
f. A description of parent education, including measurable parenting goals with baseline and criteria for goal attainment, and description of interventions. The parent goals are to include instruction in ABA principles in order to training and support generalization and maintenance of skills. Detailed description of interventions with parents to support their active participation in ABA treatment, including a plan for transferring interventions with the patient from the ABA provider to the parents. An ITP that does not adequately feature parental involvement may be subject to denial.
g. Strategies for communication and coordinating treatment with other providers and agencies including school-based special education programs, day care, and other health care providers.
h. Hours requested are itemized for each treatment modality (e.g., parent training, certified behavior technician time, lead behavior therapist, supervision, social skills group, completion of six-month progress report)
i. Measurable discharge criteria for completing treatment and plans for continued care after a discharge plan from ABA, which include **all of the following**:
   i. Plans for transition through a continuum of less intensive treatments such that patient's symptoms can be effectively managed at a lower level of care
   ii. Specific behavioral goals that, when reached, will indicate the patient is adequately participating in home, school, or community activities and/or is no longer presently a safety risk to self or others

5. Discharge Criteria - Typically individuals no longer need ABA services if **ONE of the following** is met:
   a. Patient behaviors and/or symptoms do not prevent them from adequately participating in home, school, or community activities and/or no longer present a safety risk to self or others
   b. Their behaviors and/or symptoms can be adequately addressed through alternative methods (i.e., school, developmental disability services, parent training)
   c. Functional and measurable progress toward treatment goals is not occurring as measured by (majority of goals are not being met, there is not significant progress on behaviors and/or symptoms that prevent them from adequately participating in home, school, or community activities, and/or no longer present a safety risk to self or others), improvement is not durable over time, and/or generalizable outside the treatment setting, and there is no reasonable expectation of further progress
   d. Parents have not been active participants in ABA treatment
6. Transition to a lower level of care. Discharge is often not a discrete event, but instead is a transitional process, to prevent relapse of skills. Transition to a lower level of care could include any of the following: lowered number of treatment hours (focused ABA), enhanced focus on training parents or other caregivers, or the use of other treatment modalities e.g., mental health counseling group treatments or other community support activities.
7. Coverage of development of the ITP does include time to do baseline assessments, review of past treatment (including IEPs) and development of a plan that includes parent training and coordination with other treatment providers. Six to 10 hours is usually sufficient for the development of the ITP. However, more complex cases, or cases in which a complete functional analysis is needed, may require up to 15-20 hours for the initial assessment and treatment planning.

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8. The amount of treatment is based on medical necessity. As noted in the 2014 Agency for Healthcare Research and Quality update on A Review of Research of Therapies for Children with Autism Spectrum Disorder, early intervention programs (i.e., for children typically, under the age of six) are provided for up to 25 hours a week and can last as long as 12 weeks to 3 years. These services can include direct services to member/identified patient and/or parents by program manager/lead behavioral therapist and/or therapy assistants/behavioral technicians/paraprofessionals, supervision, and the development of a six-month progress report. In the unusual case of very acute and/or unsafe patient behavior, up to 40 hours/week of treatment may be authorized.
9. Fewer hours may be required (5-15 hours per week) for Focused ABA when the primary difficulty is in one targeted area (i.e., social skills deficits).
10. Caregiver training is required for all ABA programs
    a. Caregiver training plan must include baseline behaviors, must have baselines measurable components, and mastery criteria
    b. Caregiver education must also include the teaching of ABA principles related to the patient goals (i.e., principles of reinforcement, behavior functions, schedules reinforcement, task analysis as a teaching strategy, etc.)
    c. Monthly meetings (in person or virtual) are required for generalization and maintenance of skills
11. Evaluation of progress: Every six months, the provider completes the KP ABA Progress Report. This document is used to review progress in treatment including the following information:
    a. How patient is progressing towards goals (i.e., what percentage of goals patient has achieved and how these goals have led to functional progress as it pertains to increasing patient's ability to adequately participate in home, school, or community activities, and/or decrease safety risk to self or others
    b. Progress towards parent goals (how parents have been active participants in the treatment, what percentage of parent goals have been passed, and progress towards transferring interventions with the patient to the parents.
    c. For goals that have not been met, describe reason for not meeting goals, how goals are being adjusted, and how interventions are being revised to meet goals.
    d. Any new goals that have been identified (if new goals are identified, include baseline and targeted performance). New goals should be geared towards progress or transition to less intensive interventions.
    e. A criterion referenced assessment is to be submitted every six months.
    f. How the patient is progressing towards discharge and/or plans for discharging from care and/or reducing intensity of intervention based on patient progress and/or the implementation of less intensive behavioral interventions. A discharge plan stating that ABA will be needed until he/she no longer meets criteria for ASD is not appropriate. A patient could still meet diagnostic criteria for ASD, but be able to be successfully and safely treated at a lower level of care.
    g. A brief description of what was done during the past six months to coordinate treatment with school and/or health care providers (i.e., phone call was made to speech therapist to make sure there is common picture communication system; a conference was held with the school to coordinate behavioral interventions for self-injurious behavior). This coordination must take place directly between the ABA provider and any other service providers, and not through the parents
    h. If functional progress is not occurring (i.e., one or two consecutive ITP's where patient is not meeting majority of goals and not making functional progress towards increased participation in home, school, or community activities and/or is not less of a safety risk to self or others) and there is not a reasonable expectation of further progress, then continuation of ABA services is not considered to be medically necessary
12. Every 12 months standardized (norm-referenced) developmental assessment should be re-administered to assess whether patient continues to be making functional and measurable progress. The provider is to use the same instrument over time as much as possible so scores can be compared over time to measure progress.
13. The following are not considered to be medically necessary ABA services:
    a. More than one program manager/lead behavioral therapist for a member/identified patient at any one time.
    b. More than one agency/organization providing ABA services for a member/identified patient at any one time.
    c. If the school has determined that a child is eligible to receive services under an IEP which would overlap with ABA services and the school services are declined or discontinued by the parent.
    d. Activities and therapy modalities that do not constitute application of applied behavioral analysis techniques for treatment of autism. Examples include (but not limited to):

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i. Taking the member/identified patient to appointments or activities outside of the home (e.g., recreational activities, eating out, shopping, play activities, medical appointments), except when the member/identified patient has demonstrated a pattern of significant behavioral difficulties during such specific activities
ii. Assisting the member/identified patient with academic work or functioning as a tutor, educational or other aide for the member/identified patient in school
iii. Provision of services that are part of an IEP and therefore should be provided by school personnel, or other services that schools are obligated to provide
iv. Doing housework or chores, or assisting the member/identified patient with housework or chores, except when the member has demonstrated a pattern of significant behavioral difficulties during specific housework or chores, or acquiring the skills to do specific housework or chores is part of the ABA treatment plan for the member/identified patient travel time residing in the member's home and functioning as live-in help (e.g., in an au-pair role)

14. All ABA visits with the patient and/or family should be documented. Documentation should include:
    a. Who was present at the visit?
    b. Duration of the visit
    c. What was the targeted behavior during the visit?
    d. What was the procedure/activity/intervention during visit?
    e. What was the response to procedure/activity/intervention?
    f. Intervention format (individual, group, supervision, parent training)
    g. Graphical or numerical data to track progress/participation
    h. Signature title, credentials of person completing documentation
    i. Include targeted behavior, interventions, response, modifications in techniques and plan for next visit with behavior tracking sheets that record and graph data collected for each visit

ABA Provider Qualifications and Procedure Codes

Providers delivering ABA must meet **ALL of the following** qualifications:

1. At a minimum, the lead behavioral therapist, providing treatment and clinical supervision of treatment program must demonstrate that she/he is a board-certified behavior analyst (BCBA).
2. ***Either***:
    a. Individually satisfy **ALL the following** requirements:
        i. Be a licensed health provider under Title 18, Revised Code of Washington, including but not limited to: speech therapist, occupational therapist, psychologist, pediatrician, neurologist, psychiatrist, mental health counselor, social worker; and
        ii. Be licensed to practice independently; and
        iii. Be credentialed and contracted by the Plan; ***or***
    b. Be employed by a Healthcare Delivery Organization that meets **All of the following** requirements:
        i. Be a hospital, mental health facility, home health agency or in-home agency licensed to provide home health services, or other mental health agency licensed by the Washington Department of Health; ***or*** a community mental health agency or home health agency licensed by the Washington Department of Social and Health Services; and
        ii. Be credentialed and contracted by the Plan.
        iii. Clinical supervision for unlicensed staff providing services must be provided by a lead behavioral therapist as indicated above. Must include, at a minimum bimonthly (once every 60 days) approval and review of the ITP and case review of every member receiving clinical health services; and
        iv. Must include, at a minimum, at least one hour of on-site supervision, with on-site observation for at least one hour for every 40 hours of service to the member.

Providers must use the following codes to obtain reimbursement for ABA and ABA-related services

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CPT code	Description
97151	Behavior Identification Assessment, administered by QHP, each 15 minutes of QHP's time face-to-face with patient and/or guardian(s)/caregivers(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan
97152	Behavior Identification Supporting Assessment, administered by one technician under the direction of QHP, face-to-face with the patient, each 15 minutes
97153	Adaptive Behavior Treatment by Protocol, administered by technician under the direction of a QHP, face-to-face with one patient, each 15 minutes
97153 w/HO modifier	
97154	Group Adaptive Behavior Treatment by Protocol, administered by technician under direction of QHP, face-to-face with 2+ patients, each 15 minutes
97155	Adaptive Behavior Treatment with Protocol Modification, administered by QHP, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes
97156	Family Adaptive Behavior Treatment Guidance, administered by QHP (with or without patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes
97157	Multiple-Family Group Adaptive Behavior Treatment Guidance, administered by QHP (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes
97158	Group Adaptive Behavior Treatment with Protocol Modification, administered by QHP face-to-face with multiple patients, each 15 minutes

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Autism is a neurodevelopmental disorder in the category of pervasive developmental disorders (PDD), which is a group of conditions that also include Rhett's disorder, childhood disintegrative disorder, Asperger's disorder, and pervasive developmental disorder not otherwise specified (PDD NOS). Autism is characterized by a triad of deficits involving impaired language development, reciprocal social interaction, and stereotyped repetitive patterns of behaviors and interests. The prevalence estimates released by the CDC based on 2002 data show that approximately one in fifty children in the US is autistic. These estimates indicate a dramatic increase in the recent years, which may be due to an actual increase in the occurrence of the disorder as well as the increased awareness of the disorder among the clinicians. There are no definitive medical tests to indicate the presence of any form of autism spectrum disorders (ASD). Diagnostic assessment includes use of ICD and DSM-IV diagnostic criteria and standardized methods to assess core and co-morbid conditions. Parents usually become aware of developmental problems in their child starting around the age of 18 months, but diagnosis is often not made until 2 years after the expression of parents' concerns. It may sometimes be delayed until close to the age of six (Ospina 2008, Granpeesheh 2009, Levy 2009, Spreckley 2009).

Autism is a lifelong condition with variable clinical course throughout childhood and adolescence. Many adults with autism may still require full-time care. While there is no known cure, the general agreement is that early diagnosis followed by appropriate treatment may improve outcomes in later years for most individuals. Over the past twenty years, a variety of therapies have been proposed to improve the symptoms associated with ASD, many of which have not been validated scientifically. These include pharmacological therapies, complementary therapies as diet modifications and vitamin therapy, speech and language therapy, and psychosocial treatments.

The well-researched treatment programs are based on the principles of applied behavioral analysis (ABA), sometimes called behavioral therapy or behavioral modification. The approach has been outlined by Lovaas and colleagues in the 1980s and, as originally described, involves teaching appropriate behaviors by breaking tasks

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down into small discrete steps and training in a systematic and precise way called discrete trial training. It is delivered on a 1:1 basis, for 40 hours a week over a three-year period.

The approach of ABA is based on the concept that children with ASD have significant difficulties with learning, being unable to learn through imitation, and listening as normal children do. Its overall goal is to motivate the child to want to be successful. ABA is founded on behavioral principles of learning and motivation, consisting of reinforcement, extinction, stimulus control, and generalization. The basic learning principle at the core of ABA is the idea that the consequences of a behavior can either strengthen or weaken it; behavior that is followed by the presentation of desirable consequences will be strengthened (reinforcement), whereas behavior that is followed by aversive consequences or the removal of desirable consequences will be weakened.

A defining feature of ABA programs is that they are applied consistently. This is accomplished by the use of explicitly written programs for each skill to be taught or maladaptive behavior to be treated, and by having the behavioral analyst train everyone who works with the child to implement it. To increase the likelihood of the generalization of the treatment efforts, it is critical for the therapists and parents to be trained to implement the programs across situations, settings, and people. Typically, teaching trials are repeated until they are mastered. Maladaptive behaviors such as aggression and self-injury are not reinforced, whereas specific, appropriate alternative behaviors are either taught or maintained through positive reinforcement. Each child's program is unique to his/her needs that evolve with the child's progress. Accurate records are kept so that progress can be assessed, and programmatic changes made (Spreckley 2009, Granpeesheh 2009).

Treatment based on APA represents a wide range of early intervention strategies for children with autism. As indicated earlier, the first types of behavioral treatment programs developed, the discrete trial training, were very intensive and structured. Investigators found that children may have difficulty generalizing the information from these very structured sessions to group and community settings. One comprehensive intervention program reviewed by the National Research Council (NRC) was early intensive behavioral intervention (EIBI) based on the UCLA Young Autism Project Model. This is an intensive home-based program using the manual published by Lovaas and involves up to 40 hours of therapy per week for at least 2 years. Other EIBI programs were developed by other researchers (Howlin 2009, Reichow 2009).

Less structured more naturalistic behavior programs e.g. incidental teaching and pivot response training (PRT) have been developed but were not researched in a randomized controlled fashion. Currently, even structured sessions include naturalistic methods for increasing generalization and maintenance. Parent mediated interventions have been reported to be an important aspect of intervention. Overall, structured programs share a common core of set features including: 1. starting the intervention at the earliest possible age (3-4 years), 2. Intervention is intensive (20-40 hours per week), 3. Intervention is individualized, comprehensive, and targeting a wide range of skills, 4. Multiple behavior analytic procedures are used to develop adaptive repertoires, 5. Treatment is delivered in one-to-one format with gradual transition to group activities and natural contexts, 6. Treatment goals are guided by normal developmental sequence, and 7. Parents are, to different extents, trained and become active co-therapists (Levy 2009, Virues-Ortega 2010).

Medical Technology Assessment Committee (MTAC)

ABA Therapy

04/19/2010: MTAC REVIEW

Evidence Conclusion: There is lack of published well-conducted randomized controlled trials on behavioral interventions for young children with autism. The published trials had their limitations; they had small sample sizes, the majority were not randomized, the participants were frequently diagnosed without using standardized tools, the studies examined different treatments, with different delivery approaches and intensities, over different time spans (ranging from 12 weeks to 2 years) and had different measurement approaches for assessing outcomes. IQ was a major outcome for the majority of studies, and it might not be possible to determine whether an improved IQ results from true improvement of cognitive skills, or better test taking ability. In addition, IQ is not necessarily the main problem in autistic functioning. Autism treatment needs to address every developmental area, all areas of adaptive behavior, and then a whole set of aberrant behavioral responses, involving both positive and negative symptoms (Rogers 2008). A number of systematic reviews and meta-analyses of the published studies were conducted by several authors. The methodology of the analyses was valid in general, however even a well conducted meta-analysis is only as good as the studies it includes. The studies on intensive behavioral intervention, as indicated earlier, had their limitations and biases and varied widely in the treatments

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intensity, duration, mode of delivery, and outcome measures; all of which limits generalization of the pooled results. The meta-analyses either pooled the results of controlled studies only or all studies with or without comparison groups. Their results were conflicting, while, Virues-Ortega (2010), Eldevik (2009), Reichow (2009), Howlin (2009) and others show that that ABA /EIBI interventions were associated with improved outcome (primarily measured by IQ) among some children with autism, Ospina (2008) and Spreckley et al (2009) showed no statistically significant additional benefit of APA/EIBI intervention vs. other interventions applied to young children with ASD.
Dawson and colleagues' study (2010), a more recently published randomized controlled trial with valid methodology, can be considered the most rigorous RCT on comprehensive development behavioral intervention. The authors randomized 48 young children to receive Early Start Denver Model (ESDM), a comprehensive behavioral intervention, or to be referred to community providers for intervention commonly available in the community. They were followed up for 2 years and the primary outcome was change in Mullen Scales of Early learning (MSEL) and the Vineland Adaptive Behavior Scales (VABS) composite standard scores. The results of the trial suggest that very young children with autistic disorders may achieve higher cognitive and adaptive scores and improvement in diagnosis after a 2-year comprehensive intervention strategy that includes parental involvement. The study however does not allow determining if the benefits gained would be sustained over time.
Conclusions: There is insufficient evidence from well-conducted large randomized comparative trials with long term follow-up to determine which comprehensive treatment approach is best for young children with autism, and in particular the most effective treatment for teaching specific skills given certain profiles and characteristics of the child.
Articles: The literature search revealed around 100 articles on ABA/ EIBI for young children with autism. The majority were reviews or articles not related to the current review. There were at least 6 systematic reviews with or without meta-analyses on ABA /EIBI intervention for young children with autism. A small more recent RCT (N=48) on the Early Start Denver Model for toddlers with autism was identified. The search also revealed a systematic review by Clinical Evidence on all interventions for autism including early multidisciplinary interventions based on APA and including home-based, school based, community based or multisite interventions.
Three of the meta-analyses on ABA/EIBI for young children were selected for critical appraisal as well as the recently published randomized trial. Dawson G, Rogers S, Munson J, et al. Randomized controlled trial of an intervention for toddlers with autism: The Early Start Denver Model, Pediatrics 2010;125:1:e17-e23 See Evidence Table Eldevik S, Hastings RP, Hughes JC, et al. Meta-analysis of early intensive behavioral intervention for children with autism J Clin Child Adolesc Psych 2008;38:439-450 See Evidence Table
Spreckley M, Boyd R. Efficacy of applied behavioral intervention in preschool children with autism for improving cognitive, language, and adaptive behavior: A systematic review and meta-analysis. J Pediatr 2009; 154:338-344. See Evidence Table Virues-Ortega J. Applied behavioral analytic intervention for autism in early childhood: Meta-analysis, meta-regression and dose-response meta-analysis of multiple outcomes. Clinical Psychology Review. 2010 , doi:10.1016/j.cpr.2010.01.008 See Evidence Table

The use of applied behavioral analysis therapy (ABA), early intensive behavior interventions (EIBI) for the treatment of young children with autism does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes

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97153 (with HO Modifier)	Adaptive behavior treatment by protocol, administered by physician or other qualified health professional, face-to-face with one patient.
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Date	Date Last Revised
05/07/2010	05/04/2010 MDCRPC, 05/03/2011 MDCRPC, 04/03/2012 MDCRPC, 12/04/2012 MDCRPC ,10/03/2013 MPC ,12/03/2013 MPC, 08/05/2014 MPC, 11/04/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC, 08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC,	10/04/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
02/07/2017	Revised ABA criteria for commercial members
12/05/2017	MPC approved to delete indication related to school coverage for ABA Therapy (commercial members, except MS)
01/09/2018	MPC approved to modify criteria to remove any language regarding school practices
11/01/2018	Removed the H codes and added the ABA Reimbursable Services
08/06/2019	Revised ABA criteria for commercial members and updated background information to highlight ITP updates
07/06/2021	MPC approved to adopt updates to clinical criteria for Non-Medicare members, with the exception of Microsoft, as there is separately maintained criteria for Microsoft members. Revisions made to clarify requirements, and a new requirement was added for two or more developmental and behavioral assessments used to measure gaps in functioning instead of one. Updated applicable coding to exclude H2017, 0362T, and 0373T. Requires 60-day notice, effective date 10/01/2021.
08/03/2021	Format change: merged separate non-Medicare criteria into main page (Microsoft criteria still a separate document)
01/03/2022	Updated Microsoft SPD language from 2022 document - replaced the terms child or dependent with 'member' throughout.
10/04/2022	MPC approved to modify ABA criteria to clarify coverage language.

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Clinical Review Criteria
Ankle Brachial Index Device

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Ankle Brachial Index Device*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Peripheral artery diseases (PAD) are atherosclerotic diseases resulting in occlusion of peripheral arteries (abdominal aorta, iliac, and lower extremity arteries). The prevalence of lower extremity PAD, around the globe, is estimated at 3 to 12% (Hirsch et al., 2006; Norgren et al., 2007; Olin & Sealove, 2010). Patients may experience rest pain, ulceration, claudication, hospitalizations, and even amputation of limb. PAD may also be asymptomatic. The rate of myocardial infarction, stroke, and cardiovascular mortality is significantly increased with PAD (Olin & Sealove, 2010).

Several risk factors have been identified. However, The American College of Cardiology/American Heart Association (ACC/AHA) guidelines on PAD have recognized specific risk groups with a higher prevalence of PAD. These include age ≥ 70 years, age 50 to 69 years with a history of diabetes or smoking, age 40 to 49 with diabetes and at least one other risk factor for atherosclerosis, leg symptoms indicative of claudication with

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exertion or ischemic pain at rest, abnormal lower extremity pulse examination, known atherosclerosis at other sites (coronary, carotid, renal artery disease) (Hirsch et al., 2006).

Ankle-brachial-index (ABI) using doppler is one of the tests used to diagnose peripheral artery disease (PAD). It measures the ratio of the systolic ankle to brachial pressure. PAD is defined by an ABI ≤ 0.9. However, studies have reported a low utilization of the ABI due to lack of skills to perform the procedure (Mohler et al., 2004). ABI is also incorrectly used in primary care (Davies, Kenkre, & Williams, 2014; Nicolai et al., 2009). In addition, the procedure is time consuming and this might contribute to its low use in busy healthcare centers (Davies et al., 2014; Nicolai et al., 2009). These limitations result in underdiagnosis and undertreatment of PAD.

Several automated ABI devices have been developed to overcome the limitations of Doppler ABI. These encompass devices using oscillometric technology and plethysmographic-based technology. Oscillometric-based devices seem to be less accurate (Verberk, Kollias, & Stergiou, 2012) in computing ABI.

The plethysmographic method is based on reperfusion plethysmography. “A dual-chamber cuff applied to each limb consists of an upper occlusion chamber and a lower detection chamber. When the pressure of the upper occlusion chamber has exceeded arterial systolic pressure, the distal detection chamber detects a gradual decrease in limb volume as a result of blood redistribution in the absence of arterial blood inflow. As the pressure in the occlusion chamber is then incrementally reduced and reaches systolic pressure, arterial blood flow to the limb is restored, which is detected as a volume increase in the lower chamber. The pressure in the upper occlusion chamber at the point when this lower chamber volume increase occurs, is taken as the limb arterial systolic pressure” (Davies & Williams, 2016).

Several manufacturers have developed automated ABI machines using plethysmography technology. Manufactured by Huntleigh Diagnostics, Cardiff, UK, the Dopplex Ability is an automated device that measures ankle-brachial index (ABI) and pulse volume recordings (PVR). It uses air plethysmography technology to perform these assessments (Millen et al., 2018). The Dopplex ability provides fast and easy measurements with a printout of results from integrated software package. ABI’s are computed in three minutes (without the need to rest the patient), interpreted and displayed with pulse volume waveforms on LCD panel. The Dopplex ability system includes Dopplex ability automatic machine, one box of disposable sleeves, four pieces set of standard 8½"-14"cuffs, one pack of standard thermal paper, and one set of adhesive paper. The Dopplex ability is intended for wound care for arterial disease before deciding on compression bandaging. It is also considered for PAD detection, and congestive heart disease screening (identification of risk factors) (https://www.usamedicalsurgical.com/huntleigh-dopplex-ability-automatic-abi-system/). Other manufacturers include Newman Medical (USA), Enverdis, Skidmore Medical.

Medical Technology Assessment Committee (MTAC)

Ankle-Brachial Index device using plethysmographic method for the diagnosis of peripheral artery disease
04/08/2019: MTAC REVIEW

Evidence Conclusion:

Low evidence suggests that automated ABI device using plethysmographic method (Dopplex Ability) shows:

- moderate agreement with doppler manual method and low reliability
- moderate sensitivity along with high specificity and accuracy for detection of PAD in comparison with the Doppler method as a gold standard
- a conflicting proportion of failing measurements

More studies are needed to clarify whether Dopplex Ability alone can provide enough diagnostic accuracy

Articles: PubMed was searched through March 15, 2019. Search terms include ((ABI automated system OR Dopplex Ability)) AND (peripheral artery disease OR PAD). Other terms consist of Automated plethysmography AND ankle-brachial index AND doppler ultrasound. SimpleABI system OR simpleABI automated system OR ABI Doppler system OR ABI automated system was searched. Google scholar was also searched. The search was limited to English language publications and human populations. RCTs and observational studies were included as filter in the search. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Ankle-Brachial Index device using plethysmographic method for the diagnosis of peripheral artery disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No Specific Codes	

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Date Created	Date Reviewed	Date Last Revised
05/07/2019	05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt a non-coverage policy for Ankle Brachial Index Device

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Advanced Care at Home

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Criteria

For Medicare & Non-Medicare Members

Effective 12/01/2022

As of 01/01/2023 as groups renew (please check member's contract as some groups may renew later in the year), this criteria/benefit will apply to the following plans:

- Fully Insured Large Commercial groups (all plans except for FEHB Core and Options have opted out for 2023)
- Self-Funded Large Commercial groups (please note: groups are able to opt out
- Individual Medicare (all plans except the Basic plan)
- Employer Group Medicare (please note: groups are able to opt out)

A. To receive advanced care in the home, the member must meet **ALL of the following:**
   - The member must be referred into the advanced care program by the managing provider such as in an emergency room setting
   - Advanced Care at Home requires preauthorization based on the member's health status, treatment plan, and home setting or another appropriate care location within the service area
   - The clinical condition must meet inpatient medical necessity criteria, per MCG care inpatient hospitalization guidelines appropriate to the patient's clinical condition
   - The member must consent to receiving advanced care described in the treatment plan
   - The care location, such as the member's residence, must be within 30 minutes ground travel time of an emergency department **AND**
   - The care location, such as the member's residence, must have cell service

B. Advanced Care at Home is provided through Medically Home, Kaiser Permanente's network provider, and will provide the following services in the member's home or appropriate care location:
   - Home visits by RNs, physical therapists, occupational therapists, speech therapists, respiratory therapists, nutritionist, health aides, and other healthcare professionals in accordance with the Advanced Care at Home treatment plan and the provider's scope of practice and licensure.
   - Communication devices to allow the member to contact the medical command center 24 hours a day, 7 days a week. This includes needed communication technology to support reliable connection for communication, and a personal emergency response system alert device to contact the medical command center if the member is unable to get to a phone.

C. Additional services covered under this benefit include:
   - The following equipment necessary to ensure that the patient is monitored appropriately in home: blood pressure cuff/monitor, pulse oximeter, scale, and thermometer
   - Mobile imaging and tests such as X-rays, ultrasounds, and EKGs
   - Safety items when medically necessary, such as shower stools, raised toilet seats, grabbers, long handled shoehorn, and sock aids
   - Meals when medically necessary while patient is receiving advanced care at home

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In addition, the following services and items are covered under this benefit when prescribed as part of the Advanced Care at Home treatment plan:

- Durable Medical Equipment
- Medical Supplies
- Member transportation to and from network facilities when member transport is medically necessary
- Physician Assistant and Nurse Practitioner house calls
- Emergency Department visits associated with this benefit

Exclusions: Private Duty Nursing; housekeeping or meal services not part of the Advanced Care at Home treatment plan; any care provided by or for a family member; any other services rendered in the home which are not specified in the member's Advanced Care at Home treatment plan

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Background

Advanced Care at Home is a personalized, patient-centered program that provides care for patients with certain clinical conditions in their homes, or at another appropriate care location.

Advanced Care at Home services must be associated with an acute episode and the treatment plan may include restorative care associated with the acute episode. The duration of an episode of care (which includes acute and restorative phases) is limited to a total of 30 days.

Applicable Codes

Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.

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Date Created	Date Reviewed	Date Last Revised
08/02/2022	08/02/2022[MPC]	

[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria

Autologous Chondrocyte Implantation for Treatment of Defects in Articular Cartilage of the Knee

- Matrix Autologous Chondrocyte Implantation (MACI)
- Microfracture
- Mosaicplasty
- Osteochondral Autograft Transfer System (OATS)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Autologous Chondrocyte Implantation," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Autologous Chondrocyte Implantation (ACI) Matrix Autologous Chondrocyte Implantation (MACI)	Autologous chondrocyte implantation (ACI) or autologous chondrocyte transplantation (ACT) using the MACI™ implant is considered medically necessary when **ALL** of the following criteria have been met: • Documentation should support why an alternative cartilage restoration procedure such as OATS are contraindicated • Symptomatic single or multiple full-thickness cartilage defects of the femoral condyle, patella, or trochlea with normal surrounding cartilage (Modified Outerbridge Classification grade III or IV*) and no evidence of degenerative disease such as osteoarthritis • Severe disabling knee pain limiting ambulation • Absence of systemic disease (gout, rheumatoid arthritis, etc.) • Failure of at least 3 months of provider-directed conservative therapy such as physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs (NSAIDs) • Patient is skeletally mature (closed growth plates) and not a candidate for arthroplasty (age 15 – 55) • Knee is stable with intact or reconstructed ligaments (ACL or PCL) and menisci. A concurrent ligament stabilization or meniscal procedure at the time of ACI would be acceptable • No more than 50% partial meniscectomy in the target knee

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	• Defect(s) are unipolar – there is no corresponding kissing lesion on facing cartilage • Lesion is greater than 1.0cm^{2**} (too large for bone stimulation) and less than 10cm^2, or the lesion is less than 1.0cm^2 and patient has previously failed marrow stimulation for that lesion • Has not had any knee joint surgery within the past 3 months (excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant) • Normal tibial-femoral and/or patella-femoral alignment based on weight-bearing alignment x-rays, or osteotomy is planned • BMI less than or equal to 35 • Patient is able and willing to follow post-operative protocol (6 weeks limited weight bearing) • Must be authorized by Kaiser Permanente Medical Director in consultation with Orthopedics *Modified Outerbridge Classification The Outerbridge classification is a grading system for joint cartilage breakdown. **MRI Results** **GRADE I** focal areas of hyperintensity with normal contour **GRADE II** blister-like swelling/fraying of articular cartilage extending to surface **GRADE III** partial thickness cartilage loss with focal ulceration **GRADE IV** full thickness cartilage loss with underlying bone reactive changes **Lesions less than 1.0cm^2 should be treated with marrow stimulation
Osteochondral Autograft Transfer System (OATS) or Mosaicplasty *27416, 29866* Microfracture (MFX)* *29879*	Does not currently require medical review.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Articular hyaline cartilage is a highly specialized connective tissue that covers the surface of bone in synovial joints. It is a 2-4mm thick hyaline cartilage that provides smooth low friction movement and shock absorption. Unlike most tissues, articular cartilage does not have blood vessels, nerves, or lymphatics. It is composed of a dense extracellular matrix (ECM) with a sparse distribution of highly specialized cells called chondrocytes. The ECM is principally composed of water, collagen, and proteoglycans, with other non-collagenous proteins and glycoproteins present in lesser amounts. These components help to retain water within the ECM, which is critical to maintain the unique mechanical properties of the cartilage (Fox 2009, Negrin 2013, Oussedik 2015).

The articular cartilage is prone to damage from acute high energy trauma and from repetitive shear and torsional forces applied to the surface. Lesions to the articular cartilage are often associated with pain and compromised joint function and may lead to the development and progression of osteoarthritis. The damaged cartilage has very limited capacity for self-repair due to its avascular and hypocellular nature. Surgery has thus been the standard approach for repairing articular cartilage damage. Surgical techniques intended for restoring the articular surface are classified into 3 categories: 1. Marrow stimulation procedures such as microfracture, 2. Cell-based implantation, and 3. Osteochondral grafting. Surgical interventions have also been categorized as 1. Reparative, which includes marrow stimulation such as microfracture; drilling; and abrasion arthroplasty, and 2. Reconstructive that includes allograft transplantation; osteochondral autograft transplantation (OAT); and

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autologous chondrocyte implantation (ACI). Investigators suggest that microfracture surgeries is more effective than reconstructive surgeries for the repair of smaller cartilage defects (<100mm2) while reconstructive surgeries are more effective for larger defects (>100mm2) (Crawford 2012, Perera 2012, Negrin 2013, Mundi 2015, Li 2015).

Currently, marrow stimulation through microfracture is the standard first-line surgical treatment for articular cartilage lesions of the knee. The microfracture technique was developed by Steadman in the early 1980s. It is a single-stage arthroscopic procedure that involves penetrating the subchondral bone plate after removing the damaged hyaline cartilage. Bleeding from the subchondral bone forms a clot that attracts bone marrow cells to migrate into the cartilage defect and create a 'super clot' that eventually matures into a firm repair tissue consisting of a combination of fibrous and hyaline-like cartilage. The technique is minimally invasive, technically simple, and is associated with low morbidity. However, the repair is composed of fibrocartilaginous tissue, which is mechanically inferior to the native hyaline cartilage; it has less ability to withstand shock and shearing forces leading to deterioration in function over time. In addition, the bone marrow stem cells and growth factors are released into the joint rather than being contained in the site of the defect. Some researchers suggest that microfracture is more effective in reducing pain and improving joiny function when performed for new injuries, small focal injuries, and in younger individuals with lower body mass index (Crawford 2012, Negrin 2013, Lee 2014, Mundi 2015).

Osteochondral autograft transfer (OAT), also known as osteochondral cylinder transplantation or mosaicplasty, is a whole tissue transplantation procedure that was developed in the 1990s for hyaline cartilage repair. It is a surgical technique that uses osteochondral grafts taken from the lighter-load bearing areas of the patient's own joint to fill the focal defects. There is a concern however, with the donor site morbidity, and thus the technique may not recommend for lesions larger than 400mm2 (Li 2015, Mundi 2015).

Autologous chondrocyte implantation (ACI), also known as autologous chondrocyte transplantation is a cell-based method that was introduced in the late 1980s for the treatment of symptomatic full thickness cartilage defects of the knee. The first generation of ACI (ACI-P) is a two-stage procedure. First, a cartilage biopsy is harvested from healthy cartilage of the affected knee during an arthroscopic biopsy procedure. The specimen of live articular cartilage is sent to a cell expansion laboratory for chondrocyte culture. The cells are separated from the cartilage under a strictly controlled environment, and then multiplied using a cell-culture technique for 3-6 weeks. The cultured chondrocytes are then implanted into the cartilage defect in an open arthrotomy procedure. This procedure involves removing a periosteal flap from the proximal medial tibia, suturing it to the surrounding rim of normal tissue, and implanting the expanded chondrocytes beneath the flap to start filling the defect by producing a matrix. Unlike the MS techniques, it is reported that ACI has the ability of repairing the defect by a hyaline-like cartilage with a hybrid of fibrocartilage and hyaline like tissue, or with fibrocartilaginous material containing type-1 and type II collagen. ACI-P is an invasive, technically complicated procedure that involves two operations, has a long recovery time, and requires extensive post-surgical rehabilitation. The technique has variable success rate and may be associated with periosteal hypertrophy and overgrowth that would require additional surgeries (Crawford 2012, Niemeyer 2014, Mundi 2015).

Several modifications to the first generation ACI-P have been made to reduce the procedural technical demands associated with the tissue harvest and the use of periosteal flap in order to decrease the surgical morbidity and prevent periosteal hypertrophy and overgrowth. These modifications were described as second and third generations. The second generation ACI (ACI-C) uses bioengineered bilayer collagen covers to substitute for the periosteal flap and avoid the spill over and asymmetric distribution of chondrocytes following implantation. The third generation ACI explores the use of biomaterials to construct a 3-dimensional scaffold for chondrocyte implantation; the all-in-one grafts do not need a periosteal cover or fixing stitches and can be trimmed to fit the cartilage defect with fibrin glue. It has been reported that implantation of third generation ACI can be performed arthroscopically or with a small incision (Vasiliadis 2010, Kuroda 2011, Crawford 2012, Negrin 2013, Mundi 2015, Samsudin 2015).

Medical Technology Assessment Committee (MTAC)

Autologous Chondrocyte Implantation

02/14/2001: MTAC REVIEW

Evidence Conclusion: The existing evidence is not sufficient to determine the effect of ACI on health outcomes. The only data available are from case series report that have compromised validity and are not considered to provide high quality data. Each of the two case series articles evaluated had additional limitations beyond study type including providing little information about possible adverse effects. Peterson and colleagues are involved with a prospective randomized trial of autologous chondrocyte transplantation compared to periosteum alone or

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subchondral drilling for the treatment of primary chondral lesions of the femoral condyle. Results of this study will provide higher-quality data.
Articles: Fourteen articles were identified. Eleven articles were not directly relevant, did not include clinical outcomes or were review articles; three articles presented empirical data on clinical outcomes. Articles were selected based on study type. There were no meta-analyses or randomized controlled trials. The three empirical articles were all case series. Sample sizes were 8 patients, 44 patients and 94 patients. An evidence table was created for the two-case series reports with the largest number of patients: Peterson L, Minas T, Brittberg M, Nilsson A, Sjogren-Jansson E, Lindahl, A. Two-to-9-year outcome after autologous chondrocyte transplantation of the knee. Clin Orthop 2000; 374: 212-234. See Evidence Table. Minas T. Chondrocyte implantation in the repair of chondral lesions of the knee: Economics and quality of life. Am J Orthop 1998; 27: 739-44. See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/17/2003: MTAC REVIEW
Autologous Chondrocyte Implantation
Evidence Conclusion: There were two small randomized controlled trials (Bentley et al, n=100.; Horas et al., n=40). Neither provided strong evidence that autologous chondrocyte implantation is superior to an alternate procedure for repairing osteochondral defects in the knee. The Bentley study was larger and had stronger methodology. The authors found that the overall clinical results did not differ significantly between groups (autologous chondrocyte implantation compared to mosaicplasty), but that, among the 51 patients with medial femoral defects, the autologous chondrocyte group had better post-operative knee function. The one-year arthroscopic data in the Bentley study was compromised because 40% of patients were missing from the analysis. The Horas study had inadequate randomization and several additional threats to validity. They found worse post-operative knee instability in the autologous chondrocyte transplantation group compared to a group receiving autologous osteochondral cylinder transplantation and no significant differences between groups on the two other primary measures.
Articles: Bentley G, Biant LC, Carrington RWJ et al. A prospective, randomized comparison of autologous chondrocyte implantation versus mosaicplasty for osteochondral defects in the knee. *J Bone Joint Surg (Br)* 2003; 85-B: 223-230. See Evidence Table. Horas U, Pelinkovic D, Aigne T, Schnettler R. Autologous chondrocyte implantation and osteochondral cylinder transplantation in cartilage repair of the knee joint. *J Bone Joint Surg (Br)* 2003; 85-A: 185-192.See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/14/2004: MTAC REVIEW
Autologous Chondrocyte Implantation
Evidence Conclusion: The evidence consists of three controlled trials (2 randomized, 1 pseudo-randomized), all comparing autologous chondrocyte implantation to other surgical procedures to restore articular cartilage. There are no sham controlled studies. None of the studies found significantly better clinical outcomes with ACI compared to the alternative intervention 1-2 years post-surgery; some may have been underpowered. Knutsen et al, the strongest study methodologically, found better results for the group receiving microfracture on one key outcome, the physical component score of the SF-36. The Bentley study found better histological results in the ACI group, but this analysis included only 60% of the randomized patients. In summary, ACI does not provide a clear clinical advantage over other surgical procedures to heal cartilage injuries and may be inferior to microfracture.
Articles: The Medline search yielded 42 articles, many of which were on technical aspects of the procedure or on related technologies. There were three randomized controlled trials and all three were critically appraised. References are as follows: Knutsen G, Engebretsen L, Ludvigsen TC. Autologous chondrocyte implantation compared with microfracture in the knee. *J Bone Joint Surg* 2004; 86-A: 455-464. See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/05/2006: MTAC REVIEW
Autologous Chondrocyte Implantation
Evidence Conclusion: One new RCT compared autologous chondrocyte implantation to an alternative procedure. The study (Dozin et al., 2005) did not find a significant difference in the clinical success rate of patients

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who received ACI or mocaicplasty. The study was underpowered to detect a clinically meaningful difference between groups due to low compliance rate. Only 12/22 (54%) in the ACI group and 11/22 (50%) in the mosaicplasty group actually received the surgery, which occurred 6 months after an initial debridement. The best evidence on ACI for treatment of defects in articular cartilage of the knee remains the randomized controlled trials reviewed in 2004. The conclusion from the previous MTAC report was: The evidence consists of three controlled trials (2 randomized, 1 pseudo-randomized), all comparing autologous chondrocyte implantation to other surgical procedures to restore articular cartilage. There are no sham controlled studies. None of the studies found significantly better clinical outcomes with ACI compared to the alternative intervention 1-2 years post-surgery; some may have been underpowered. Knutsen et al, the strongest study methodologically, found better results for the group receiving microfracture on one key outcome, the physical component score of the SF-36. The Bentley study found better histological results in the ACI group, but this analysis included only 60% of the randomized patients. In summary, ACI does not provide a clear clinical advantage over other surgical procedures to heal cartilage injuries and may be inferior to microfracture. A 2005 technology assessment conducted by the National Institute for Health and Clinical Effectiveness (NICE) in England concluded that there is inconsistent evidence on the clinical effectiveness of ACI and did not recommend ACI except in the context of ongoing clinical trials.
Articles: Three new randomized controlled trials were identified. Two trials, one by Bartlett and colleagues and the other by Gooding and colleagues, were not evaluated further because they compared two types of autologous chondrocyte replacement and did not include a control group that received an intervention other than ACI. (In addition, the Gooding study was only available as an abstract). The other trial compared ACI and mosaicplasty and was critically appraised: Dozin B, Malpeli M, Cancedda R et al. Comparative evaluation of autologous chondrocyte implantation and mosaicplasty. Clin J Sport Med 2005; 15: 220-226. See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/21/2016: MTAC REVIEW
Autologous Chondrocyte Implantation (Autologous Chondrocyte Transplantation) For the Treatment of Chondral Defects in the Knee
Evidence Conclusion: Autologous chondrocyte Implantation (Carticel, the first generation) was previously reviewed by MTAC, four times between 1998 and 2006. At the time the best published evidence consisted of four controlled trials (three randomized and one pseudo-randomized), none of which found significantly better clinical outcomes with ACI compared to the alternative interventions at 1-2 years post-surgery. Knutsen, et al (2004), the strongest study methodologically, at the time, found better results for the group receiving microfracture on one key outcome (the physical component score of the SF-36). The Bentley et al's study (2003) found better histological results in the ACI group, but the analysis included only 60% of the randomized patients. In summary the 2006 report concluded that ACI does not provide a clear clinical advantage over other surgical procedures to heal cartilage injuries and may be inferior to microfracture. The updated literature search for the current re-review of ACI, identified a number of published comparative and non-comparative studies evaluating the effectiveness of ACI, marrow stimulation (MS, mainly with MF techniques), and OAT, in improving the clinical outcomes of patients with cartilage lesions in the knee. Different ACI generations and techniques were evaluated and /or compared to other interventions used for restoring knee function. The published studies were relatively small, and in addition to the variations in the surgical techniques and approaches used for ACI and other procedures, there were differences between the studies in the criteria for patient selection, lesion sizes, outcomes, duration of follow-up, and measures used to evaluate histological and/or functional outcomes. In addition, none of the trials was blinded and pain and function measures mainly relied on subjective evaluation, which may bias the results. Few studies showed minimal differences between ACI compared to MF, or OAT, and many others found no significant differences in outcomes with the different surgical techniques. The majority of the studies were underpowered to detect statistical differences, and a lack of significant differences between procedures does not necessarily indicate that they are equivalent or have similar effects. Combining the studies into meta-analyses increases the power, but the significant heterogeneity between the published studies on the treatment of chondral lesions in the knee precluded pooling the results of the individual studies in many cases, and/or performing subgroup analyses to determine the optimal procedure to the patient according to the lesion size, type of activity, comorbidity, and other characteristics. Few authors cautiously pooled the results of studies into meta-analyses, but these have to be interpreted with caution as the results of a meta-analysis are as good as the quality of the studies it includes.
ACI versus microfracture (MF): Mundi and colleagues (2015) (Evidence Table 1), performed a systematic review and meta-analysis of RCTs to compared ACI, MF, and OAT. The authors could only pool the results of the studies comparing ACI versus marrow stimulation (MS), mainly using the microfracture (MF) technique. The meta-analysis had valid methodology and analysis, but the included studies had their limitations, and were significantly heterogeneous. The overall pooled results showed no significant difference between ACI and MF in improving knee function and pain at intermediate-term follow-up. Oussedik and colleagues (2015) performed a systematic review to compare the outcomes of MF and ACI in patients with articular cartilage lesions of the knee.
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The review included 34 articles only 9 of which were comparative studies, the rest were observational with no control groups, and 2 were animal model studies. The authors could not pool the results of the comparative studies into a meta-analysis due to the significant heterogeneity between the studies. They concluded that low quality (grade IV) evidence suggests that MF may be effective in smaller lesions and is usually associated with a greater proportion of fibrocartilage production which may affect its durability. They also suggested that the multiple lesions treated with MF have poorer outcomes compared with single lesions. ACI was an effective treatment that may result in a greater proportion of hyaline-like tissue at the repair site, appears to be effective for larger lesions. The authors noted however, that the variation in techniques and modifications used for repairing chondral lesions of the knee, together with the different outcomes and measures used, and lack of long-term follow up make it hard to compare techniques and /or determine the optimal procedure for the different patient groups. Negrin and colleagues (2013) (Evidence Table 2), conducted a systematic review and meta-analysis to compare the clinical outcomes of MF and ACI after equal follow-up periods. The review included 7 RCTs and 2 observational studies with at least one-year follow-up. The meta-analysis had some disadvantages which may limit generalization of its results. It included a small number of studies with relatively small population sizes, and the authors pooled the results of the RCTs together with the observational studies that used different scores and values for assessing the outcomes. They performed two meta-analyses: the first included all three ACI generations, and the second only included the second and third generations. The first analysis showed a small statistically insignificant difference between MF and all three ACI generations combined after 1 year, and the second meta-analysis showed a significant improvement with ACI after the first-generation study (Knutsen et al, 2007) was excluded. The authors noted however, that the observed statistically significant difference was clinically irrelevant. They indicated that the two procedures are complementary, and that large RCTs with long-term follow-up are needed to determine which groups of patients would benefit more from each procedure. Vanlauwe J, and colleagues (2011) published 5-year follow up results of an earlier study (Saris et al, 2008) that compared ACI using characterized chondrocyte implantation (CCI) (ChondroCelect, Belgium) vs. MF in 118 patients with a single symptomatic cartilage defect in the knee. The study had 90% power to detect a significant difference in the success rate between the two techniques. The first article reporting the results of one-year follow up showed significant clinical improvement with the two techniques when compared to baseline. There were no significant differences between the two procedures in the short-term clinical outcomes or complication rates, but the tissue regenerate was superior with ACI. The published 5-year results showed that the clinical improvements reported at 12 months and 24 months were maintained for the duration of follow-up. There were no significant differences between the two groups in clinical outcomes, radiological outcomes, or treatment failures. However, the latter tended to occur earlier with MF (in those treated in less than 3 years from onset of symptoms). Subgroup analyses showed no significant differences by age (at 35 years cutoff), and that females had more treatment failures irrespective of the procedure they underwent. Knutsen and colleagues' (2007) long-term follow-up results of the RCT that compared first generation of ACI vs. MF (published in 2004 and reviewed earlier by MTAC) showed no significant difference between the two techniques in the clinical or radiological outcomes at 5 years posttreatment. There was a 23% failure rate (need for a reoperation due to lack of healing) in each of the treatment groups at 5 years compared to only 2.5% failures in the MF and 5% with ACI at 2 years. Younger patients (<30 years of age) had better outcomes than older patients irrespective of the treatment group. One third of the patients had radiographic evidence of early osteoarthritis at 5 years. The authors noted that the study was limited by only including patients with chronic symptomatic cartilage defect of the knee, and by the lack of a control group that did not undergo surgical treatment or who were simply treated with arthroscopic lavage. The authors concluded that further long-term follow-up is needed to determine if one method is superior to the other, and to study the progression of osteoarthritis. ***ACI versus Osteochondral autograft transplantation (OAT)*** Li et al, 2015 (Evidence Table 3) performed a systematic review and meta-analysis of RCTs to compare the efficacy of OAT versus ACI in the treatment of large cartilage defects of the knee. The analysis included 5 relatively small trials two of which evaluated the same cohort at different time periods. There were differences between the studies in the surgical techniques and scoring of outcomes. The authors quantified the results into crude grades for comparisons. The overall pooled results of the trials, after performing a sensitivity analysis suggest that there were no significant differences between OAT and ACI results in the short-term, but ACI has superior outcomes on the long-term. Patients undergoing OAT were more likely to have worse conditions on the long-term when compared to those receiving ACI. The authors explained that the injuries for autografts in OAT, the absence of fill and difference in orientation may influence the patient outcomes and limit further OAT procedures. On the other hand, ACI can be performed repeatedly in the same patient using tissue engineered material. Clave, et al (2016), randomized 55 patients with isolated symptomatic femoral osteochondral defects 2.5-7.5 cm^2 to receive Cartipatch (third generation ACI) or mosaicplasty (OAT). Patients were followed-up or 2 years, and the primary outcome measure was the change in the functional outcome from baseline to month 24 postoperatively. This was subjectively measured by International Knee Documentation Committee (IKDC) score. The investigators could only recruit 55 of the 76 (72%) patients needed to provide sufficient power, 15% of those randomized were lost to follow-up, and only 54% were included in the analysis. The authors indicated that contrary to the hypothesis of the study, the results showed that mosaicplasty was superior to Cartipatch in improving IKDC score 2 years after
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surgery. The significant difference between the two procedures was observed for defects measuring ≥ 3.5 cm^2. No significant difference was observed for smaller lesions. The trial was randomized and controlled but had several disadvantages that would limit generalization of its results. It was small in size, the patients were not blinded to the procedure they underwent, only 55% of those randomized were included in the analysis, the outcome was subjective, and the follow-up duration was insufficient to determine the long-term outcomes of the interventions. Bentley and colleagues, 2012 (included in Li et al's 2015 meta-analysis discussed earlier) published 10-year results of an earlier RCT that compared ACI to mosaicplasty among 100 patients with chronic lesions. The mean articular cartilage lesion size was 440.9 mm^2 (range 100-1050 mm^2) in the ACI group, and 399.6 mm^2 (100-2000 mm^2) in the mosaicplasty group. The early results of the trial showed significantly better outcome with ACI at 18 months post-surgery. This has been sustained over the years. At ten years, the functional outcome was significantly better with ACI vs. mosaicplasty when measured by the Cincinnati score, but insignificant with Stanmore-Bentley score. It is to be noted however, that only 15 of 48 patients randomized to OAT were included in the 10-year assessment of function. The failure rate (needed revision operations) was significantly higher in the mosaicplasty group vs. the ACI group (55% and 17% respectively). The pattern of failure was different; the ACI showed a low steady failure rate across 10 years, while the mosaicplasty group remained relatively satisfactory for the first 2 years then experienced a steep failure rate over the next 2 years. ***ACI versus any other treatment for articular cartilage lesions*** Vasiliadis and colleagues, 2010 conducted a systematic review of RCTs and quasi-randomized trials to compare ACI with any other type of treatment (including no treatment or placebo). The authors could not pool the results into a meta-analysis due to the clinical and methodological heterogeneity between the studies. They concluded that the studies show that ACI is an effective treatment for full thickness chondral defects and associated with improvement in clinical outcomes compared to baseline. The published evidence, however, does not suggest any superiority of ACI over other treatments; complications rates were comparable between the different interventions except with an increased graft hypertrophy with ACI-P (the first generation ACI). Mundi and colleagues (2015) (Evidence Table 1), systematic review and meta-analysis of RCTs (discussed earlier) compared ACI, marrow stimulation (MS mainly using MF), and OAT to determine whether a single technique has superior outcomes at an intermediate follow-up period. The review included 11 RCTs (published through April 2014) with a total of 765 patients. 5 trials compared ACI vs MS, 3 compared ACI vs. OAT, and 3 evaluated different generations of ACI. The authors could only pool the results of the RCTs comparing ACI versus MS and found no significant difference between the two procedures in improving function or reducing pain at intermediate term follow-up. They indicated that ACI, MS, and OAT are all generally efficacious in improving symptoms in patients with focal knee cartilage defects, The authors pointed to the limitations and heterogeneity of the published studies and noted that the current best evidence does not show that any of the three techniques is superior to the others in improving the intermediate-term pain and function. They concluded that high quality studies with sufficient power and long-term outcomes are needed before any specific intervention is recommended over others. Samsudin and Kamural (2015) conducted a systematic review to compare different generations of ACI to other treatment modalities. Like many other researchers, they could not pool the results of the trials into a meta-analysis due to the heterogeneity between the studies. They concluded that the literature shows a trend towards similar outcomes when comparing ACI generations with other repair techniques, and that there is insufficient evidence to conclude that that ACI and its newer generations are more effective than other techniques in in repairing articular cartilage defects of the knee. Conclusion: There is insufficient published evidence from adequately powered large RCTs with valid methodology and long-term follow-up duration to determine that ACI and its newer generations are superior to other surgical techniques in repairing articular defects of the knee. The variations between the published studies make it difficult to accurately compare one intervention versus another or to determine the optimal procedure and technique for the individual patient. The literature suggests but does not provide sufficient evidence that the newer generations of ACI may be associated with better long-term outcomes compared to microfracture in patients with larger full thickness, focal chondral defects in the knee.

Articles: The literature search revealed a large number of experimental and observational studies on autologous chondrocyte implantation. Several small randomized controlled studies compared one or more generation ACI with MF, with OAT, or versus another ACI generation. The search also identified a number of systematic reviews with or without meta-analyses on ACI compared to one or more of the other treatment modalities. The more recent meta-analysis comparing ACI with microfracture (Negrin, 2013), a meta-analysis comparing ACI to OAT (Li, 2015), an analysis comparing all three procedures (Mundi, 2015) were selected for critical appraisal. Studies comparing one generation ACI to another generation were excluded from the review. Mundi R, Bedi A, Chow L, Crouch S3 Cartilage Restoration of the Knee: A Systematic Review and Meta-Analysis of Level 1 Studies. *Am J Sports Med.* 2015 Jul 2. pii: 0363546515589167. See Evidence Table. Negrin LL, Vécsei V. Do meta-analyses reveal time-dependent differences between the clinical outcomes achieved by microfracture and autologous chondrocyte implantation in the treatment of cartilage defects of the knee? *Orthop Sci*. 2013 Nov; 18(6):940-948. See Evidence Table. Li Z, Zhu T, Fan W. Osteochondral autograft transplantation or autologous chondrocyte implantation for large cartilage defects of the knee: a meta-analysis. *Cell Tissue Bank*. 2015 Jun 12. See Evidence Table.

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The use of Autologous Chondrocyte Implantation (Autologous Chondrocyte Transplantation) For the Treatment of Chondral Defects in the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/12/2021: MTAC REVIEW

Matrix-Induced Autologous Chondrocyte Implantation (MACI) for the Repair of Articular Cartilage of the Knee

Evidence Conclusion:

Hayes Review: A large, moderate-quality body of evidence suggests that MACI is associated with improved symptoms, function, QOL, and ability to perform normal ADL for young and middle-aged and typically nonobese adults with symptomatic articular cartilage defects of the knee. Evidence also suggests that benefits may be durable beyond follow-up periods of 5 years. The evidence consistently favors MACI over MFX, and more limited evidence suggests that MACI and older-generation ACI procedures have similar clinical benefit. Evidence comparing MACI with other surgical procedures was too limited to draw conclusions. Although the majority of studies reported few safety concerns, additional studies are needed to further evaluate the comparative safety of MACI. There remains uncertainty as to when MACI is optimally prescribed in the chondral defect treatment hierarchy, and definitive patient selection criteria have not been clearly elucidated.

INTC recommendations/statements: There is sufficient evidence to determine that the technology improves net health outcomes for select patients. There is insufficient evidence regarding the efficacy and safety of the technology as compared to alternative procedures for the indication. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is of insufficient quantity and/or quality. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is conflicting or inconsistent. There is **no** evidence on the use of this technology in the prevention or diagnosis or treatment or management of this health condition. There is sufficient evidence to determine that the technology does not improve net health outcomes for any patients.

Applicable Codes

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
27412	Autologous chondrocyte implantation, knee
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/1998	11/11/1998[MPC], 02/14/2001[MPC], 04/17/2003[MPC], 07/14/2004[MPC], 06/05/06[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	12/07/2021

[MPC] Medical Policy Committee

Revision History	Description
04/05/2016	Added MTAC review
11/22/2017	Added language to use Non-Medicare language for Medicare
12/07/2021	MPC approved to adopt MTACs recommendation of coverage and the clinical criteria for this medical procedure. Requires 60-day notice, effective date 05/01/2022.

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Clinical Review Criteria
Actigraphy Testing for the Evaluation of Sleep Disorders

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Polysomnography and Other Sleep Studies (L34040)
Local Coverage Article	Billing and Coding: Polysomnography and Other Sleep Studies (A57698)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A sleep disorder (somnipathy) is a medical disorder of the sleep patterns. The international classification of sleep disorders (ICSD)-2 lists over 80 sleep disorders under eight major categories including insomnia, sleep-related breathing disorders, hypersomnia, circadian rhythm sleep disorders, parasomnia, sleep-related movement disorders, and others. It is estimated that 30-40% of Americans have a sleep complaint at any one time and that 10-15% suffer from chronic insomnia (Quan 2006).

The proper diagnosis and management of patients with sleep disorders depends on an accurate clinical history. There is a variety of sleep history questionnaires including the Epworth Sleepiness Scale (ESS) and the Pittsburgh Sleep Quality Index (PSQI). Keeping a sleep-wake diary is a standard procedure used for the subjective assessment of sleep and may give a more complete picture of the individual's sleep patterns and variability from day to day. Sleep diaries are useful for evaluating sleep over extended periods of time in the patient's home environment; they represent an important clinical tool and are often used in behavioral treatment of sleep disorders such as insomnia. However, self-documentation of sleep frequency and duration is prone to bias. The fully attended traditional polysomnography (PSG) is the basic diagnostic procedure and is considered the standard for evaluating sleep disorders. It is an overnight test performed in a sleep laboratory and comprises continuous recording of several physiological variables including airflow, chest/abdominal movements, arterial oxygen saturation, electroencephalography (EEG), electrocardiogram [ECG], electromyography (EMG), and electrooculography (to measure eye movement). The EEG activity, eye movements, and muscle tone reveal the differences between wakefulness and sleep. Some investigators indicate that while the full PSG is widely considered the standard in clinical practice, it is not a true gold standard as it had not been validated. The use of PSG is limited by its high cost, time consumption, complexity, and considerable utilization of hospital resources. It may be impractical in some cases

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among whom sleep patterns must be assessed over extended periods of time. Moreover, PSG assesses sleep in an abnormal environment, which can alter its structure. These disadvantages of PSG have led to the search for alternative tools to diagnose and/or monitor sleep disorders in a natural environment (Bar 2003, Buysse 2005 Broughton 1996, Zou 2006, To 2009, Sunwoo 2010, Martin 2011).

Actigraphs, also called actometers or actimeters, were first used to record sleep and wakefulness based on movement in the early 1970s. The term actigraphy refers to methods utilizing miniaturized sensors that translate physical motion into a numeric presentation. Actigraphy simply measures movement, and is one dimensional, whereas polysomnography comprises at least three distinct types of data (EEG, EOG, and EMG), which jointly determine if a patient is asleep or awake. The actigraphy device may be placed on the wrist, ankle, or trunk. The best placement site for the actigraph to obtain the most reliable data is still controversial. In most studies it is worn on the nondominant wrist based on observations that wrist may detect more movements compared with the ankle and trunk, and that placement on the dominant arm detects more movement than the nondominant arm. The actigraphy device includes a small accelerometer that monitors and records the occurrence and degree of motion. It can collect data continuously over an extended period of one week or longer. Autographic data can be displayed and scored manually or downloaded to a computer for display and analysis by software and algorithms that give estimates of sleep-wake and circadian rhythm parameters. The collected data are translated into epochs (typically 30 seconds or 1 minute) of activity. Using validated algorithms, the epochs are scored as sleep or awake. The device interprets the presence of movement as time awake, and absence of movement as sleep time. Some investigators treat PSG and actigraphy measures as equally valid or alternative measures that provide an estimation of the time an individual spends sleeping and awake. However, actigraphy only measures movement; and electrographic sleep-wake status and motor activity/inactivity are not equivalent. Despite the sophisticated algorithms for actigraphy that may potentially estimate the time an individual spent sleeping and awake based on movement, actigraphy just provides an indirect estimate of sleep-wake as it is commonly defined (Broughton 1996, Lotjonen 2003, Ancoli 2003, Flemons 2003, Kuna 2010, Sanchex-Ortuno 2010, Calogiuri 2013).

Actigraphs vary widely in sizes and features and can be expanded to include sensors which monitor light, sound, temperature, and parkinsonian tremors. Some devices are programmable and allow the selection of specific modes of operation while others have only one fixed mode. New devices, scoring algorithms and operating procedures are continuously being developed and updated. Newer devices have the advantage of the small size and light weight making them more convenient for all patients. Different devices have different measuring mechanisms and scoring algorithms, but their results are usually interpreted equally between studies, despite the fact that research found that their accuracy in estimating sleep varies between population groups and from one device to the other (Broughton 1996, Lotjonen 2003, Ancoli 2003, Flemons 2003, Kuna 2010, Meltzer 2012, Blackwell 2011).

Actigraphy was reviewed by MTAC in 2007 and 2011 for detecting obstructive sleep apnea (OSA), and in 2008 for the assessment of sleep disorders, and did not meet the Committee's evaluation criteria. The technology is being re-reviewed for its use for the evaluation of insomnia and circadian rhythm disorders.

Medical Technology Assessment Committee (MTAC)

Actigraphy in the Treatment of Sleep Disorders

12/03/2007: MTAC REVIEW

Evidence Conclusion: The studies that evaluated the use of actigraphy for the assessment of sleep apnea did not use the technology alone but embedded/ or combined it with other devices as peripheral arterial tonometers (PAT), or respiratory polygraphs. Watch-PAT 100 was the device most commonly used in the published studies. The actometer estimated the total sleep time while the tests of respiratory function were used to calculate the apnea severity, and apnea hypopnea index (AHI). To date, there are no published controlled trials that would determine whether actigraphy can replace PSG or provide incremental information that would impact patient management decisions or improve health outcomes.

The population sizes of the studies varied from <20 patients to just over 200, and the majority assessed the portable monitors simultaneously with PSG in sleeping laboratories in the presence of sleep clinicians, and not in unattended settings. This would be ideal for testing the ability of the monitors to work but does not assess its performance in the patient's home where it is intended, which in turn may limit extrapolation of the results. Moreover, the studies mainly included patients referred to sleep laboratories for suspected OSA. The high prevalence of the disorder among these patients would affect the sensitivity, specificity and likelihood ratios of the test that would also limit generalization of the results.

Diagnostic accuracy: Different algorithms were used for the evaluation of data. The investigators examined multiple respiratory disturbance index (RDI) thresholds for determining abnormal apnea hypopnea index (AHI) and define a positive result. The cutoff for used for AHI was arbitrary and varied between studies. Some

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investigators question the use of AHI as the correct reference standard. The Watch-PAT does not measure airflow and thus cannot differentiate hypopneas from apneas. Overall the results of the studies show that using PSG as the gold standards, the sensitivity of actigraphs embedded in peripheral arterial tonometers ranged from 82-90%, and specificity ranged from 68-90% depending on severity of the obstructive sleep apnea. The sensitivity tended to be lower, and specificity higher with increasing severity the disorder. The area under the curve (AUC) also varied between studies with severity of sleep apnea, and its measures. It ranged from 0.82 for patients with RDI.>10 in Bar's study, to 0.98 for AHI >30 in Garcia-Diaz study. This latter study also compared the respiratory polygraph (RP) performed in the hospital versus that at home, either with or without the addition of actigraphy. Its results showed that RP performed at the laboratory was more accurate than that done at home, and that the addition of actigraphy did not result in significant improvement but tended to overestimate sleep time. The agreement rate between actigraphy devices and PSG was reported in some studies and ranged from 80% to 93%, also depending on the severity of the obstructive sleep apnea.
Diagnostic impact: There is insufficient evidence to determine that actigraphy can provide information that may influence the management decisions for patients diagnosed with obstructive sleep apnea. Therapeutic impact: There is insufficient evidence to determine that using actigraphy for the diagnosis of obstructive sleep apnea would improve health outcomes.
Articles: The literature search revealed over 500 articles on actigraphy. The majority of the published studies used the technology to investigate patients with insomnia, circadian rhythm sleep disorders, and as an outcome measure to determine response of therapy, mainly melatonin 1. Diagnostic accuracy There were no randomized or nonrandomized trials that compared the results of actigraphy used alone, to polysomnography to determine if it can be used as an alternative to PSG in the diagnosis of obstructive sleep apnea. There were several studies that focused on the accuracy and usefulness of actigraphy in evaluating patients with obstructive sleep apnea. These studies, however, did not use actigraphs alone, but combined it with tests of respiratory function in order to calculate the apnea hypopnea index which measures the severity of apnea in these patients. The studies that compared the wrist worn devices with embedded actigraphs used PSG as the gold standard, and reported sensitivity, specificity, likelihood ratios or areas under the receiver operator curves were selected for critical appraisal. 2. Diagnostic impact the literature search did not reveal any study that would determine the influence of the technology on management decisions. 3. Therapeutic impact No studies on the impact of technology on patient outcomes were identified by the search. *The following studies were critically appraised:*
Ayas NT, Pittman S, MacDonald M, et al. Assessment of a wrist-worn device in the detection of obstructive sleep apnea. Sleep Medicine 2003;4:435-442 See Evidence Table. Bar A, Pillar G, Dvir I, et al. Evaluation of a portable device based on peripheral arterial tone for unattended sleep studies. Chest 2003;123:695-703 See Evidence Table. Garcia-Diaz E, Quintana-Gallege E, Ruiz A, et al. Respiratory polygraphy with actigraphy in the diagnosis of sleep apnea-hypopnea syndrome. Chest 2007; 131:725-732. See Evidence Table. Hedner J, Pillar G, Pittman SD, et al. A novel adaptive wrist actigraphy algorithm for sleep-wake assessment in sleep apnea patients. Sleep 2004; 27:1560-1566. See Evidence Table . Zou D, Grote L, Peker Y, et al. Validation a portable monitoring device for sleep apnea diagnosis in a population-based cohort using synchronized home polysomnography. Sleep 2006; 29:367-374. See Evidence Table.

The use of actigraphy in the treatment of obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/04/2008: MTAC REVIEW
Actigraphy in the Treatment of Sleep Disorders
Evidence Conclusion: The published studies that evaluated actigraphy for the assessment of insomnia were conducted on selected groups of patients and used different actigraph models, software, and scoring algorithms. Most studies were conducted in sleep laboratories where recording conditions are standardized, and the artifacts controlled. These controls would be lost when the actigraphy devices are used in the home environment, where it is intended for use. Also, the algorithms that were validated for a specific model, mode of operation, or in a selected population may by not be equally accurate when used with a different brand of device, different gender or age group. The studies reviewed compared actigraphy to PSG, but the authors did not indicate whether the investigators interpreting the results of one test were blinded to the results of the other. The overall results of the studies reviewed, indicate that compared to polysomnography, actigraphy had a high sensitivity (92-98%) but very low specificity (28-48%) in detecting insomnia. It was also found to overestimate the total sleep time and sleep efficiency. Actigraphy tends to overestimate sleep in people with insomnia when they are lying quietly as quiet wakefulness could be miscoded as sleep. Insomnia patients can remain inactive for a period of time attempting to fall asleep. On the other hand, actigraphy may underestimate the amount of sleep and overestimate the duration awake among those who are asleep but are restless or have large amounts of movements during sleep. The use of actigraphy for the assessment of periodic leg movements in sleep was evaluated in only a few small studies with methodological limitations. It was compared with polysomnography with bilateral anterior tibialis
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electromyelography (BATEMG). However, EMG and leg actigraphy are not interchangeable, and each measures a different event. One records electrical activity of a certain muscle and the other records leg acceleration. Leg activity may be due to movement artifacts produced by obstructive sleep apnea. Kemlink et al (2007) did not exclude patients with suspicious sleep apnea and did not adjust for it in the analysis. In conclusion there is insufficient evidence to determine that actigraphy would replace PSG or add to its value in the diagnosis and management of patients with sleep disorders.
Articles: The following questions were considered in screening the published articles:
1) What is the diagnostic accuracy of actigraphy in the evaluation of patients with sleep disorders?
2) Does the use of actigraphy influence management decisions?
3) Does actigraphy lead to better treatment outcomes?
The literature search revealed over 500 articles on actigraphy. Due to the continuing development in the actigraphic devices, operating procedures, software, and scoring algorithms, the literature was screened to identify the more recent studies. Many of these used actigraphy to assess treatment effects or compared results from one actigraphy scoring algorithm to another. Others reported on the use of actigraphy in specific groups as very young infants, children with ADHD, patients with depression, dementia, Parkinson's disease, and others. There were a number of nonrandomized studies that compared actigraphy with other tools for the evaluation of patients with insomnia, periodic leg movement, narcolepsy and other medical disorders other than sleep disorders. The literature search did not reveal any study that would determine the influence of the technology on management decisions or its impact on patient outcome. *The following studies that compared actigraphy with the gold standard of polysomnography were critically appraised:* Kushida CA, Chang A, Gadkary C, et al. comparison of actigraphic, polysomnographic, and subjective assessment of sleep parameters in sleep-disordered patients. Sleep Medicine 2001;2:389-396. See Evidence Table 3 and see Evidence Table 4. Sivertsen B, Omvik S, Havik OE, et al. A comparison of actigraphy, polysomnography in older adults treated for chronic primary insomnia. Sleep 2006; 29:1353-1358. See Evidence Table. Lichstein K, Stone KC, Donaldson J, et al. Actigraphy validation with insomnia. Sleep 2006; 29:232-239. See Evidence Table. Kemlink D, Pretl M, Sonka K, et al. A comparison of polysomnographic and actigraphic evaluation of periodic limb movement in sleep. Neurol Res 2007; 000:1-5. See Evidence Table. King MA, Jaffre MR, Morrish E, et al. The validation of a new actigraphy system for the measurement of periodic leg movement in sleep. Sleep Medicine 2005; 6:507-513. See Evidence Table.

The use of actigraphy in the treatment of sleep disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/04/2011
Actigraphy in the Treatment of Sleep Disorders
Evidence Conclusion: Accuracy of actigraphs/portable monitors for the detection of OSA. There were no published studies that compared portable monitors head-to-head. The accuracy of one devise cannot be extrapolated to others even from the same class due to the differences in the number and types of signals recorded, sensors used, and the processing of signals. It is unknown which sensors or combinations have the highest sensitivity and specificity. Moreover, differences in scoring, testing environment, and night to night variability in the apnea hypopnea index (AHI) make generalization of results difficult. The studies that evaluated the use of actigraphy for the assessment of sleep apnea did not use the technology alone but embedded or combined it with other devices such as peripheral arterial tonometers (PAT), or respiratory polygraphs. Watch-PAT 100 was the device most commonly used in published studies. The actometer estimated the total sleep time while the tests of respiratory function were used to calculate the apnea severity, and apnea hypopnea index. As indicated in the 2007 review of the technology, the overall results of the studies reviewed showed that using PSG as the gold standards, the sensitivity of actigraphs embedded in peripheral arterial tonometers ranged from 82-90%, and specificity ranged from 68-90% depending on severity of the obstructive sleep apnea. The sensitivity tended to be lower, and specificity higher with increasing severity the disorder. The agreement rate between actigraphy devices and PSG was reported in some studies and ranged from 80% to 93%, also depending on the severity of the obstructive sleep apnea. Therapeutic impact of actigraphs/portable home monitors: In a randomized controlled trial that included 106 subjects with a high likelihood of OSA, Berry and colleagues (Evidence table 1) compared a clinical pathway with the watch-PAT 100 for the diagnosis and unattended autotitrating continuous positive airway pressure (CPAP) for those with an respiratory disturbance index (RDI) > 5 events /hour) to select an effective CPAP, versus standard in-laboratory PSG for diagnosis of OSA and CPAP titration. Using a similar approach, Skomro and colleagues' trial (Evidence table 2) randomized 102 subjects with high a probability of OSA to either home-based diagnosis (using Embletta device that incorporates an actigraph) and auto-CPAP (APAP) or in-laboratory PSG. The in-home study was considered positive if the respiratory disturbance index (RDI) was > 5, and patients were offered auto-CPAP therapy for 1 week followed by fixed-pressure CPAP based on the auto-CPAP P95 results. An earlier trial (Mulgrew 2007) compared a type IV portable monitor and APAP titration to in-laboratory PSG in 68 patients (22% of the eligible population) with moderate to
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severe OSA and followed the patients for 3 months. All three trials showed no statistically significant differences in the Epworth Sleepiness Scale scores, quality of life scores, and other outcome studied between patients in the in-home diagnosis and auto CPAP titration group versus those in-laboratory PSG diagnosis and CPAP titration. These results however, should be interpreted with caution, and may not be generalized to the population at large due to several factors including but not limited to: participants in the studies were highly selected, had high pre-test probability of OSA, were mainly men, those with co-morbidities were excluded, short duration of follow-up, patients and/or providers were not blinded, and most of the participants in the PSG group had split-night PSG, which may lead to different outcomes of CPAP therapy than those derived from a full-night of CPAP titration. In addition, the studies were powered as superiority and not equivalence trials, and lack of significant differences does not necessarily indicate equivalence. Berry and colleagues powered their trial as noninferiority, but only for the compliance outcome. More high-quality randomized trials are needed to compare clinical outcomes of laboratory PSG versus home monitoring for sleep disorders among diverse population groups e.g. ethnic groups, women, the elderly, and patients with cardiopulmonary and neurological diseases as COPD, asthma, heart failure, neuromuscular diseases, and other sleep disorders.
Articles: The literature search revealed over 400 articles on actigraphy. The great majority were unrelated to the current review. The technology was frequently used to determine response of therapies for insomnia, mainly melatonin. There were few small validation studies on different portable monitor devices for diagnosing obstructive sleep apnea. There were no head-to- head comparisons between the devices for accuracy in detecting OSA. The search identified two published trials that compared the outcomes of in-laboratory diagnosis and treatment of OSA versus home-based diagnosis and treatment using portable monitoring devices that incorporated an actigraph. Both were critically appraised. Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep 2008; 31:1423-1431. See Evidence Table. Skormo RP, Gjevra J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. Chest 2010; 138:257-263. See Evidence Table.

The use of actigraphy in the treatment of sleep disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/19/2013: MTAC REVIEW
Actigraphy in the Treatment of Sleep Disorders
Evidence Conclusion: The published studies that evaluated actigraphy for the assessment of insomnia as a primary outcome or in a secondary analysis were conducted on selected groups of patients and used different actigraph models, software, and scoring algorithms. The majority of sleep studies were conducted in sleep laboratories where the recording conditions are standardized, and the artifacts controlled. These controls would be lost when the actigraphy devices are used in the home environment, which is the primary intention for their use. In addition, the authors of the studies that compared actigraphy to PSG did not indicate whether interpretation of the results of one test was blinded to the results of the other. According to Sadeh (2011), a point that deserves attention is that actigraphic validation studies against PSG are all based on “time in bed” period whereas the main advantage of actigraphy is documenting sleep wake patterns continuously over 24-hour periods across days. Generalization of the results of the published studies may be limited to similar devices and population groups as the algorithms that were validated for a specific model, mode of operation, or in a selected population may not be equally accurate when used with a different brand of device, different gender, or age group. The results of the studies previously reviewed for MTAC showed that compared to polysomnography, actigraphy had a high sensitivity (92-98%) but very low specificity (28-48%) in detecting insomnia. These older as well as the more recent studies showed that actigraphy in general underestimates wake and overestimates the total sleep time and sleep efficiency. Individuals with insomnia can remain inactive for a period of time attempting to fall asleep, and actigraphy tends to overestimate sleep in these people as quiet wakefulness could be miscoded as sleep. On the other hand, actigraphy may underestimate the amount of sleep and overestimate the duration awake among those who are asleep but are restless or have large amounts of movements during sleep. A number of studies measured the correlation of actigraphy and PSG sleep outcomes as a measure of validity of actigraphy. These ranged between studies from 0.51-0.93 for total sleep time (TST), 0.48-0.85 for wake time after sleep onset (WASO), 0.36-0.81 for sleep efficiency (SE), and 0.30-0.95 for sleep onset latency (SOL). The MrOS Sleep Study (Blackwell et al, 2011), (Evidence Table 1) was embedded in the Osteoporotic Fractures in Men (MrOS) study and examined whether there was a difference between in home-PSG and actigraphy (using the Sleepwatch-O device) in estimating the total sleep time (TST). The authors used 3 modes for collecting actigraphic data to determine the one that corresponds highest with PSG. These modes were the proportional integration mode (PIM), time above threshold (TAT), and zero crossings mode (ZCM). PIM mode is a measure of the activity level or vigor of motion, the TAT mode measures time spent in motion or time spent in active state, and the ZCM measures the frequency of movement. The study had the advantage of including a large population size of community dwelling individuals and the use of in-home PSG as a gold standard. It however, only included
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men >60 years of age; and the PSG data were collected in 30-minute epochs while the actigraphy data were collected in 1-minute epochs with no synchronization in the clock time. This did not allow direct comparisons for each epoch. In addition, the authors did not explain whether the study participants were asked to complete sleep diaries. The results of the analysis showed that the three actigraphy modes either over-estimated or underestimated sleep and wake compared to PSG. The PIM mode of actigraphy corresponded more closely with PSG estimation of total sleep time (TST) than the TAT or ZCM modes, yet the correlation was weak to moderate. These results, however, may not be generalized to populations in different age groups or to other actigraphy devices. Van Den Berg and colleagues, 2008 (Evidence Table 2) measured the disagreement among actigraphy and sleep diary in estimating the total sleep time (TST) among 969 community dwelling elderly men and women participating in a cohort study that primarily investigated the incidence and risk factors of disabling disease. The participants in this sub study wore an actigraph (Actiwatch model AW4) and kept a sleep diary over a period of 5-7 consecutive days and nights. PSG was not used as the gold standard, but the authors only used the Actiwatch algorithm that was validated against polysomnography. The results of the analysis showed that, the estimated TST in the sleep diaries deviated more than one hour from that measured by actigraphy among 34% of the participants. The level of this disagreement decreased with subjective and actigraphic measures of sleep quality and increased with male gender, poor cognitive function, and functional disability. In a smaller study, Levenson and colleagues 2013 (Evidence Table 3) also compared the accuracy of actigraphy versus sleep diary among a group of older insomniac patients participating in a larger study that examined the effect of behavioral therapy on insomnia in older adults. The study included 119 participants with a mean age of 71.7 years (79 with insomnia confirmed with PSG, and 40 controls who did not undergo a PSG). The participants completed at least 7 nights of sleep diary and actigraphy (using the Minimitter Actiwatch). The results of the analyses indicate that the sleep diary parameters discriminated individuals with insomnia from good sleepers more accurately than actigraphy. The AUC of actigraphy was in the low to moderate range (0.58 for sleep efficiency, and 0.61 for total sleep time, the 95% CI contained the value of 0.5 for many of the parameters). Johnson and colleagues, 2007 (Evidence Table 4) examined the level of agreement between actigraphy and polysomnography among 181 adolescents 12-16 years of age. All participants completed an overnight PSG in a clinical research center. The week prior to the PSG and during the overnight PSG study, they wore a wrist actigraph (Octagonal Sleep watch 2.01) and completed daily sleep logs. Data were digitized in 1-minute epochs and the activity count was calculated and stored based on 1 of 3 data modes: PIM, TAT, and ZCM. The results of the analysis showed significant differences between the assessments of total sleep time by actigraphy vs. PSG. The differences were more pronounced for boys vs. girls and for those with sleep disturbed breathing. In conclusion there is insufficient evidence to determine that actigraphy would replace PSG or add to its value in the diagnosis and management of patients with insomnia or circadian rhythm disorders.
Articles: The literature search revealed over 800 articles published on actigraphy and sleep in the last 5 years. The great majority was unrelated to the current review; many reported on the use of actigraphy in specific groups as very young infants, children with ADHD, patients with depression, dementia, Parkinson's disease, and others. There was a lack of published studies on the use of actigraphy in patients with circadian rhythm sleep disorders. The studies that compared the use of actigraphy versus PSG for the evaluation of insomnia were mainly embedded in larger community-based studies conducted among specific age groups and for studying different conditions and/or factors that were not necessarily related to sleep. The following studies with more valid methodology, larger population size, and used actigraphy concurrently with PSG and /or sleep diary were selected for critical review. Blackwell T, Ancoli-Israel S, Redline S, Stone KL; Osteoporotic Fractures in Men (MrOS) Study Group. Factors that may influence the classification of sleep-wake by wrist actigraphy: the MrOS Sleep Study. J Clin Sleep Med. 2011;7:357-367 See Evidence Table. Johnson NL, Kirchner HL, Rosen CL, et al. Sleep estimation using wrist actigraphy in adolescents with and without sleep disordered breathing: a comparison of three data modes. Sleep. 2007; 30:899-905. See Evidence Table. Levenson JC, Troxel WM, Begley A, et al. A quantitative approach to distinguishing older adults with insomnia from good sleeper controls. J Clin Sleep Med. 2013; 9:125-131. See Evidence Table. Van Den Berg JF, Van Rooij FJ, Vos H, et al. Disagreement between subjective and actigraphic measures of sleep duration in a population-based study of elderly persons. J Sleep Res. 2008; 17:295-302. See Evidence Table.

The use of actigraphy in the evaluation of obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

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CPT® or HCPC Codes	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/20/2007	12/07/2010 MDCRPC, 04/05/2011 MDCRPC,10/04/2011 MDCRPC, 08/07/2012 MDCRPC ·06/04/2013 MDCRPC ,10/01/2013 MPC, 04/01/2014 MPC, 04/07/2015 MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC, 10/04/2022MPC	02/07/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description of Change
04/01/2004	Criteria was retired
04/07/2015	Remove criteria from retired status. Medical necessity review will be effective July 5, 2015.
02/07/2017	Medicare is silent; MPC approved to adopt KAISER PERMANENTE criteria for Medicare members

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

PATIENT REFERRAL GUIDELINES
Heart Transplantation[i]

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Heart Transplants (260.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for Heart transplantation. These guidelines for referral for transplant evaluation and are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.

1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

1.3. Uncontrollable active infection is a contraindication to transplant.

1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low [ii], [iii], [iv]. Exceptions may be made on a case-by- case basis.

1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six
(6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines and kidney) may require abstinence from tobacco products to be actively listed.

1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

1.6.1. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

1.6.2. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow

[i] Note: All patients must be continuously re-evaluated for indications and contraindications. Candidates considered for re-transplantation must be evaluated using the same indications.

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medication regimens or failure to accomplish the activities required for maintenance on the waiting list.

1.7. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

1.8. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.9. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR HEART TRANSPLANT

2.1. End-stage heart disease as evidenced by one or more of the following:

2.1.1. Functional class III or IV

2.1.2. Not correctable by medical or other surgical therapies

2.1.3. A low VO2 maximum: [ii]

2.1.3.1. ≤14 ml/kg/min in patients not on a beta blocker

2.1.3.2. ≤12 ml/kg/min in patients on a beta blocker [iii]

2.1.3.3. <19 ml/kg/min adjusted for lean body mass in patients with a BMI >30 kg/m²

2.1.3.4. Less than 50% of age predicted maximum.

2.1.4. A VE/VCO2 >35 in a patient with a sub-maximal cardiopulmonary exercise test (RER <1.05)²

2.1.5. Cardiac index < 2 L/min/m²

2.2. Unable to wean from mechanical or inotropic support.

2.3. Amyloid Cardiomyopathy

2.3.1. TTR Amyloid

2.3.2. (AL) Amyloidosis without significant extra-cardiac involvement.

2.4. Refractory Life-Threatening Arrhythmias

3. The transplant should only be offered for conditions in which cardiac transplant has proven clinical benefits.

CONTRAINDICATIONS FOR HEART TRANSPLANT (In conjunction with the *General* Principles listed above in Section1 of these guidelines):

3.1. Significant diseases such as:

3.1.1. Severe uncontrolled or poorly controlled hypertension.

3.1.2. Clinically significant vascular disease not correctable by intervention.

3.1.3. Pulmonary hypertension not reversible by drug manipulation despite maximum tolerated medical management. [iv]

3.1.3.1. Adults: PVR > 4-6 Wood units or transpulmonary gradient > 15 mm Hg

3.1.3.2. Children: PVR > 9 Wood units

3.1.4. Severe pulmonary disease after optimal treatment of severe heart failure.[viii]

3.1.5. Severe hepatic disease after optimal treatment of severe heart failure.[viii]

[ii] Journal of Heart & Lung Transplantation, Vol.25 Number 9, pp1024 -1042. Listing Criteria for Heart Transplantation ISHLT Guidelines for the Care of Cardiac Transplant Candidates – 2006.

[iii] Patients on Beta blockers should have a cut-off of ≤12 ml/kg/min, and patients intolerant to beta blockers a VO_2 ≤14 ml/kg/min.

[iv] Circulation; 84 (3), 329 – 337. *Journal of Heart Transplantation* (1990): 526 – 537.

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

3.1.6. Kidney disease with creatinine clearance <34 ml/kg/min or GFR < 30 ml/min after optimal treatment of heart failure. [v], [vi], [vii]

3.1.7. Active and/or progressive central nervous system disease excluding patients with embolic stroke who have recovered completely.

3.1.8. Evidence of cachexia or malnutrition (BMI < 19 kg/m2 or < 80% ideal body weight).x

3.1.9. Obesity (BMI>35 kg/m2 or > 140% ideal body weight) xi has been associated with poor outcomes after cardiac transplant.

3.1.10. Diabetes with complications resulting in severe end-organ damage.

3.1.11. Auto/acquired immune disease with multi-organ manifestation

3.1.12. Acute pulmonary embolus

3.1.13. Active peptic ulcer disease

3.1.14. Severe symptomatic osteoporosis

3.1.15. Age over 70 (Carefully selected patients over 70 years of age may be considered for cardiac transplantation)

3.1.16. AL Amyloidosis with significant extra-cardiac manifestations

3.1.17. Patients with viral hepatitis will require additional evaluation, including hepatology consultation.

3.1.18. Any other co-morbid condition that would limit life expectancy or quality of life.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

A heart may be irreversibly damaged by long-lasting heart disease or viral infection. When the heart can no longer adequately work, and a person is at risk of dying, a heart transplant may be appropriate.

Cardiac transplant has become increasing successful over the past several years. Adult heart transplant recipients have a one-year survival rate of eighty to ninety percent and a five-year survival rate of sixty to seventy percent. Kaiser Permanente contracts have included coverage for heart transplantation for several years. Members with coverage who meet the selection criteria are considered for transplantation.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33940	Donor cardiectomy (including cold preservation)

[v] Selected patients for possible combined or staged heart/kidney transplant will be evaluated on a case-by-case basis.

[vi] Must have 20mg per kilogram of creatinine in a 24-hour collection period. Creatinine clearance can also be calculated by the Cockcroft-Gault formula.

[vii] The Journal of Heart & Lung Transplantation, Vol. 35, Issue 7, p893-900. Evidence Supports Severe Renal Insufficiency as a relative contraindication to heart transplantation—2016.

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33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

****Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
05/1996	07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013MDCRPC, 01/07/2014MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	04/06/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MDCRPC Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt Kaiser Permanente National Criteria for Heart Transplant
03/03/2020	MPC approved updates for Kaiser Permanente National Transplant Services patient referral guidelines
06/12/2020	Changed “criteria” to guidelines” where appropriate; updated to reflect current patient referral guidelines that were approved 03/03/2020
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”

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Clinical Review Criteria

AVISE MTX Test for Measuring Methotrexate Polyglutamate Levels

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***AVISE MTX Test for Measuring Methotrexate Polyglutamate Levels***" for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Rheumatoid arthritis is a chronic, systemic, inflammatory disorder that affects approximately 0.5–1% of the Western population. If left untreated, this disease can result in permanent joint damage (Binker 2010). Evidence from recent studies suggests that achieving early control of rheumatoid arthritis minimizes joint destruction and increases long-term disease control.

Methotrexate is one of the most effective and commonly prescribed drugs for the treatment of rheumatoid arthritis. Although methotrexate is effective, it is not without side effects. Side effects of methotrexate include gastrointestinal disturbance, mucositis, fatigue, alopecia, elevated serum transaminase levels, and bone marrow toxicity. Frequent blood tests are required to monitor for the development of these adverse effects. Additionally, patient response to methotrexate, both in terms of efficacy and toxicity is highly variable. It is estimated that approximately 30–40% of patients with rheumatoid arthritis taking methotrexate do not adequately respond to treatment (Danilia 2010, Goodman 2010). Currently, there is no reliable means of predicting patient response to methotrexate.

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After administration and absorption, serum methotrexate levels fall rapidly as it is actively transported into a variety of cells. In the cells, up to six additional glutamate residues are added, converting methotrexate into the more stable polyglutamate form. Methotrexate polyglutamate can be converted back to methotrexate to permit efflux from the cell. The therapeutic effect of methotrexate depends on its conversion to methotrexate polyglutamate. It has been suggested that if methotrexate polyglutamate levels were associated with adverse events or therapeutic response then knowledge of these levels could be used to help optimize methotrexate therapy in rheumatoid arthritis (Binker 2010, Danilia 2010, Goodman 2010).The Avise PG test (Cypress Bioscience, San Diego, CA) measures methotrexate polyglutamate levels and was developed to aid in dosage optimization for rheumatoid arthritis patients who have been on methotrexate for at least three months. Results of the Avise PG test are reported as therapeutic (> 60 nmol/L), intermediate (20-60 nmol/L), and subtherapeutic (< 20 nmol/L).

Medical Technology Assessment Committee (MTAC)

Avise PG Test for Measuring Methotrexate Polyglutamate Levels

06/20/2011: MTAC REVIEW

Evidence Conclusion: Analytic validity - There are a variety of rapid, sensitive, and accurate methods for the detection of methotrexate polyglutamate (Dervieux 2003, Li 2007). Clinical validity - Two cross-sectional studies that examined the association between methotrexate polyglutamate levels and disease activity were selected for review. The first study included 192 subjects with rheumatoid arthritis who had been taking methotrexate for at least 3 months and had a stable dose for at least a month prior to study entry. Before adjusting for confounding factors results suggest that higher disease activity, measured using the swollen joint count (SJC), the physician's global assessment, the physician's assessment of response to methotrexate, the Disease Activity Score in 28 joints (DAS28), the Clinical Disease Activity Index (CDAI), and the Simplified Disease Activity Index (SDAI), was associated with higher MTX PG concentrations (MTX PG_4, MTX PG_5, MTX PG_{1-5}, and MTX PG_{3-5}). After adjusting for confounding factors, patients with higher disease activity measured using TJC, SJC, and DAS28 still had higher MTX PG_5 concentrations. There was no association between methotrexate polyglutamate concentration and adverse events (Stamp 2010). Two other studies also failed to find an association between methotrexate polyglutamate concentration and adverse events (Dervieux 2006, Angelis-Stoforidis 1999). The second study included 226 subjects with rheumatoid arthritis who had been taking methotrexate for at least 3 months. After controlling for confounding factors, low methotrexate polyglutamate levels were associated with poor clinical status (high number of tender and swollen joints, physician's assessment of disease activity, and the modified Health Assessment Questionnaire) (Dervieux 2005). The same group of authors also conducted two other studies that examined the relationship between methotrexate polyglutamate levels and clinical status. Both of these studies along with two other observational studies also found that low methotrexate polyglutamate levels were associated with poor clinical status (Angelis-Stoforidis 1999, Dervieux 2004, Dervieux 2006, Hornung 2008).
Clinical utility -
No studies were identified that addressed the clinical utility of measuring methotrexate polyglutamate levels to aid in dosage optimization for rheumatoid arthritis patients.
Conclusion: Analytic validity: There are a variety of rapid, sensitive, and accurate methods for the detection of methotrexate polyglutamate. Clinical validity: Several observational studies have investigated the association between methotrexate polyglutamate levels and clinical status. While the majority of these studies found that low methotrexate polyglutamate levels were associated with poor clinical response, not all studies have found this association. Clinical utility: There is insufficient evidence to determine the clinical utility of measuring methotrexate polyglutamate levels to aid in dosage optimization for rheumatoid arthritis patients.
Articles: Two studies were identified that address analytic validity. Several observational studies were identified that examined the relationship between methotrexate polyglutamate levels and clinical status (clinical validity). Two of the larger studies were selected for review. No studies were identified that addressed the clinical utility of measuring methotrexate polyglutamate to aid in dosage optimization for rheumatoid arthritis patients. The following studies were critically appraised: Stamp LK, O'Donnell JL, Chapman PT, et al. Methotrexate polyglutamate concentrations are not associated with disease control in rheumatoid arthritis patients receiving long-term methotrexate therapy. *Arthritis Rheum 2010;* 62:359-638. See Evidence Table. Dervieux T, Frust D, Lein DO, et al. Pharmacogenetic and metabolite measurements are associated with clinical status in patient's rheumatoid arthritis treated with methotrexate: results of a multicentered cross sectional observational study. *Ann Rheum Dis 2005;* 64:1180-1185. See Evidence Table**.**

The use of Avise PG test for measuring methotrexate polyglutamate levels does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered Not Covered:

CPT® Codes	Description
84999	Unlisted chemistry procedure
ICD-10 Codes	**Description**
M05.60-M05.69	Rheumatoid arthritis with involvement of other organs and systems
M05.70-M05.79	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80-M05.89	Other rheumatoid arthritis with rheumatoid factor
M06.00-M06.09	Rheumatoid arthritis without rheumatoid factor

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Dates	Date Last Revised
07/05/2011	07/05/2011[MDCRPC], 07/03/2012[MDCRPC] ,05/07/2013 [MDCRPC] ,03/04/2014 [MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/05/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	Added CPT code 84999 and rheumatoid arthritis ICD-10 codes M05.60-M06.09
05/06/2022	Medicare retired LCA A54378 Billing and Coding: MolDX: Avise PG Assay

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Clinical Review Criteria
Air Ambulance

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 10 - Ambulance Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Rural Air Ambulance Service Protocols A52917

For Non-Medicare Members

Air Ambulance Services

Medically appropriate air ambulance transportation is a covered service regardless of the State or region in which it is rendered. However, KPWA will approve claims only if the beneficiary's medical condition is such that transportation by either basic or advanced life support ground ambulance is not appropriate.

There are two categories of air ambulance services: fixed wing (airplane) and rotary wing (helicopter) aircraft. The higher operational costs of the two types of aircraft are recognized with two distinct payment amounts for air ambulance mileage. The air ambulance mileage rate is calculated per actual loaded (patient on board) miles flown and is expressed in statute miles (not nautical miles).

1. Fixed Wing Air Ambulance (FW)
   a. Fixed wing air ambulance is furnished when the beneficiary's medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Generally, transport by fixed wing air ambulance may be necessary because the beneficiary's condition requires rapid transport to a treatment facility, and either great distances or other obstacles, e.g., heavy traffic, preclude such rapid delivery to the nearest appropriate facility. Transport by fixed wing air ambulance may also be necessary because the beneficiary is inaccessible by a ground or water ambulance vehicle.
2. Rotary Wing Air Ambulance (RW)
   a. Rotary wing air ambulance is furnished when the beneficiary's medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Generally, transport by rotary wing air ambulance may be necessary because the beneficiary's condition requires rapid transport to a treatment facility, and either great distances or other obstacles, e.g., heavy traffic, preclude such rapid delivery to the nearest appropriate facility. Transport by rotary wing air ambulance may also be necessary because the beneficiary is inaccessible by a ground or water ambulance vehicle.

Coverage Requirements

Air ambulance transportation services, either by means of a helicopter or fixed wing aircraft, may be determined to be covered only if **ALL the following** are met:

1. The vehicle and crew requirements described in §10.1* are met; and
2. The beneficiary's medical condition required immediate and rapid ambulance transportation that could not have been provided by ground ambulance; and either

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a. The point of pickup is inaccessible by ground vehicle (this condition could be met in Hawaii, Alaska, and in other remote or sparsely populated areas. or
b. Great distances or other obstacles are involved in getting the patient to the nearest hospital with appropriate facilities as described in §10.4.4. *

3. Transport is only to the nearest acute care facility equipped to provide the appropriate treatment for the patient's condition.

Medical Reasonableness
Medical reasonableness is only established when the beneficiary's condition is such that the time needed to transport a beneficiary by ground, or the instability of transportation by ground, poses a threat to the beneficiary's survival or seriously endangers the beneficiary's health. Following is an advisory list of examples of cases for which air ambulance could be justified. The list is not inclusive of all situations that justify air transportation, nor is it intended to justify air transportation in all locales in the circumstances listed.

1. Intracranial bleeding - requiring neurosurgical intervention;
2. Cardiogenic shock;
3. Burns requiring treatment in a burn center;
4. Conditions requiring treatment in a Hyperbaric Oxygen Unit;
5. Multiple severe injuries; or
6. Life-threatening trauma.

Time Needed for Ground Transport
Differing Statewide Emergency Medical Services (EMS) systems determine the amount and level of basic and advanced life support ground transportation available. However, there are very limited emergency cases where ground transportation is available but the time required to transport the patient by ground as opposed to air endangers the beneficiary's life or health. As a general guideline, when it would take a ground ambulance 30-60 minutes or more to transport a beneficiary whose medical condition at the time of pick-up required immediate and rapid transport due to the nature and/or severity of the beneficiary's illness/injury, KPWA will consider air transportation to be appropriate.

Hospital to Hospital Transport
Air ambulance transport is covered for transfer of a patient from one hospital to another if the medical appropriateness criteria are met, that is, transportation by ground ambulance would endanger the beneficiary's health and the transferring hospital does not have adequate facilities to provide the medical services needed by the patient. Examples of such specialized medical services that are generally not available at all type of facilities may include but are not limited to: burn care, cardiac care, trauma care, and critical care. A patient transported from one hospital to another hospital is covered only if the hospital to which the patient is transferred is the nearest one with appropriate facilities which are not available at the patient's current location. Coverage is not available for transport from a hospital capable of treating the patient because the patient and/or the patient's family prefer a specific hospital or physician.

Special Coverage Rule
Air ambulance services are not covered for transport to a facility that is not an acute care hospital, such as a nursing facility, physician's office, or a beneficiary's home.

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A0430	Ambulance service, conventional air services, transport, one way (fixed wing)
A0431	Ambulance service, conventional air services, transport, one way (rotary wing)
A0435	Fixed wing air mileage, per statute mile

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A0436	Rotary wing air mileage, per statute mile

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Date Created	Date Reviewed	Date Last Revised
04/03/2018	04/03/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	04/03/2018

[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Allogeneic Meniscal Transplant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Allogeneic Meniscal Transplant***," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Meniscal Allograft Transplant (A-0216) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedics/podiatry)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The knee meniscus is a fibrocartilaginous crescent-shaped structure that plays an important part in the biomechanics of the joint. It functions as load bearing, shock absorption, stabilization of the joint as well as lubrication. Partial or complete loss of the meniscus alters the joint function and predisposes the articular cartilage to degenerative changes. In the past, total or subtotal meniscectomy was routinely performed for patients with meniscal tears. More recently, repair of the meniscus has become the standard treatment for tears. If un-repairable, arthroscopic partial meniscectomy of only the torn segments is recommended (Yoldas 2003). Subtotal or complete meniscectomy is however performed when the entire meniscus is torn and irreparable. Meniscectomy leads to deterioration of the articular cartilage and narrowing of the knee joint. Allograft meniscal transplantation has become an option for these patients and is believed to prevent progression of degenerative changes of the knee.

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The first meniscal allograft was performed in 1984 by Milachowski and Wirth. The technique of the transplantation has evolved over the years, and different graft types were used. These include meniscus prosthesis, scaffolds, genetically engineered tissue, meniscus xenografts, meniscus autografts, and meniscus allografts. The allografts used are fresh, fresh-frozen, lyophilized, or cryopreserved menisci. Fresh menisci are thought to be superior as the architecture is unchanged, and chondrocytes and other cells are still viable. However, fresh grafts are logistically difficult to obtain. Fresh-frozen and cryopreserved menisci are reported to have good results but are associated with storage and availability problems. The Lyophilized and freeze-dried menisci can be stored for a long time but have the disadvantage of the decay of ground substance and destruction of the architecture in the freeze-dried menisci, and shrinkage in the lyophilized. Cryopreservation may maintain fibrochondrocytes for 2-4 weeks but is very expensive in cost. The success of the transplantation depends on the revascularization and the cell proliferation for the restitution of the lost ground substance. Sizing of the meniscus before transplantation is also important to have a good geometrical fit in the joint, and a proper function.

The indications of the transplantation are not well defined. Persistent pain after meniscectomy is a common indication. Some authors believe that a knee with minimal or no arthritic changes is the ideal for transplantation, and others indicate it only for knees with degenerative changes. Some investigators in the US (Felix N, and Paulos L 2003), indicate meniscal transplantation for those <40 years old, with pain and swelling not responding to conservative treatment, minimal degenerative changes, stable knee, and axial alignment. In other countries e.g., Germany (Peters 2003) the indications include total meniscectomy with early arthritis, loss of anterior cruciate ligament, concomitant osteotomy, and prophylactic transplantation. It is contraindicated in patients with severe degenerative changes in the joint, instability, malalignment, and history of infection of the joint.

Medical Technology Assessment Committee (MTAC)

Allogeneic Meniscal Transplant

07/14/2004: MTAC REVIEW

Evidence Conclusion: The results of the studies reviewed are promising but do not provide sufficient evidence, on the effectiveness of the meniscal allograft transplantation in restoring the knee function and preventing degenerative osteoarthritis. The prospective study, the two-case series appraised, as well as the other published case series and reports were small, included heterogeneous patients at different ages, and with different indications for the meniscal transplantation. None of the studies used a consistent protocol. The grafts used were fresh, deep-frozen, cryopreserved, or lyophilized allografts. The duration from the meniscectomy to the transplant varied among patients from few months to more than 30 years. In several reports and within studies some patients received an anterior cruciate ligament repair, together with the meniscal transplant. In others, patients underwent different procedures after the transplantation. The rehabilitation programs varied between and within studies, as well as the duration of follow-up. Overall the results of the studies show that meniscal transplantation may alleviate pain and improve the knee function. However, there is insufficient data to determine which patients will benefit most, and if benefits observed would be maintained over time, and whether the transplantation will prevent degenerative changes from occurring within the joint.

Articles: The search yielded 75 articles many of which were review articles. There were no meta-analyses or randomized controlled trials. One prospective cohort study and several case series reports with limited number of patients were identified. The prospective cohort study and two case series reports were selected for critical appraisal. Selection for the case series reports for review was based on the population size, duration of follow-up, and/or primary outcomes. *Evidence tables were created for the following studies:*

Wirth CJ, Peters G, Milachowaski KA, et al. Long-term results off meniscal allograft transplantation. *Am J Sports Med* 2002;30:174-181.See Evidence Table van Arkel ERA, and de Boer HH. Survival analysis of human meniscal transplantations. *J Bone Joint Surg* 2002;84-B:227-31. See Evidence Table Rath E, Richmond JC, Yassir W et al. Meniscal allograft transplantation. Two-to eight-year results. *Am J Sports Med* 2001; 29:174-181. See Evidence Table

The use of allogeneic meniscal transplant in the treatment of knee pain and swelling does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Applicable Codes

Considered Not Covered:

CPT® Codes	Description
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/14/2004	05/03/2011[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 04/01/2014[MDCRPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018MPC, 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC] , 06/06/2023[MPC]	06/14/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD Non-Covered Services (L34886)
06/14/2016	Revised Medicare language and added date that code was taken off the non-covered services list

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Laboratory Tests for Detection of Heart Transplantation Rejection

- AlloMap® Heart (Molecular Expression Testing, CareDx)
- Heartsbreath Test

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Heartsbreath Test for Heart Transplant Rejection (260.10) **The Heartsbreath test is not covered per Medicare criteria.*
Local Coverage Determinations (LCD)	MolDX: Molecular Diagnostic Tests (MDT) (L36256)
Local Coverage Article	AlloMap Billing and Coding Guidelines (A54366)

For Non-Medicare Members

Service	Criteria
AlloMap Test	AlloMap is covered for patients who have undergone heart transplant. **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist • Last 6 months of radiology notes if applicable
Heartsbreath Test	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. **If requesting review for this service, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Approximately 3,500 people worldwide now undergo heart transplantation every year with at least 40% of recipients experiencing at least one episode of rejection in the first year after transplantation (Stehlik, Edwards et al. 2012). Clinical features of acute cellular rejection are unreliable resulting in a variety of monitoring techniques which may include frequent blood tests, lung function tests, electrocardiograms echocardiograms and biopsies of the heart tissue.

The current gold standard for heart transplant rejection diagnosis is a series of endomyocardial biopsies (EMB) (Miller, Fildes et al. 2013). Typically, EMB is performed through the jugular or femoral veins and is invasive, painful and commonly associated with risks of procedural complications (From, Maleszewski et al. 2011). With rejection most likely to occur within the first year after transplant, EMB is performed and repeated frequently post-transplant exposing patients to long-term complications including, but not limited to, severe tricuspid valve regurgitation. Additional limitations include, evidence indicating discrepancies in biopsy readings by different pathologists sufficient to demonstrate adverse treatment implications (Winters and McManus 1996) and finally, the notion that biopsy cannot be used to identify patients at risk of rejection, limiting the ability to initiate therapy to interrupt the development of rejection. For these reasons, the gold standard has been considered flawed resulting in many attempts to develop non-invasive tools to detect heart transplant rejection.

Gene expression profiling (GEP) of circulating leukocytes has been recently introduced as a new non-invasive modality for cardiac allograft rejection monitoring. This is based on the assumption that recirculating peripheral blood mononuclear cells (PBMC) may reflect earlier host responses to the allograft than those at local sites. The test uses real-time polymerase chain reaction (PCR) technology to measure the expression of 20 genes (11 informative, 9 control and normalization). Using a multigenic algorithm, a score ranging from 0 to 40 is generated. Some researchers found that this score may discriminate between quiescence and moderate/severe acute rejection. The lower scores are associated with a very low likelihood of moderate/severe graft rejection (Starling 2006). The score however, may be influenced by several factors including time post-transplant, peripheral alloimmune activity, corticosteroid dose, and cytomegalovirus infection (Yamani 2007, Starling 2006). According to Starling and colleagues (2006), the candidates for GEP testing are clinically stable cardiac transplant recipients, >15 years of age, > 6 months post- transplant, and at low risk for moderate/severe cellular rejection. It was also reported that the frequency of performing a GEP test to monitor the rejection should be individualized according to the patient's rejection history, immunosuppression regimen, time post transplant, and transplant centre protocol. The GEP test is not recommended for patients at high risk for acute rejection or graft failure, <15 years of age, pregnant women, patients who had a blood transfusion within 12 months before the transplant, received hematopoietic growth factors within the previous 30 days, high dose steroids within the past 21 days, or are on >20 mg/day of prednisone equivalent.

AlloMap® gene expression test, XDx, Inc, South San Francisco, CA, is the first commercially available molecular test developed for acute rejection monitoring. The test was introduced for clinical use in January 2005. It uses simple blood samples and is performed at CLIA-certified XDx laboratory in South San Francisco.

Currently, potential non-invasive alternatives to biopsy range from imaging techniques to genetic expression profiling with limited established evidence (Miller, Fildes et al. 2013). The Heartsbreath test™ (HBT) was developed by Menssana Research, Inc. and is an intrinsically safe, painless and non-invasive test for heart transplant rejection. The HBT is currently indicated for use as an aid in the diagnosis of grade 3 heart transplant rejection in patients who have received heart transplants within the previous year (Menssana 2004). It is meant for use in addition to, and not as a substitute for, EMB. The HBT works specifically by measuring the amount of methylated alkanes in a patient's breath with the rationale based on two observations the first being that allograft rejection is accompanied by oxidative stress resulting from increased production of reactive oxygen species in the myocardium (Schimke, Schikora et al. 2000) and, the second, that reactive oxygen species degrade cellular membranes by lipid peroxidation of polyunsaturated fatty acids generating alkanes that are excreted in the breath as volatile organic compounds and may provide markers of the intensity of rejection (Kneepkens, Ferreira et al. 1992). The HBT subtracts the amount of mythelated alkanes in a patient's breath from the number of methylated alkanes in the rooms air (Phillips 1997). The value generated by the test is compared to the results of a biopsy performed during the previous month to measure the probability of the implanted heart being rejected. The tests greatest value may be in helping to separate less severe organ rejection (grade 0,1 and 2) from more severe organ rejections (grade 3). In general, the evaluation of non-invasive techniques for the identification of heart transplant rejection is difficult due to the imperfect nature of the current gold standard.

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The FDA approved the HBT under the Humanitarian Device Exemption program in February of 2004 to be used in patients who have had heart transplants within the past year (FDA 2004). A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year (FDA 2010). A device manufacturers research and development costs could exceed its market returns for diseases or conditions affecting small patient populations. The HUD provision of the regulation provides an incentive for the development of devices for use in treatment or diagnosis of diseases affecting these populations. The labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

Medical Technology Assessment Committee (MTAC)

AlloMap in the Detection of Cardiac Allograft Rejection

06/04/2007: MTAC REVIEW

Evidence Conclusion: The CARGO study was an observational study conducted to develop and evaluate a gene expression profiling test (AlloMap test) from peripheral blood mononuclear cells sample to discriminate between quiescence (grade 0 rejection) and moderate /severe (grade >3A) rejection in heart transplant patients, according to the International society for Heart Lung Transplantation (ISHLT) grading. The endomyocardial biopsy (EMB) was used as the gold standard for detecting acute cellular rejection. EMB however has its limitation. It may only detect rejection after cellular infiltration and/or graft damage has occurred and cannot be repeated beyond a certain frequency. In addition, its histopathological interpretation and grading is often not clear-cut, and subject to sampling error and inter observer variability. Overall the results of the study showed that at a predefined threshold of 20 (score range 0-40), the test had an 84% sensitivity to detect a grade >3A rejection compared to the endomyocardial biopsy. After one-year post-transplant the test had a very high negative predictive value (99.6%) i.e. very high ability to rule out moderate /severe rejection. It however had a very low positive predictive value (6.8%) and low specificity (approximately 40%). The study evaluated the ability of the test to discriminate between quiescence and moderate/severe rejection of the transplant. There is no published evidence to date on the clinical outcomes associated with using the test for long-term monitoring of cardiac rejection, on the predictive capacity of the test for future clinical events, or its effect on improving the management of the patients, e.g. tailoring and individualizing immunosuppressive medications. The “Invasive Monitoring Attenuation through Gene Expression” (IMAGE) ongoing study might provide evidence on the long-term health outcomes associated with this gene expression testing.

Articles: The literature search yielded just over 20 articles, the majority of which were reviews and editorials. There was a relatively large observational study (CARGO) that evaluated the ability of gene expressing profiling of peripheral blood test to discriminate between quiescence and from moderate/severe rejection in cardiac allograft recipients, two small case series, and a few other observational studies published in abstract forms. The CARGO study was selected for critical appraisal. Deng MC, Eisen HJ, Mehra MR, et al for the Cardiac allograft Rejection Gene Expression Observational (CARGO) study Investigators. Noninvasive discrimination of rejection in cardiac allograft recipients using gene expression profiling. Am J Transplant.2006;6:150-160. See Evidence Table.

The use of AlloMap in the detection of cardiac allograft rejection does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/19/2003: MTAC REVIEW

Heartsbreath Test in the Detection of Cardiac Allograft Rejection

Evidence Conclusion: The HARDBALL (heart allograft rejection: detection with breath alkanes in low levels) study was a three-year multicenter case-control study supported by the National Heart Lung and Blood Institute (Philips, Boehmer et al. 2004). The original clinical study evaluated a new marker of heart transplant rejection, the breath methylated alkane contour (BMAC) with the idea that rejection is accompanied by oxidative stress which degrades membrane polyunsaturated fatty acids, evolving alkanes and methylalkanes which are excreted in the brain as volatile organic compounds (VOCs). Prior to scheduled EMB, the HBT was employed on 539 heart transplant recipients to collect 1061 breath VOC samples. The breath VOCs were analyzed by gas chromatography and mass spectroscopy, and the BMAC was derived from the abundance of C4-C20 alkanes and monomethylalkanes. The gold standard of rejection was the concordant set of International Society for Heart and Lung Transplantation (ISHLT) grades in biopsies read by two cardiac pathologists. The authors of the HARDBALL study reported that the abundance of breath markers of oxidative stress was significantly greater in grade 0,1 or 2 rejection than in healthy normal persons. Whereas in grade 3 rejection, the abundance of breath markers of oxidative stress was reduced most likely due to accelerated catabolism of alkanes and methyl alkanes that comprise the BMAC. The authors also reported finding that in identifying grade 3 rejection, the negative

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predictive value of the breath test (97.2%) was similar to EMB (96.7%), and that the breath test could potentially reduce the total number of biopsies performed to assess for rejection in patients at low risk for grade 3 rejection. The sensitivity of the breath test was 78.6% vs. 42.4% with biopsy. However, the breath test had lower specificity (62.4%) and a lower positive predictive value (5.6%) in assessing grade 3 rejection than biopsy (specificity 97%, positive predictive value 45.2%). Additionally, the breath test was not evaluated in grade 4 rejection. Breath test results revealed nine breath samples whose levels represented markers of grade 3 rejection. The cross-validated model, indicated that the HBT had a sensitivity of 59.5% and specificity of 58.8% for detecting grade 3 heart transplant rejection, compared to biopsy. The negative predictive value of the breath test for grade 3 rejection was 97.3% such that in a patient with a negative breath test, EMB would contribute little additional clinical information.
Limitations include a surprising lack of consistency between biopsy interpretation by the pathologists at the transplant program site and the independent pathologist working with the authors. The study results are made difficult to interpret given these disparities. Further studies should investigate the HBT in populations with concurrent patient illness which theoretically, could affect the markers of oxidative stress. It is also important to note that the primary investigator has substantial financial and professional ties with the developer of the device under investigation. The major potential benefit of the HBT would be that it may reduce the risk of a patient getting the wrong treatment because of an erroneous biopsy report. Despite the clear potential benefits that a non-invasive approach such as the HBT could offer, there is no evidence to demonstrate that the use of the HBT will result in better patient management and improvements in health outcomes. Ultimately, a clinically meaningful investigation of the HBT would require assessment in multicenter, outcome-based trials with adequate power, blinding and randomization to control for baseline differences between groups and determine whether additional testing provides a significant advantage over the standard of care in any of the proposed uses of these laboratory tests.
Articles: A search of the PubMed database as well as the Clinical Trials database was completed for the period from database inception through June 2013 for studies on the diagnostic value of the Heartsbreath Test for patients with heart allograft rejection. The search strategy used the terms non-invasive, heart transplant, rejection, Heartsbreath and test with variations. Articles were limited to those published in English language and with enrolled human subjects. The search was supplemented by an examination of article bibliographies in addition to the PubMed related articles function. The HARDBALL study was selected for critical appraisal:

Phillips M, Boehmer JP, Cataneo RN, et al. Heart allograft rejection: detection with breath alkanes in low levels (the HARDBALL study). *The Journal of Heart and Lung Transplant* 2004;23(6):701-708. See Evidence Table

The use of Heartsbreath test in the detection of cardiac allograft rejection does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

AlloMap - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score

Heartsbreath - Considered Not Medically Necessary:

CPT® Codes	Description
No specific codes	

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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
06/26/2007	09/06/2011[MDCRPC],07/03/2012[MDCRPC],04/02/2013[MDCRPC],05/07/2013[MDCRPC], 10/01/2013[MPC], 03/04/2014 [MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/04/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/28/2016	Added LCA for AlloMap
12/20/2018	AlloMap is now covered for member who have had a heart transplant (before they had to fail biopsy)
05/04/2021	Removed deleted code 0085T for Heartsbreath

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KAISER PERMANENTE®

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Clinical Review Criteria

Donor-derived cell-free DNA testing for Kidney Transplant Rejection

- AlloSure

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	MolDX: ALLOSURE® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts (L38380)
Local Coverage Article (LCA)	Billing and Coding: MolDX: ALLOSURE® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts (A57233)

For Non-Medicare Members

Donor-derived cell-free DNA testing (e.g., AlloSure) is considered medically necessary when **ALL** of the following criteria are met:

- Patient is 18 years of age or older
- Patient is at least 14 days post renal transplant
- A renal biopsy is not already planned or is contraindicated or considered high risk per nephrologist
- No active BK inflammation based on BK PCR results (will result in false positive)

AND 1 or more of the following representing a clinical suspicion of rejection:

- Creatinine is worsening (≥ 20% above baseline) without an identified cause (e.g., related to medication or dehydration) OR
- Immunosuppression must be lowered below basal dose for at least one month and if there is a concern for subclinical rejection, one test may be considered medically necessary OR
- Chronically decreased immunosuppression for persistent leukopenia (post-transplant lymphoproliferative disorder); one test may be medically necessary OR
- Routine* check for patients with one or more of the following:
  - High pre-transplant Panel Reactive Antibodies (PRA) (> 80%),
  - Pre-existing donor-specific antibodies (DSA)
  - High antigen mismatch (at least 5)

  *Monitoring for subclinical rejection is reasonable in this high risk population, but should not be done more frequently than every 3 months, limited to 3 tests in one year

Not indicated:
Routine use in otherwise uncomplicated transplant course is ***not*** indicated.

If requesting this service, please send the following documentation to support medical necessity:

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- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

From Southern California Evidence-Based Medicine (EBM) Inquiry Service (July 22, 2020)
Kidney transplantation is the best treatment option for patients with end-stage renal disease. Current surveillance options for allograft injury such as serum creatinine (SCr) and estimated glomerular filtration rate (eGFR), urinalysis, urinary protein, donor specific antibody (DSA), and BK virus surveillance have limitations.

Although biopsy is the gold standard to identify allograft dysfunction, it is an invasive procedure, not without complications, and can encounter challenges including sampling errors, inadequate tissue sample, and variability of interpretation among pathologists. Thus, an urgent need exists for noninvasive and sensitive diagnostic tools for the detection of early rejection that precede a rise in SCr and offer the opportunity to better inform therapeutic decision-making. An emerging area of research are assays that detect donor-derived cell-free DNA (dd-cfDNA), which measure the proportion of total cell-free DNA that is derived from the donor and the recipient. dd-cfDNA assays including AlloSure and Prospera, use targeted amplification and sequencing of single-nucleotide polymorphisms (SNP) to quantify donor and recipient DNA contributions, without the need for prior genotyping of the donor and recipient.

The AlloSure test is intended to assess the probability of allograft rejection in kidney transplant recipients with clinical suspicion of rejection and to inform clinical decision-making about the necessity of renal biopsy in such patients at least two weeks post-transplant in conjunction with standard clinical assessment. AlloSure is indicated for use in renal transplant patients who are 18 years of age or older and at least 2 weeks (14 days) post-transplant. dd-cfDNA is measured in the blood via targeted amplification and sequencing of a set of carefully selected and validated SNPs. The AlloSure bioinformatics software calculates the percent dd-cfDNA in the sample tested and applies the cut-off values. dd-cfDNA is usually <1% of the total cfDNA when there is no active damage to the allograft. However, during allograft rejection, significantly higher amounts of dd-cfDNA are released into the bloodstream.
A comprehensive search was conducted on July 9, 2020 to identify studies that evaluated the clinical validity and/or clinical utility of AlloSure or Prospera for kidney transplant recipients.

Medical Technology Assessment Committee (MTAC)

AlloSure Test for Kidney Transplant Recipients
Date: 04/26/2021
Evidence Conclusion:
AlloSure:
Clinical validity: Low quality and limited evidence (two studies) showed that AlloSure test may diagnose active rejection in kidney transplants recipients. It has moderate sensitivity & specificity as well as moderate to high NPV. However, more studies are needed to validate its performance.

Clinical utility: There is insufficient evidence to evaluate the impacts of AlloSure on patient management, including the decision to undergo kidney biopsy or change in medication for treatment of active rejection.

There is insufficient evidence, currently, for or against AlloSure test.

Prospera:
Clinical Utility: No studies were identified.

Ongoing Clinical Studies: SCPMG reported three ongoing studies with no posted results.

There is insufficient evidence for or against the use of Prospera for surveillance of rejection.

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The use of AlloSure and Prospera for Kidney Transplant Recipients does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
81479	Unlisted molecular pathology procedure
Dx Codes	**Description**
T86.10	Unspecified complication of kidney transplant
Z94.0	Kidney transplant status

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
08/03/2021	08/02/2022[MPC]	08/03/2021

[MPC] Medical Policy Committee

Revision History	Description
12/03/2019	MPC approved a non-coverage policy for Donor-derived cell-free DNA testing (e.g., Allosure)
08/03/2021	Non-coverage for donor-derived cell-free DNA (AlloSure) testing was previously listed on Genetic Screening and Testing criteria. Separate criteria created for donor-derived cell-free DNA after clinical indications for coverage adopted at MPC. Requires 60-day notice, effective date January 1, 2022.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiac Ambulatory Monitoring for Extended Duration

- CardioNet®
- CardioNet ECG Monitor
- eVolution
- Implantable Loop Recorder
- MCOT
- Zio®Patch

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	NCD Manual, Part 1 – Electrocardiographic Services Electrocardiographic Services (20.15)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Implantable Loop Recorder

I. An implantable loop recorder (cardiac event monitor) may be indicated for **1 or more of the following**:
   A. Atrial fibrillation, known or suspected, as indicated by **ALL of the following**:
      1. Cryptogenic stroke confirmed by neurology
      2. Noninvasive cardiac monitor contraindicated, or results unrevealing or-inconclusive after minimum 14-day period
      3. Recurrent paroxysmal atrial fibrillation suspected, and test results may impact patient management

B. Syncope as indicated by **ALL of the following**:
      4. Cardiac etiology of syncope, suspected, as indicated by **1 or more of the following**:
      a) ECG results abnormal (eg, cardiac rhythm other than normal sinus, significant conduction abnormalities, Brugada ECG pattern, long QT syndrome)
      b) Family history of sudden death
      c) History of chronic heart failure
      d) History of structural heart disease (eg, valvular aortic stenosis, congenital heart disease, hypertrophic cardiomyopathy) or severe coronary heart disease
      e) Recent history of palpitations, abnormal heart rate, or symptomatic arrhythmia
      f) Use of medication known to cause malignant arrhythmias (eg, antiarrhythmics, antidepressants, antihistamines)
      5. Recurrent syncope, suspected
      6. Test results negative or inconclusive, as indicated by **1 or more of the following**:
      a) Electrophysiologic study
      b) Non-implantable (external) loop recorder, worn for 14 days at a minimum

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c) Tilt table testing

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

Service	Criteria
CardioNet® CardioNet ECG Monitor eVolution MCOT Zio®Patch	Medical necessity review no longer required.

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Background

Cardiac rhythm abnormalities are common. Many are harmless, but some cause symptoms such as palpitation, chest pain, pre-syncope and syncope, and others may be a signal for potential stroke or cardiac arrest. Electrocardiographic (ECG) documentation of the cardiac rhythm during symptoms is necessary for making accurate diagnosis, therapeutic decisions, assessing the effectiveness of suppression, and monitoring adverse drug effects. However, symptoms of arrhythmia are often infrequent and episodic, and the underlying heart rhythm may not be detected during physical examination and routine ECG that permits a few seconds of recording. It is thus essential to have extended periods of ECG recording while the patients are pursuing their normal routine (Kowey 2003, Naccarelli 2007, and Saarel 2008).
Devices used:

- *Holter monitors* are portable devices that record heart rhythms continuously for up to 48 hours. These devices are used to record events that occur at least once a day.
- *Non-implantable cardiac event monitors* are portable devices that record heart rhythms intermittently for up to 30 days. These devices capture ECG data before, during and after the time of activation.
- *Standard loop recorders* have just a few minutes of memory. Newer, more sophisticated devices have extended memory features that can store up to several hours of ECG data. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias. These devices are used to record infrequent or irregular events.
- *External mobile cardiovascular telemetry* consists of a monitor that continuously records the electrocardiographic rhythm from external electrodes placed on the patient's body. Segments of the ECG data are automatically (i.e., without patient intervention) transmitted to a remote surveillance location by cellular or landline telephone signal. The transmitted events are triggered automatically by preprogrammed algorithms or by the patient during a symptomatic episode. There is continuous, real-time data analysis in the device and attended surveillance of the transmitted rhythm segments by a surveillance center technician. The surveillance center technician reviews the data and notifies the physician depending on the prescribed criteria. These devices are used to record suspected asymptomatic arrhythmias.

The most commonly used method for extended ECG recording is the Holter monitor which records an ECG continuously for 24 to 48 hours via leads placed on the chest to yield 2 or 3 channels of ECG data. The Holter monitor provides complete rhythm recording and excellent quality tracing. However, it has a diagnostic yield of only 5-28% due to its limited time of recording which is usually too short to capture infrequent arrhythmias. In addition, some clinically important arrhythmias such as atrial fibrillation may be asymptomatic and pass unnoticed by the Holter recording (Kowey 2003, Naccarelli 2007, Rothman 2007, Saarel 2008).

External patient-activated loop event monitoring (LOOP) devices were found by researchers to improve the diagnostic yield of arrhythmias up to 63%. These may be used for up to 30 days; however, they have limited

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storage, and require appropriate patient activation during the occurrence of symptoms. Patient activation may be a difficult task for the elderly or those whose arrhythmias cause functional impairment. It was reported that one in four patients does not activate the recorder during symptomatic episodes despite the education received on operating the device. Developments are continuously being made to improve the diagnostic yield of the rhythm monitors. Newer loop recorders continually record and erase so that data gathered from 1 to 4 minutes before, and those recorded 30-60 seconds after activation of the device can be retained. Other loop monitors are automatically activated and start the recording once an abnormal rhythm of any kind is detected, without patient activation. An implantable form of continuous-loop event recorder is also currently available. It is a small device in the size of pacemaker that is implanted subcutaneously to the right or left side of the sternum and is triggered by placing an activator over it. The device has a programmable antegrade and retrograde memory and may be left in place for up to 18 months and can be explanted once the diagnosis is made or battery life has ended. Data from the device however, cannot be transmitted wirelessly (Zimetbaum 1999, Kowey 2003, Naccarelli 2007 Rothman 2007).

Mobile Cardiac Outpatient Telemetry (MCOT, CardioNet®, CardioNet device or recorder) was introduced in 1999 for continuous real-time ambulatory electrographic monitoring and analysis. The device consists of a three-electrode, and a two-channel sensor that transmits wirelessly to a small PDA sized portable monitor which can be clipped to the waist or worn on a strap around the neck. Rhythm strips are recorded continuously and analyzed by an automated arrhythmia analysis algorithm. When an arrhythmia is detected (according to the physicians 'predesignated thresholds) the monitor can transmit the ECG data to the monitoring center utilizing a cellular modem or telephone data line. Patients are monitored for 24 hours/day for up to 30 days, by central station technicians with immediate referral to the prescribing physician for evaluation of rate and rhythm changes and their symptoms. The patient can also initiate the recording and transmission of ECG data if symptoms are felt. MCOT thus potentially improves diagnosis of arrhythmias by allowing continuous monitoring of cardiac rhythm for extended periods of time, detecting asymptomatic arrhythmias, and allowing the patients to submit their symptoms and level of activity from a menu to the device (FDA web page, Rothman 2007, Naccarelli 2007).

The CardioNet ECG monitor was approved by the Food and Drug Administration in 2002 for cardiac monitoring for non-life-threatening arrhythmia detection, its evaluation, and monitoring of antiarrhythmic therapy.

Medical Technology Assessment Committee (MTAC)

Mobile Cardiac Outpatient Telemetry (MCOT)

06/04/2008: MTAC REVIEW

Evidence Conclusion: The literature search revealed only one randomized controlled study (Rothman 2007), and several observational studies. Rothman and colleagues' study were a multicenter, randomized, controlled study that compared the diagnostic yield of the mobile cardiac outpatient telemetry (MCOT) system (CardioNet, USA) with the patient-activated external loop devices (LOOP). Patients with symptoms of syncope, pre-syncope or severe palpitations, and a nondiagnostic 24-hour Holter, were randomized to receive one of the two monitoring devices for up to 30 days. The patients and investigators were not blinded to the monitor received, but the electrophysiologist who reviewed the monitor strips and verified the diagnosis was blinded to the patient allocation. There was a higher noncompliance rate in the MCOT group, and 14% of all participants did not complete the study. The study compared the MCOT (CardioNet) system with the patient-activated external loop device and not to the auto-triggered or the implanted loop systems which are known to have better diagnostic yield.
Overall, the results of the study show that diagnosis (confirmation or exclusion) of arrhythmias was made in 88% of the patients randomized to the MCOT group, vs. 75% of the patients in the LOOP group ($P<0.001$). A significant difference was also observed for patients with syncope or presyncope, where a diagnosis was made in 89% of patients in the MCOT group vs.69% in the LOOP group ($p=0.008$). Conclusion: There is fair evidence from one RCT with limitations, that CardioNet system may have a higher diagnostic yield compared to the patient-activated external loop device for up to one month. There is no published evidence to date to determine that the device is superior to the auto-triggered loop system that was found to have better diagnostic yield, or to the implanted loop system. There is insufficient evidence to determine the efficacy and safety of the CardioNet system for detecting less frequent syncopal episodes. There is insufficient evidence on the efficacy of CardioNet system in assessing the safety and efficacy of antiarrhythmic agents, or outpatient monitoring for medication titration and dose adjustments.
Articles: The search yielded around 50 articles. Many were reviews, or articles that dealt with the analysis of data or feasibility of using the device. Only one randomized controlled study (Rothman 2007) that compared the diagnostic yield of MCOT to the external patient-activated loop event monitoring up to 30 days, was identified. There were a few other relatively small observational prospective and retrospective studies that evaluated the
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safety and diagnostic yield of the CardioNet system. Rothman and colleagues' RCT were selected for critical appraisal. Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: A prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. J Cardiovasc Electrophysiol 2007; 18:241-247. See Evidence Table.

The use of Mobile Cardiac Outpatient Telemetry (MCOT) in the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/03/2009: MTAC REVIEW
Mobile Cardiac Outpatient Telemetry (MCOT)
Evidence Conclusion: There is no new published evidence that would alter the conclusion of the previous MTAC review. The only published RCT (Rothman 2007) that compared mobile cardiac outpatient telemetry to LOOP event monitoring was reviewed earlier in 2008. The study was randomized, controlled and multicenter. However, it was not blinded, had a 14% drop-out rate, non-compliance was more common in the MCOT group, and analysis was not based on intention to treat. Moreover, the mobile cardiac outpatient telemetry (MCOT) system (CardioNet, USA) was compared with the patient-activated external looping event recorders. The study did not compare MCOT with the implanted loop recorders and was not designed to compare it with the auto-trigger loop recorders which were used in only 16% of the patients in the LOOP group. Both the implanted and auto-trigger loop recorders are reported to have higher diagnostic yield than the patient activated loop recorders. Overall the results of the study indicate that MCOT was superior to loop recordings with a diagnosis made in 88% MCOT patients vs. 75% LOOP patients (p=0.008). A significant difference in the diagnostic yield was also observed for patients with syncope or presyncope (89% vs. 69% respectively, p=0.008). More recently only retrospective case series (Saarel 2008, and Tayal 2008) on the use of MCOT for the detection of suspected arrhythmias were published. Saarel and colleagues (2008) reported on the use of MCOT among 54 children and adolescents with suspected arrhythmia. Thirty-three subjects transmitted ECGs during symptoms yielding a diagnostic rate of 61%. The remaining 21 (39%) failed to transmit ECG while experiencing symptoms. Comparing the diagnostic yield of MCOT with historical data from transtelephonic electrocardiographic event monitors (TTMs) showed no significant differences between the two systems. Tayal and colleagues (2008) performed a retrospective analysis of 56 patients with cryptogenic stroke (undetermined cause). This showed that MCOT detected 27 asymptomatic atrial fibrillations in thirteen patients (23%). 23 (85%) of these episodes were less than 30 seconds in duration, and the remaining 4 (15%) were 4-24 hours in duration. None of the published studies to date indicate that the MCOT (CardioNet system) is superior to the auto-trigger LOOP device currently used, or that it leads to an improvement in net health outcome. Conclusion: There is fair evidence from one RCT with limitations, that CardioNet system may have a higher diagnostic yield compared to the patient-activated external loop device for up to one month. There is insufficient evidence however to determine that the device is superior to the auto-triggered or the implanted loop systems that were found to have better diagnostic yield than the patient-activated external loop monitors. There is insufficient evidence to determine that CardioNet system improves the management of patients e.g. monitoring for medication titration and dose adjustments. There is insufficient evidence to determine that CardioNet system improves patients' health outcomes.
Articles: The search did not reveal any controlled trial on MCOT published after the RCT reviewed earlier in MTAC. Only two relatively small retrospective case series were identified; one reported on the use of MCOT among adult patients with stroke, and the other evaluated its use among children and adolescents with suspected arrhythmias. None were selected for critical appraisal.

The use of Mobile Cardiac Outpatient Telemetry (MCOT) in the detection of arrhythmias does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Zio®Patch
12/16/2013: MTAC REVIEW
Evidence Conclusion: There is a lack of published literature on the use of Zio®Patch for detecting atrial fibrillation and other arrhythmias in asymptomatic or symptomatic patients. A pilot study conducted by Rosenberg and colleagues (2013) compared the Zio®Patch with the traditional 24 hours Holter monitor in 74 patients with paroxysmal atrial fibrillation who were referred to Holter monitoring for evaluation. The Zio®Patch was well tolerated and had a mean monitoring period of 10.8 +2.8 days (range 4-14 days). During the simultaneous 24-hour recording time when the patients wore both devices, there was a strong correlation between the Zio®Patch and the Holter monitor (r=0.96) for identifying AV events and estimation AF burden.18 additional cardiac events were recorded with the Zio®Patch due to longer duration of use. Other clinically relevant cardiac events recorded by the Zio®Patch after the 24 hours of monitoring, including symptomatic ventricular pauses, led to change in medications or referrals for pacemaker placement. Overall clinical management was changed in 28.4% of the

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patients as a result of the Zio®Patch findings. The authors concluded that the Zio®Patch was well tolerated and allowed longer monitoring that resulted in meaningful changes in clinical management. They indicated that more studies are needed to examine the long-term impact of the device in AF management. The other published study (Turakhia et al, 2013) was only a retrospective analysis of data obtained from the device manufacturer. No comparison was made with Holter monitor or any other ambulatory cardiac rhythm monitor. There are no published studies, to date, that compared the Zio®Patch to any of the other longer-term outpatient ambulatory cardiac rhythm monitors. Conclusion: There is weak evidence from one small single-center pilot study that Zio®Patch was well tolerated and allowed longer monitoring than Holter monitoring. This resulted in the detection of more AF episodes and cardiac events in symptomatic patients and making changes in the clinical management among more than one fourth of the study participants. There is insufficient published evidence on the use of Zio®Patch for detecting atrial fibrillation and other arrhythmias in asymptomatic patients with AF. There is insufficient evidence to determine the equivalence or superiority of Zio®Patch to any of the other longer-term outpatient ambulatory cardiac rhythm monitors.
Articles: The literature search revealed only two published studies on the use of Zio®Patch as a noninvasive monitoring device for arrhythmias in general in one study, and for atrial fibrillation in the other. A retrospective study among 285 patients seen in emergency departments was identified from a review article, but it was not published in a peer review journal; it was only presented in a conference. The two published studies were critically appraised. Rosenberg MA, Samuel M, Thosani A, et al. Use of a noninvasive continuous monitoring device in the management of atrial fibrillation: a pilot study. *Pacing Clin Electrophysiol*. 2013;36:328-333.See Evidence Table, Turakhia MP, Hoang DD, Zimetbaum P, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. *Am J Cardiol*. 2013; 112:520-524. See Evidence Table.

The use of Zio®Patch the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Implantable Loop Recorder

BACKGROUND

Syncope has a complex differential diagnosis. Syncope that remains unexplained after standard evaluation does not appear to be associated with excess mortality (Savage et al., 1985) or serious adverse cardiovascular events (Kapoor, 1990). However, syncope recurrences are associated with fractures, automobile accidents and other complications (Kapoor, 1987).

Standard techniques for diagnosing syncope include history and physical examination, laboratory testing, exercise stress testing, Holter monitoring, tilt table testing and external loop recording. External loop recorders (“King of Hearts” model) store ECG data up to 4 minutes prior to and 1 minute after activation by a patient. They are worn on the wrist or around the waist, generally for up to 1 month.

The implantable loop recorder (ILR) is a new diagnostic tool for unexplained infrequent syncope. The ILR is a 61x19x8mm, recording device produced by Medtronic Reveal. It stores an ECG signal in a circular buffer capable of retaining 21 minutes of uncompressed signal or 42 minutes of compressed signal (can be divided into 1-3 parts). The ILR requires the patient or family member to use a hand-held pager-sized activator to “freeze” the memory buffer during or immediately following an episode of syncope. The device is implanted into the left infraclavicular region. Using local anesthesia, a 2 cm incision is made, a pocket the size and shape of the device is made and the ILR is placed in the pocket. The ILR can monitor patients for up to 14 months. The device is removed after a diagnosis of syncope is made or at the end of battery life.

Medicare approved coverage for this implantable device effective 10/1/1999. Kaiser Permanente added it to the medical criteria subject area at that time.

MTAC reviewed this device at the February 2000 meeting and found the technology appears to be promising and safe for patients whose syncope is undiagnosed but there is not enough evidence to draw conclusions regarding reproducibility, safety and accuracy. The Health Plan Medical Director Group at their February 2000 meeting reviewed the MTAC findings and determined that there was good reason to recommend coverage for patients who had infrequent, undiagnosed episodes of syncope.

02/10/1999: MTAC REVIEW

Evidence Conclusion*:* The one study evaluating the potential of the ILR to diagnose unexplained syncope obtained a diagnostic yield of 59% during a mean of 10.5 months of recording. Possible selection bias, conflict of interest on the part of the investigators and a lack of comparison with external loop recorders limit the ability of

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this study to determine efficacy of the ILR. Two studies evaluating the external loop recorders found point estimates for diagnostic findings of 25% and 36% after approximately one month of recording.
Articles: Krahn D, Klein G, Yee R, Takle-Newhouse T, Norris C. Use of an extended monitoring strategy in patients with problematic syncope. Circulation 1999; 99: 406-410. See Evidence Link.

The use of implantable loop recorder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Implantable Loop Recorder - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
HCPC Codes	**Description**
C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator, and programmer
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

External Loop Recorder –

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Medical Necessity review no longer required

CPT® Codes	Description
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis

External Patient Activated EKG -

Medicare - Considered not medically necessary
Non-Medicare - Medical Necessity review no longer required

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CPT® Codes	Description
0497T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection
0498T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recording without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/17/08	06/04/2008, 08/03/2009, 5/4/2010 MDCRPC, 3/1/2011 MDCRPC, 1/03/2012MDCRPC,11/06/2012 MDCRPC, 09/03/2013 MPC , 03/04/2014MPC, 11/03/2015MPC , 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
04/05/2016	Added “Following a cryptogenic stroke” as an indication
08/09/2016	Merged Implantable Loop Recorder into one policy as External Loop Recorder
02/01/2017	Medical management approved medical necessity no longer required
03/06/2018	MPC approved commercial criteria for Implantable Loop Recorder effective date 7/1/2018
05/05/2020	Removed deleted codes 33282 and 33284 (ILR)
07/07/2020	MPC approved to adopt updates to the *Implantable Loop Recorder* clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020.
08/06/2020	Removed CPT code 33286
05/04/2021	Updated applicable coding

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Anti-Malignin Antibody Test for Cancer Detection

- Four Kallikrein Markers
- Kallikrein Panel

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Anti-Malignin Antibody Test for Cancer Detection,” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A tumor marker is a biological substance or irregularity that indicates the presence of a tumor. These markers are used in clinical practice for diagnosis, anatomical localization, and monitoring a variety of malignancies. The more specific the marker is for the tumor histotype, the more useful it is as a marker; and the earlier the marker is detected, the earlier a possible diagnosis can be made.

Serum measurement of the majority of markers did not prove to be very reliable for screening purposes or for the early detection of cancer. These tests measure the tumor-associated antigens that appear on the surface of the cell membrane following the malignant transformation. Serum tests become more reliable as the tumor load increases and more antigens are released into the bloodstream. The tumor-associated antigens are recognized by the immune system of the host that in turn produces specific antibodies. Theoretically, antibodies are more readily detected than antigen early in the disease *(Abrams 1994, Botti 1997)*.

Malignin, a 10 kDa polypeptide, has been found by some researchers to be elevated in most patients with a wide range of malignancies regardless of site or cell type. Two researchers in Boston (Drs. S. Bogoch and E. Bogoch) reported that they discovered anti-malignin antibodies (AMAs) in the serum of patients with cancer. The antibodies were described as IgM produced by the patient against the oncoprotein malignin. Bogoch reported that

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antibody concentration is reduced or eliminated in terminal cancer or in the presence of a large tumor mass present for 3 or more years *(Bogoch 1982)*. The human antimalignin antibody serum (AMAS) test was developed to measure the antibody concentrations against malignin. It is claimed that the test may potentially be useful in the early detection of cancer as well as managing and monitoring the progress of the cancer.

The AMAS test is based on the specific immunoadsorption of the antibody from serum to Target® reagent. The Target® reagent consists of malignin bound covalently to bromoacetylcellulose *(Abrams 1994, Botti, 1997)*. After washing with cold saline, the serum sample is added to the reagent, the AMA eluted with acetic acid, and the results are quantified. The test should be performed within 24 hours of serum collection to reduce the false-positive results that increase with the use of frozen stored serum.

The AMAS test does not replace the conventional screening and diagnostic procedures but, as reported, it may be performed with other routine procedures and in relation to risk factors, history, clinical signs and symptoms, and other factors.

Medical Technology Assessment Committee (MTAC)

Anti-Malignin Antibody Test

10/03/2005: MTAC Review

Evidence Conclusion: The two studies reviewed (Bogoch 1982, and Thornwaite 2000) compared the serum antimalignin antibody levels in patients with diagnosed cancer to those of healthy controls. Thornwaite studied it for patients with breast cancer, and Bogoch for patients with carcinomas in different organs. Both studies had their limitations. The test was performed on patients already diagnosed with or without cancer, there is no indication that the antibody cutoff-level used was validated, the authors did not discuss how they selected the study participants, and the patients with terminal cancers were excluded from the analysis.

Articles: The search yielded 16 articles. Three empirical studies were identified: Bogoch 1982, studied the relation of antimalignin antibody and malignin to survival, Bogoch 1991, published in an abstract form, and Thornthwaite (2000) compared AMAS testing for breast cancer with histopathology and other cancer markers. Another article identified by the search (Abrams 1994), compiled the results of the test performed in 42 practices in 11 states that performed AMAS test for the detection and monitoring of cancer.

The following articles were critically appraised: Thornthwaite JT. Anti-malignin antibody in serum and other tumor marker determinations in breast cancer. Cancer Letters. 2000; 148:39–48. See Evidence Table.

The use of Anti-Malignin Antibody does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/03/2005	10/03/2005[MDCRPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	10/25/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision	Description

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Date Sent: 6/28/23
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History	
10/25/2019	Adopted Kaiser Permanente policy for MA members

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Artificial Spinal Discs for Lumbar or Cervical Disc Disease

- Bryan™
- Charité™
- Prestige™ Artificial Discs
- ProDisc-C™
- ProDisc-L™
- Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Lumbar Artificial Disc Replacement (LADR) (150.10) Per NCD - this service is not covered for Medicare beneficiaries over 60 years of age.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for lumbar artificial disc replacement for Medicare members under 60 years of age or for cervical artificial disc replacement, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Artificial Spinal Discs for Lumbar or Cervical Disc Disease"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

I. Artificial cervical discs may be considered medically necessary for the following:
   A. For treatment in adults with symptomatic cervical degenerative disc disease when **ALL** of the following are met:
      1. FDA-approved prosthetic intervertebral discs are used;
      2. Performed at one level or two contiguous levels from C3-C7;
      3. Objective evidence in the clinical record documents cervical radiculopathy and/or myelopathy; and
      4. Patients have failed at least six weeks of conservative management (which may include rest, application of heat/ice, physical therapy, exercise, pain and/or anti-inflammatory medications).
   B. A subsequent, second-level, anterior total cervical disc replacement using an artificial intervertebral disc following complete decompression may be considered medically necessary in skeletally mature patients with symptomatic cervical disc degeneration when **ALL** of the following are met:
      1. The planned subsequent procedure is at a different cervical level then the initial cervical artificial disc replacement; and
      2. Clinical documentation that the initial cervical artificial disc replacement is fully healed; and
      3. Criteria A, 1-4 are met

II. Prosthetic intervertebral discs are considered investigational for **ALL** of the following:

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- In patients with isolated axial neck pain without cervical radiculopathy or myelopathy;
- When requested adjacent to a prior fusion; or
- At a level of prior surgery
- When more than two levels are requested

III. Lumbar Disc
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes from requesting provider &/or specialist that include a current history and physical exam
- Detailed documentation of extent and response to non-operative conservative therapy or procedural interventions
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Degeneration of the intervertebral disc, also known as degenerative disc disease (DDD) is the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration can occur at any level of the spine but is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment, however the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels (Lee 2004, Mobbs et al, 2007, Sasso 2008, Yang 2008, Heidecke 2008).

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear (Yang 2008, Burkus 2010, Cepoiu-Martin 2011).

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), and Prestige Cervical Disc (Medtronic Sofamor Danek). ProDisc-C

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has a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and PRESTIGE has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. FDA clearing of the artificial disc systems required post-approval studies to evaluate the long-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate 3, 5, 7, and 10-year data for cervical discs.

Lumbar
The Charité ® (DePuy) and ProDisc®-L (Synthes Spine) have received approval from the US Food and Drug Administration. The approval was contingent on completion of post-marketing studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate the 5-year data for lumbar discs. The Charité ® and ProDisc®-L devices are indicated for:

1. Spinal arthroplasty in skeletally mature patients, with pain from degenerative disc disease (DDD).
2. One level of the spine (L3-S1 for the ProDisc-L, L4-S1 for the Charité).
3. Patient may have no more than a grade 1 spondylolisthesis.
4. Patients must have failed to find pain relief after at least 6 months of non-surgical therapies.

Contraindications to total lumbar disc replacement include active infection, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and DDD at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Cervical
The cervical artificial discs are FDA approved for the following:
1. Reconstruction of cervical disc from C3-C7 following single-level discectomy for intractable.
2. Symptomatic cervical disc disease confirmed by imaging.
3. Patient is skeletally mature.
4. Cervical disc disease should have failed at least six weeks of non-operative treatment prior to implantation.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Medical Technology Assessment Committee (MTAC)

Artificial Disc in the Treatment of Back Pain

02/07/2005: MTAC REVIEW

Evidence Conclusion: The trial reviewed on Charité artificial spinal disc was randomized, controlled, and multicenter, but had some limitations. Authors concluded that the clinical outcomes and incidence if major neurological complications at 2 years of follow-up were equivalent to those of BAK fusion. The trial, however, was not designed as an equivalence study. Equivalence trials are planned and analyzed differently from superiority studies, and generally require larger sample sizes. Lack of significant superiority is not necessarily the same as equivalence, and the absence of statistical significance may be due to insufficient power to detect differences between the study groups. The comparison group in this trial was the BAK fusion technique, which was the preferred fusion procedure at the time, but might not be the current up-to-date procedure. Moreover, the 24-months follow-up period might not sufficient to determine the long-term safety and effectiveness of the implant as well as its impact on other discs and on the bony structures on the back of the spine.
Articles: The search yielded 56 articles. The majority were review articles, or reports that dealt with the design, technical aspects and/or evolution of the technology. The search revealed four articles published by the same group of authors reporting on the Charité artificial disc evaluated in a multicenter RCT in the US. The article that reported the results of the trial in all centers was selected for critical appraisal.

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The search also revealed a report on the early 6 months results for the first 53 patients randomized in an ongoing multicenter RCT of ProDisc in the United States. The system is not currently FDA approved.
Geisler FH, Blumenthal SL, Guyer RD, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: Results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. *L Neurosurg (Spine 2)2004;1:143-154.* See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

10/04/2006: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence that artificial discs approved by the FDA or pending approval are effective, particularly in the long-term. There is only one completed RCT and this is on the Charité device. There are no completed published RCTs on the Prestige or ProDisc devices. The Charité RCT may not have used appropriate equivalence trial methods, including failure to compare the new device to an intervention with proven effectiveness. The safety of the artificial discs after a minimum of 2 years appears similar to that of surgical fusion. Authors of the Charité had financial links to the manufacturer, which could introduce bias.
Articles: An April 2005 Blue Cross BlueShield TEC report was identified. In their literature search, they found one completed RCT, the same study included in the first MTAC review. There was also a systematic review (Freeman & Davenport, 2006) that searched the literature through April 2006 and also identified the same single completed RCT. *Literature on individual devices identified through Medline search:*
Charité device: Several additional publications on the RCT previously reviewed by MTAC (Geisler et al., 2004) were identified: Blumenthal et al. (2005) reported updated data on primary outcomes (more patients had reached 24-month follow-up). McAfee et al. (2005) reported on radiographic outcomes e.g. restoration of disc height. Regan et al. (2006) examined outcomes in the treatment group according to centers' surgical volume. McAfee et al. (2006) reported on the re-operation rate of patients in the RCT as well as other patients, for a total sample size of 688. The updated study on the primary outcomes (Blumenthal et al., 2005) and the study on re-operation rates (McAfee et al., 2006) were critically appraised. The other publications were not evaluated further because they do not add substantially to our ability to evaluate the long-term safety and efficacy of the Charité device. ProDisc device: The RCT identified in the previous MTAC search comparing ProDisc to surgical fusion is still ongoing. The study is taking place at 19 centers and has an enrollment goal of 500 patients. At the time of the first MTAC review, an article reporting initial findings for 53 patients at one center was identified. A 2005 article was identified that reported additional preliminary findings from the same center, this time for 78 patients. This study was not critically appraised because results from all centers are not yet available. Prestige device (not included in 2005 MTAC review): There was a 2004 publication reporting on preliminary findings from a randomized controlled trial on Prestige II conducted at four sites in Europe. This study was critically appraised. The article appears to report on all randomized patients, although not all patients had completed the final follow-up. No subsequent publications on outcomes of this RCT were identified. In addition, an older case series with 17 patients using the Prestige I device was identified, but not evaluated further due to the small size and the availability of higher-grade evidence. Blumenthal S et al. A prospective, randomized, multicenter food and drug administration investigational device exemptions study of lumbar total disc replacement with the Charité artificial disc versus lumbar fusion. Spine 2005; 30: 1568-1575. See Evidence Table. McAfee PC et al. Revisability of the Charité artificial disc replacement. Spine 2006; 31: 1217-1226. See Evidence Table. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurgery Focus 2004; 17: 36-43. See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

10/01/2007: MTAC REVIEW

Evidence Conclusion: The Prestige cervical disc system was first reviewed by MTAC before final FDA approval. At that time, there was one relatively small published RCT reporting preliminary findings (Porchet & Metcalf, 2004). At the time of data analysis, the investigators did not find a significant difference in pain and disability outcomes at 12 months for patients who underwent either artificial disc replacement or anterior cervical fusion. Limitations of this RCT included insufficient follow-up (only about two-thirds of participants had completed the 12-month follow-up and about 15% had completed the 24-month follow-up), unclear equivalence study methods, and funding from the device manufacturer. A larger multicenter RCT among patients with symptomatic single-level

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cervical degenerative disc disease (DDD) was identified for the evidence update (Mummanemi et al., 2007). Mummanemi and colleagues randomized 541 patients to receive either the Prestige cervical disc system or anterior cervical discectomy and fusion. Using a composite success measure developed by the investigators that considered efficacy and safety, the Prestige artificial disc system was found to be superior to ACDF in a completer analysis. In an intention to treat analysis with a "worst case scenario" analysis, Prestige was found to be non-inferior to ACDF. Advantages of the Mummanemi study were that it was randomized and there was a high follow-up rate. Disadvantages are that the study was non-blinded, and the authors have financial links with the manufacturer. In conclusion, there is fair evidence from one reasonably valid multicenter RCT that use of the Prestige artificial disc in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety. The evidence would be strengthened by longer-term follow-up data and studies conducted by impartial researchers. The Porchet & Metcalf, 2004 study does not add substantially to the body of evidence, especially since only preliminary findings were reported in the published literature.

Articles: At the time of the previous MTAC review of artificial discs (October 2006), there was one published randomized controlled trial on the Prestige disc with 55 patients from 4 sites in Europe. The article reported preliminary findings of the RCT (Porchet & Metcalf, 2004). No follow-up publication was identified that reported final results of this RCT. The updated literature search identified a new, larger RCT. This study randomized 541 patients at 32 sites in the United States to discectomy with artificial disc replacement or ACDF (Mummaneni et al., 2007). This was the key study submitted to the FDA for device approval. The Mummaneni et al. RCT was critically appraised: Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table.

The use of Prestige artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/01/2010: MTAC REVIEW

Evidence Conclusion: The published randomized controlled trials on lumbar and cervical artificial disc replacement, reviewed for this report, were all US FDA investigational device exemption (IDE) studies designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD, or ACDF for cervical disc disease (non -inferiority design). Lumbar total disc replacement with artificial intervertebral discs (Charité, and ProDisc-L). The trials on artificial total lumbar disc replacement compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the CHARITE IDE trial had a maximum study duration of two years which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration.

CHARITE IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with non-blinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated.

In conclusion, there is insufficient evidence to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration. Cervical total disc replacement with artificial intervertebral discs (ProDisc-C, Bryan, and PRESTIGE). The trials on artificial total cervical disc replacement compared the procedure in conjunction with discectomy to anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with radiculopathy or myelopathy from a single-level cervical disc disease From C3 to C7, that failed conservative treatment of at least 6 weeks. The trials were randomized, controlled and multicenter, but were not blinded, the postoperative care was not standardized and left to the

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discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturer, all of which are sources of bias. Moreover the 2-year follow-up duration insufficient to examine the long-term efficacy, safety, and durability of the artificial disc replacement, or to determine whether it is associated with the risk of adjacent risk degeneration. In conclusion, the short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or PRESTIGE artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease.
Articles: *Lumbar artificial disc replacement* the updated literature search identified two randomized controlled trials that compared total lumbar disc replacement with Charité (Guyer 2009) or ProDisc-L (Zigler 2007) systems versus lumbar fusion. Guyer et al reported on 5-year follow up of patients enrolled in the Charité IDE trial that was the key study submitted to the FDA for device approval. Zigler et al's trial was also the key trial for FDA approval for ProDisc-L. Both RCTs was critically appraised. Guyer RD, McAfee PC, Banco RJ, et al. Prospective, randomized multicenter Food and drug Administration investigational device exemption study of lumbar total disc replacement with the Charité artificial disc and versus lumbar fusion: Five-year follow-up. Spine J. 2009; 9:374-386. See Evidence Table. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine. 2007; 22:1155-1162. See Evidence Table *Cervical artificial disc replacement:* The literature search revealed two RCTs on ProDisc-C total disc replacement as well as two trials on Bryan cervical disc arthroplasty (conducted by the same principle investigators, and published in 5 articles). Two studies, one for each system (Murrey 2009 for ProDisc-C, and Heller 2009 for Bryan cervical disc arthroplasty), were selected for critical appraisal based on the methodological quality of the trial, population size and duration of follow-up. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine. 2009; 9:275-286. See Evidence Table. Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:107-107. See Evidence Table.

The use of artificial spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: *CERVICAL* The three large published trials on cervical arthroplasty were industry sponsored studies submitted to the U.S. Food and Drug Administration for premarket approval of the devices: Prestige, ProDisc-C, and Bryan cervical disc. All three trials were designed as noninferiority trials i.e. attempting to show that cervical artificial disc replacement is at least as good as ACDF for cervical disc disease. They had similar inclusion and exclusion criteria, similar follow-up schedules, and similar outcome measures and success criteria defined by the FDA. The three trials are still ongoing as the FDA required that the investigators conduct post-approval studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to provide 3, 5, 7, and 10-year data for cervical discs. Each of the three studies compared total replacement with an artificial disc (Prestige, ProDisc-C, or Bryan) in conjunction with discectomy to a single-level anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with a single level cervical radiculopathy or myelopathy between C- 3 and C-7 that had failed conservative treatment of at least 6 weeks. The trials were relatively large, randomized, controlled, and multicenter, but were not blinded, the postoperative care was not standardized and left to the discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturers who supported the trials, all of which are sources of bias. The 24 months interim analyses of the three trials were previously reviewed by MTAC. The conclusion of the last 2010 MTAC assessment of the technology was as follows, "The short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or Prestige artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease." After the last MTAC review of 2010, mid-term follow-up data were published for all three trials: 48 months postoperative data for ProDisc and Bryan artificial discs and 60 months postoperative data for Prestige cervical disc. These mid-term follow-up data were only available for just over two thirds of the
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population in the Bryan disc trails, and around 50% for each of the 60 months follow-up data for the Prestige disc trials and the 48 months follow-up for ProDisc-C trial. The published results of all three studies show that the one level cervical disc arthroplasty appears to be at least as effective as cervical fusion in up to 2 years of follow-up. The results the extended, mid-term analyses suggest that the outcomes the artificial disc arthroplasty continues to be noninferior to those of fusion. However, the follow-up rates are poor, and the results on sustained effect and durability should be interpreted with caution. The 48 and even 60 months follow-up duration is still insufficient to determine the long-term efficacy, durability, and safety of the system, and the potential risk on adjacent risk degeneration. The trials are still ongoing and long-term results for up to 10 years follow-up are expected. In conclusion, the additional information does not change the conclusions of the previous reports; data on long-term safety and efficacy is still lacking, and there is no evidence to date to determine if one of these three FDA approved artificial discs is superior to the others. A recent update of the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) (November 2011) concluded that artificial intervertebral disc arthroplasty for the treatment of patients with cervical degenerative disc disease does not meet their criteria. The TEC update however did not include Sasso et al's 2011 article that reports on the 48 months outcomes of all participating centers in the Bryan cervical disc trial. At the time of the TEC review only one center had published the 48-month follow-up results (BCBS 2011). *LUMBAR* As indicated in the last 2010 MTAC review, the published randomized controlled trials on lumbar artificial disc replacement were U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) studies that were designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD. The studies (reviewed in earlier reports) compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the Charite IDE trial had a maximum study duration of two years, which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration. Charite IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with nonblinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated. Yajun, et al's meta-analysis, 2010 (Evidence table 1) pooled the results of five studies involving 837 patients. The meta-analysis had valid methodology and analysis, and according to its reviewers, four of the five trials had good methodological quality. They indicated however, that the studies had limited population sizes and did not indicate that the assessors of the outcomes were blinded. The pooled results of the analysis showed that at 2 years of follow-up the patient functioning ability as measured by the Oswestry Disability Index (ODI) in the total disc replacement (TDR) group was better than the fusion group but, according to the authors a mean difference of 4 Oswestry points is not clinically relevant. There was also a statistically significant but clinically irrelevant difference in the pain score in favor of the TDR. After performing a sensitivity analysis excluding one large study that compared TDR with BAK cages, the difference in ODI, pain, and patient satisfaction were no longer significant. The authors concluded that TDR is not superior to fusion in treating lumbar degenerative disc disease. In conclusion, there is still insufficient published evidence to date, to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration.
Articles: *CERVICAL DISC* The literature search revealed four articles reporting on long-term outcomes of three pivotal clinical trials on Prestige ST, ProDisc-C, and Bryan artificial discs (one in a single center, and the other on the entire population studied). The search also identified an RCT on KineflexIC artificial disc with 2-year follow-up, and a recent meta-analysis (Cheerag, et al. 2011) that pooled the 2-year follow-up results of the three first trials. No trials comparing the three FDA approved artificial disc systems to one another were identified.
All three initial studies on Bryan, ProDisc, and Prestige cervical discs initial trials with 2-year outcomes that were submitted to the FDA for premarket approval were previously reviewed by MTAC. The reports on long-term follow-up outcomes of the studies were reviewed and their results added to the last MTAC report to update the findings and conclusions. The meta-analysis was not critically appraised as it does not add more evidence to 24 months interim results of the individual trials. Pooling these results still provide 2-year results when long-term safety, durability, and efficacy are needed. The recent RCT on KineflexIC was also not selected for appraisal as it only provides 24 months data. The following initial trials and more recent publications were critically appraised:
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Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with The Prestige disc: results from a prospective randomized controlled trial. J Neurosurg Spine 2010; 13:308-318. See Evidence Table. Delamarter, RB, Murrey D. Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients SAS Journal. 2010; 4:122–128. See Evidence Table**.** Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:101-107. See Evidence Table**.** Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J. 2009; 9:275-286. See Evidence Table**.** Sasso RC, Anderson PA, Riew D, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: Four-year clinical outcomes in a prospective randomized, controlled, trial. J Bone Joint Surg A. 2011; 93:1684-1692. See Evidence Table**.** *LUMBAR* The literature search for studies published after the MTAC 2010 re-review of the technology, did not identify more recent reports on extended follow-up of the key trials on the Charité IDE or ProDisc-L used for the treatment of a single level generative disc disease (DDD). There was a recently published RCT (Delamarter et al 2011) conducted by the same investigators of Pro-disc-L total replacement, but for the treatment of two-level lumbar DDD which the focus of the current review is not. The search also revealed one meta-analysis of studies on artificial lumbar disc replacement for single level DDD, a systematic review, and once case series on with a 2-7 years follow-up of 57 patients who received an artificial Charite III total disc arthroplasty. The meta-analysis was selected for critical appraisal: Yajun W, Yue Z, Xiuxin H. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease*. Eur Spine J.* 2010; 19:1250-1261. See Evidence Table.

The use of cervical artificial disc in the treatment of back pain meeting the *Kaiser Permanente Medical Technology Assessment Criteria* is inconclusive.

The use of artificial lumbar spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

BACKGROUND

Degenerative disc disease (DDD) is defined as any changes that occur at any level of the spine. It's the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment. However, the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels [1-4].

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. In addition, many trials [5, 6] have shown that cervical disc arthroplasty (CDA) is as safe and effective as ACDF for the treatment of CDD at a single level. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear [3, 7, 8].

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The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité ™ (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), Prestige Cervical Disc (Medtronic Sofamor Danek), Mobi-C Cervical Disc (LDR Spine USA), and Kineflex|C Spinal System (SpinalMotion Inc.). ProDisc-C have a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and Prestige has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received the US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. The Mobi-C has received the US Food and Drug Administration (FDA) premarket application approval on August 2013.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

09/21/2016: MTAC REVIEW
Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease
Evidence Conclusion: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) (evidence table 1) This meta-analysis of RCT aimed to determine the safety and efficacy of cervical disc arthroplasty (CDA) at two contiguous levels cervical disc degeneration. The search was performed between January 2000 and July 2015. Evaluation of study quality was performed using the Cochrane Collaboration's tool for assessing risk of bias. Mean follow-up of included studies ranged from 20-48 months. CDA group patients showed fewer blood loss, lower post-operative complications, lower reoperation rate and better range of motion at all angles and levels. No significant difference was identified in mean surgical time, neck disability index and neck and arm pain VAS scores. Limitations remain in the variety of artificial intervertebral disc types. Furthermore, there is limited number of articles on artificial cervical disc for 2 levels.
Overall, CDA is more effective; the study has valid methodology with some limitations.

Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) (evidence Table 2) This multicenter RCT, FDA investigational device exemption pivotal trial aimed to compare the Mobi-C cervical artificial disc to anterior discectomy and fusion (ACDF) for treatment of cervical DDD at 2 contiguous levels of the cervical spine. This study shows that the overall study success rates met the non-inferiority margin and provided statistical superiority of the total disc replacement (TDR) treatment over ACDF. Results should be interpreted with caution since several authors had received clinical or research support for this study from LDR, the sponsor. In addition, many other authors had financial ties with LDR.

Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) (evidence Table 3) This is a 4-year follow-up result of the study performed by the same author in 2013. The follow up in the 2013 study presented earlier is 24 months. The current study follow-up is 48 months. At 48 months, total disc replacement (TDR) had greater improvement than ACDF in: neck disability index scores, 12-Item Short Form Health Survey Physical Component Summary scores, patient satisfaction, and overall success. In addition, TDR patients had lower subsequent surgery rates and showed a lower rate of adjacent-segment degeneration; TDR also maintained segmental range of motion. The study shows that TDR continue to be safe, effective and superior to ACDF at 48 months for the treatment of degenerative disc disease at 2 contiguous cervical levels.

A systematic review and meta-analysis of RCTs [9] indicated that CDA is more effective and safer than ACDF for the treatment of symptomatic cervical disc disease in mid- to long-term follow-up. However, only one study

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including 2-level was included in the review. A prospective, randomized study [10] compared the safety and effectiveness of the Bryan Cervical Disc in patients with myelopathy caused by two-level cervical disc disease in Han Nationality. The authors found that the Bryan Cervical Disc replacement was shown to be reliable and safe for the treatment of patients with two-level cervical disc disease.

Conclusion:

- Two-level cervical artificial disc replacement shows positive outcomes on the short-term
- There is low evidence to support the effectiveness and safety of two-level cervical artificial disc replacement over anterior cervical discectomy and fusion (ACDF) on the short-term for the treatment of cervical degenerative disc disease
- Studies with longer term follow-up are needed to confirm these findings

Articles: The literature revealed a number of articles; the following articles were selected for critical appraisal: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) See Evidence Table 1. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) See Evidence Table 2. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) See Evidence Table 3.

The use of Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Cervical:

CPT® or HCPC Codes	Description
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

Considered Not Medically Necessary:

Lumbar:

CPT® or HCPC Codes	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

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0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
02/07/2005	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 03/06/2012[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	01/04/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34866 and L35008
10/04/2016	Added MTAC review
11/01/2016	MPC approved criteria for two contiguous levels from C3-C7
06/04/2020	Removed deleted and inaccurate CPT code 0357T
01/04/2022	Defer to KPWA policy for Medicare members for lumbar disc replacement if younger than 60 years old and for cervical disc replacement for all ages.

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Clinical Review Criteria

Patient Referral Guidelines for Use of Mechanical Circulatory Support Devices as a Bridge to Cardiac Transplant

Artificial Hearts

- AbioCor
- SynCardia

Ventricular Assistive Devices

- Implanted Ventricular Assist Devices (VAD)
- Percutaneous Left Ventricular Assist Device (PLVAD)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Artificial Hearts and Related Devices (20.9) Ventricular Assist Devices (20.9.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Percutaneous Endovascular Cardiac Assist Procedures and Devices (A52967)

For Non-Medicare Members

OVERVIEW

These guidelines have been developed from the major clinical trials. However, acute changes occur in this group of patients and it is often uncertain which parameters are reversible. It is important to know that these are guidelines and should be applied together with careful clinical judgment.

Devices: The type of device used is dependent upon the implanting center and the device used by the center. Common devices include Heartmate I, II or III, HeartWare and Total Artificial Heart. Non-durable devices include Impella, ECMO, V-A ECMO. These are common devices and *not* an all-inclusive list.

Inclusion Guidelines (one or more should be present to indicate the patient is ill enough to warrant MCS support):

1. NYHA class III-IV symptoms, and/or intractable ventricular arrhythmia, approved by Kaiser Permanente for, and currently listed by UNOS as a candidate for heart transplant, or are being evaluated as a candidate for transplant.
2. INTERMACS Profile 1, 2, 3, or 4 (see Appendix 1).
3. One or more objective indicators of failing support despite maximum reasonable and tolerated medical therapy may include one or more of the following:

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3.1. Systemic mean BP < 60mmHg or systolic BP <80 mmHg

3.2. Cardiac index < 2.0 L/min/m^2

3.3. Pulmonary capillary wedge pressure (or PA diastolic) > 20 mmHg

3.4. A low VO_2 maximum[1]

3.4.1. VO_2 < 12 mL/kg/min on a beta-blocker

3.4.2. VO_2 < 14 mL/kg/min off beta-blockade

3.4.3. VO_2 < 19 mL/kg/min adjusted for lean body mass in patients with a BMI > 30 kg/m.[2]

3.4.4. Less than 50% of age predicted maximum.

3.5. A VE/VCO_2 > 35 in a patient with a submaximal cardiopulmonary exercise test (RER <1.05)[1]

3.6. Inability to wean from other mechanical or inotropic support

3.7. Refractory Life-Threatening Arrhythmias

4. Exclusion guidelines include:

4.1. Severe renal dysfunction unlikely to be reversible such as creatinine > 3.0 mg/dl (unless patient is listed for combined heart/kidney transplant).

4.2. Severe hepatic dysfunction unlikely to be reversible such as bilirubin > 5.0 mg/dl,

4.3. Infection as evidenced by ongoing fever (T > 38°C), WBC > 15,000/mm3 or positive blood cultures or specific site of infection (e.g. pneumonia, diverticulitis, pyelonephritis),

4.3. Platelet or coagulation disorder likely to compromise survival with the anticoagulation protocol required with the device,

4.4. Other conditions which would negate transplant candidacy such as peripheral or cerebral vascular disease, or cancer,

4.5. Co-morbidities, which alone may not be considered contraindications to transplantation but, taken together, may make the combination of MCS use and transplantation unreasonable or ill-advised.

5. Special Considerations:

5.1. Aortic Valve Disease Patients with mechanical prosthetic aortic valve or uncorrected valvular disease, such as severe aortic insufficiency, will require additional surgical intervention at the time of MCS implant.

5.2. Right Ventricular Dysfunction Evidence of right-sided cardiac dysfunction may indicate the need for biventricular support.

5.3. Pulmonary hypertension not reversible by drug manipulation (PVR >4-6 Wood units or transpulmonary gradient >15mmHg, despite maximum tolerated medical management) is not a contraindication to MCS implantation. Some patients may experience reversal of pulmonary hypertension with MCS implantation and may then become eligible for cardiac transplantation.

Appendix 1

INTERMACS Profiles:

1 = Critical cardiogenic shock
2 = Progressive decline on Inotropic support
3 = Inotrope dependent but stable
4 = Resting symptoms on home oral therapy
5 = Exertion intolerant

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6 = Exertion limited
7 = Advanced NYHA class III

REVISED BY CMS: AUGUST 6, 2019

ADVISORY COUNCIL APPROVED EFFECTIVE DATE: OCTOBER 24, 2019

If requesting this service, please send the following documentation to support medical necessity:

- Last 2 Cardiology/Cardiovascular Surgery consults

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Artificial Hearts

Congestive heart failure is a major health problem affecting more that five million patients in the United States. There is a wide variety of options for medical management of heart failure, but many patients eventually deteriorate and fail to respond to any of the medical therapies and require mechanical circulatory support for survival. In order to provide long-term systemic flow for patients with end-stage heart failure, the National Heart Institute established the artificial heart program in the mid 1960s with the intent to develop a totally implantable mechanical heart.

The AbioCor (Abiomed Inc, Danvers, MA, USA) is the world's first fully implantable total artificial heart. This was first implanted in 2001 at the Jewish Hospital in Louisville, KY. AbioCor is a pneumatically-driven biventricular cardiac support device designed to last at least 18 months. It is made of titanium and Angioflex, a proprietary polyurethane plastic and can produce a flow of up to 8 L/min, sufficient for moderate activity. It is divided into the implantable components and the external drive system. The implanted components consist of the thoracic unit, controller, Transcutaneous Energy Transmission system, and a battery that provides about 30 minutes of power that is designed to allow patients to conduct activities such as taking a shower without an external power source. The external drive system consists of the AbioCor console and support electronics worn or carried by the patient in a waist belt (providing power for 2-4 hours) and an RF communication system for a computer (Samuels 2003, Meyer 2011).

In September 2006, the FDA granted restricted approval of the AbioCor device through the Humanitarian Use Device (HUD) provision. A HUD is a device that the FDA determines is intended to benefit fewer than 4,000 U.S. patients per year. The FDA approval included an agreement by the manufacturer to conduct a post-marketing study, evaluating the AbioCor device in an additional 25 patients. According to the FDA, the AbioCor artificial heart is indicated for use in patients who have both ventricles failing, have end-stage heart disease, are not transplant candidates, are less than 75 years old, are not treatable by single left ventricular heart assist devices for destination therapy, and are not able to be withdrawn from heart support measures. It should not be used for patients who are eligible for a heart transplant, have only left sided heart failure, cannot be successfully treated for blood clotting disorders, or in those where the device will not fit (FDA webpage accessed November 2011).

SynCardia temporary CardioWest™ Total Artificial Heart (TAH), originally developed 30 years ago as the Jarvik TAH and later renamed the CardioWest TAH, continues to be used clinically in over 50 centers within the US and Europe. This is an implantable artificial heart intended to keep hospitalized patients alive while they are waiting for a heart transplant. It is a pulsating bi-ventricular device that is implanted into the chest to replace the patient's left and right ventricles and all four valves of the native heart. The device is sewn to the patient's remaining atria. Hospitalized patients are connected by tubes from the heart through their chest wall to a large power-generating console, which operates and monitors the device. SynCardia was approved by the FDA in 2004 for use only in the hospital as a "bridge to transplant" for patients waiting for a heart transplant who have both sides of their heart failing (biventricular heart failure), do not respond to other treatments, are at imminent risk of death, and are waiting for a donor heart. The temporary CardioWest™ TAH is should not be used in patients who are not eligible for a heart transplant, do not fit the device, cannot be adequately anticoagulated, or have left sided heart failure only (Meyer 2011, FDA Web page accessed November 2011).

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SynCardia temporary CardioWest™ Total Artificial Heart (TAH) has not been previously reviewed by MTAC; AbioCor was reviewed by MTAC in 2007 and did not meet its evaluation criteria. The technology is being reviewed due to the coverage of SynCardia temporary CardioWest™ Total Artificial Heart by other health plans as a bridge to heart transplant.

Medical Technology Assessment Committee (MTAC)

AbioCor

04/02/2007: MTAC REVIEW

Evidence Conclusion: There are no published empirical studies on the safety and efficacy of the AbioCor permanent total artificial heart. Unpublished data consists of a feasibility study with 14 patients submitted to the FDA by the device manufacturer. The 12 patients who survived the operation experienced multiple serious adverse effects; only 1 was discharged from the hospital.

Articles: The Medline search yielded 32 articles. These consisted of reviews/commentaries, several empirical studies on technical aspects of the device or device implantation, case reports and 2 case series reporting on 7 patients. The study submitted to the FDA, which included 14 patients, has not been published.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

12/19/2011: MTAC REVIEW

AbioCor

Evidence Conclusion: *AbioCor TAH* There is no new published evidence after the initial small feasibility study conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. *SynCardia temporary CardioWest™ Total Artificial Heart* The published evidence on CardioWest TAH consists of a retrospective study, and a few case series of patients receiving the device as a bridge to transplantation. Due to the eligibility criteria for the implantation, it would be unethical to conduct a randomized trial. The only valid control would be no intervention as the eligible patients for the implant are those who failed medical therapy and are not candidates for left ventricular assist device (LVAD). The results of Copeland and colleagues' case series (Evidence table 1) show that 68% of the critically ill patients who received the CardioWest implant survived to heart transplantation and hospital discharge. Adverse events included bleeding in 20% of cases and device malfunction in 5% of cases. Other complications that occurred at a lower rate included mediastinal infection, fit complications, and stroke. The cause of death was multi-organ failure in 50% of the cases, and sepsis or valve entrapment among the rest. A similar experience was observed in a French study among 42 patients. In this series 12 (28.5%) patients died while receiving device support, and 30 patients (71.5%) underwent transplantation. Actuarial survival rates for the transplanted patients were 90% (n = 25), 81% (n = 14), and 76% (n = 10) at 1, 5, and 10 years, respectively. Causes of death during device support included multi-organ failure (50%), sepsis, acute respiratory distress syndrome, and alveolar hemorrhage. There were no device malfunctions that led to patient death. Adverse events included stroke in 3 patients (7%) and infections in 35 patients (85%) during support.

Articles: The literature search for AbioCor total heart transplant did not reveal any study conducted after the initial small feasibility study (Dawling 2003) conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. The search for SynCardia CardioWest temporary TAH identified a few case series for patients who received the device as a bridge to transplantation, and a retrospective study comparing the device to left ventricular assist devices. The larger case series was selected for critical appraisal. Copeland JG, Smith RG, Arabia FA, et al. Total artificial heart bridge to transplantation: A 9-year experience with 62 patients. *J Heart Lung Transplant* 2004; 23:823-831. See Evidence Table.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of the SynCardia implantable replacement heart in the treatment of irreversible heart failure does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Background

Implanted Ventricular Assist Devices (VAD)

Heart failure is a clinical condition characterized by the heart's inability to generate a cardiac output sufficient to meet the body's circulation demands. It is a major and growing public health problem responsible for high morbidity and mortality, in addition to the economic impact of medical costs, disability, and loss of employment. According to the Heart Failure Society of America, nearly 5 million people suffer from CHF in the United States and it is responsible for about 200,000 deaths each year (Abraham 1998).

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The cause of heart failure in many patients is pump failure due to poor left ventricular systolic function, which is often due to myocardial infarction or dilated cardiomyopathy. In approximately 30% of patients with chronic heart failure, the disease process not only depresses cardiac contractility, but also affects the conduction pathways by causing a delay in the onset of right or left ventricular systole, and in turn the loss of coordination of ventricular contraction. This dyssynchronous pattern of ventricular contraction is believed to reduce the already diminished contractile reserve of the heart (Nelson 2001).
Patients in end-stage heart failure have two primary treatment options:

1. Pharmacological therapy (including digoxin, ACE inhibitors, diuretics and inotropes), and
2. Heart transplantation.

Both treatments have their limitations. Pharmacological therapy is only palliative and improves the short-term survival for patients. Moreover, as the heart failure worsens, medication becomes ineffective in treating the low contractility and pulmonary venous stasis resulting from the increased dilatation of the heart. Cardiac transplantation on the other hand, is limited to the number of available hearts, and the criteria for being a transplant candidate.

In September 1994, the FDA approved the first pneumatically driven left ventricular assist device (LVAD) from TCI for bridging end-stage patients to cardiac transplantation. Patients on these devices had to stay in the hospital connected to a pneumatic console or could go home with extensive home health care support. (FDA News 2002). Four years later, in September 1998, the FDA approved two portable heart assist devices (HeartMate and Novocar LVAS) to support patients outside the hospital while they wait for a transplant. These two devices were approved as a bridge to transplant for patients eligible for heart transplants and waiting for an available heart. Eligible patients were those with irreversible heart failure and a rapidly deteriorating condition. In addition, they had to be on their hospital's transplant list in order to qualify for one of these devices (FDA News, September 1998).

The LVAD does not replace the heart. It works along with the patient's own heart to provide additional strength to the weakened left ventricle to pump blood throughout the body. The portable device consists of a blood pump implanted in the abdominal area and attached to both the left ventricle and the aorta. Blood from the heart flows into the device which then pumps it through the aorta to the rest of the body. The system is also connected by a cable through the skin to a small external computer (the "controller") worn on the waist. The computer can be powered by a base unit that is plugged into the wall or by batteries worn at the waist or, in the case of the HeartMate device, under the arms.

There are risks associated with the surgery to implant the HeartMate, as well as risks and complications with the device itself such as infections, bleeding, thromboembolism, and stroke. Implanting the device requires a major surgery for already seriously sick patients. Moreover, the device requires a percutaneous line that can become a medium for bacterial and fungal infections that are difficult to treat and may require a change of the device, which increases the morbidity and mortality. Another complication reported by Rose et al (2000), is aortic stenosis of variable severity that may be caused by the device. LVAD may also lead to significant changes in the systemic immunologic and thrombostatic functions of the patients (Itesu S, 2000). Failure and malfunctioning of the device may also occur which may contribute to higher morbidity, mortality, and cost.

In November 2002, the FDA expanded the use of the HeartMate device to be implanted permanently in certain terminally ill patients; those who have a severe end-stage CHF, are ineligible for heart transplant, and have a body surface area >1.5 sq. m. It required that the manufacturer (Thoratec) conduct a post-approval study to assess the device's long-term safety and effectiveness for permanent use.

Percutaneous Left Ventricular Assist Device (PLVAD)
Cardiogenic shock is a state of inadequate tissue perfusion due to cardiac dysfunction. It occurs in a variety of settings such as myocardial infarction, post-cardiotomy shock, decompensated chronic heart failure, acute valve failure, and myocarditis. Despite the major advances in the treatment and aggressive perfusion strategies, cardiogenic shock is still associated with high in-hospital mortality rates that range from 40% to 80% depending on the clinical circumstances. The Intra-Aortic Balloon Pump (IABP) is the left ventricular mechanical assistance device most commonly used to stabilize patients in cardiogenic shock. It decreases afterload, increases coronary perfusion, and improves cardiac output. However, IABP pump delivers an output of only 0.5 L/min, lacks active cardiac support, does not decrease infarct size, or improve clinical outcomes of patients with acute ST-segment elevation myocardial infarction. New technologies such as percutaneous left ventricular assist devices (LVADs) have been developed to provide more effective hemodynamic short-term support for the failing heart. The three main indications for percutaneous LVAD support include: 1. Reversible left ventricular failure to provide

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temporary circulatory support until recovery or revascularization, 2. Large ischemic area at risk to provide temporary circulatory support during high-risk percutaneous or surgical revascularization, and 3. Bridging therapy to provide temporary circulatory support as a bridge to a permanent surgical assist device or heart transplantation (Burkoff 2006, Windecker 2007, Seyfarth 2008, Cheng 2009).

Currently two percutaneous LVADs are available for clinical use: The TandemHeart and the Impella Recover system. The TandemHeart utilizes a drainage cannula placed via transseptal puncture into the left atrium to aspirate oxygenated blood, which is then injected through a transfugal pump into the femoral artery, establishing a left-atrial-to-femoral arterial bypass. The Impella Recover is based on a miniaturized impeller (microaxial pump) that can be advanced into the left ventricle through an arterial vascular system. It has a caged blood flow inlet that is placed retrograde into the left ventricle to aspirate oxygenated blood, which is then injected by means of a microaxial pump into the ascending aorta establishing a left ventricular to aortic by-pass. The TandemHeart requires both venous and arterial femoral access whereas the Impella Recover system requires only femoral arterial access. Currently two Impella Recover systems are available: The Impella Recover LP 2.5 and the Impella Recover LP 5.0 models. The Impella LP 2.5 (Abiomed Europe GnbH, Aachen, Germany) is a catheter suitable for percutaneous implantation, while the Impella Recover LP 5.0 catheter requires surgical cut of the femoral artery for device insertion (Windecker 2007).

The Impella Recover LP 2.5 is a catheter-based, impeller-driven, axial -flow pump. It has a diameter of 6.4 mm at the body of the pump and 7.3 mm diameter at the level of the outflow opening. A small electric motor is built into the device, and a thin 2.8 mm cable leading to the device contains the electrical power supply, which is connected to an external control unit as well as a purge line connected to a purge perfuser. Through this perfuser, heparin (in a glucose solution) is flushed continuously in the motor housing and throughout the pump, and the patient does not need systemic anticoagulation. A pressure sensor within the device continuously monitors pressure differences between inflow and outflow. The pump is inserted percutaneously in the catheterization laboratory via a standard guidewire through the femoral artery into the left ventricle. The circulatory support provided by the device can be adjusted at nine different levels of speed. At its maximal rotation speed of 50,000 rpm, the pump can deliver an output of up to 2.5 liters of blood per minute from the left ventricle into the ascending aorta. This actively unloads the ventricle, increases the cardiac output, and increases both coronary and end-organ perfusion. The Impella pumps are indicated for temporary use (up to 6 hours) however, it has been reported that the device can be safely left in place to support hemodynamics for up to 5 days. (Seyfarth 2008, Vecchio 2008, Cheng 2009, Wiktor 2010).

Impella Recover 2.5 and 5.0 devices (ABIOMED Inc) have both received FDA clearance for circulatory support for periods up to 6 hours. The current review focuses on the use of the Impella Recover 2.5.

Medical Technology Assessment Committee (MTAC)

LVAD in the treatment of End Stage Heart Failure

08/13/2003: MTAC REVIEW

Evidence Conclusion: The REMATCH trial reviewed was conducted among a highly selected group of patients with end stage heart failure, and contraindication for heart transplantation. The trial compared the patients who received the LVAD to those who were treated medically. The methodology of the trial was generally valid; however, it was not blinded. Blinding in such a trial is not possible, and non-blinding may be a source of observation bias. The authors tried to partly overcome this limitation by using independent blinded observers to measure the outcome events. In this trial survival was higher among patients receiving LVAD vs. those in the optimum medical management group. The difference between the two groups was statistically significant, at one year (NNT=4), but not at 2 years. The two years survival among patients receiving the LVAD was only 22%, and according to the survival graph, the 26 months survival was 8%. The LVAD was associated with serious adverse events. Sepsis and device failure were responsible for the majority of deaths in the LVAD group (41.5%, and 17.1% respectively), and left ventricular dysfunction was the cause of death in 92% of the cases in the medical treatment group. The authors concluded that the quality of life was better among LVAD recipients, however the analysis of QoL was only performed among survivors who were able to complete the questionnaires (35% in the LVAD group, and 18% in the medical treatment group). In conclusion the REMATCH trial provides some evidence that LVAD may improve survival, however for a short duration, and not without serious adverse events, among a selected group of patients with and end stage heart failure, and who are not candidates for heart transplantation. It does not provide evidence that LVAD may be used as an alternative to transplantation, in patients eligible for a heart transplant.

Articles: The search yielded 32 articles many of which were reviews, opinion pieces, or dealt with the technical aspects of the procedure. One randomized controlled trial, 5 case series and several case reports were

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identified. The RCT was selected for critical appraisal. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med 2001; 345:1435-43. See Evidence Table.

The use of LVAD in the treatment of End Stage Heart Failure does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/14/2011: MTAC REVIEW
Percutaneous Cardiac Support Systems
Evidence Conclusion: The literature search revealed only one small randomized controlled trial that evaluated the safety and efficacy of the Impella Recover LP 2.5 for the treatment of cardiogenic shock caused by myocardial infarction. The trial compared the Impella device with the IABP, the most commonly used device to treat cardiogenic shock. However, the study was too small, blinding and randomization method were not discussed, and it was only powered to detect the difference between the two devices in hemodynamic improvements. It was not powered to evaluate impact on clinical outcomes. The results of the RCT (Evidence table 1) show that the Impella LP 2.5 resulted in better hemodynamic improvement compared to the IABP. However, this was not translated to an improvement in the 30-day survival of the patients in cardiogenic shock after an acute myocardial infarction.
Patients treated with the Impella device tended to have more device-related bleeding, and more limb ischemia.
Articles: The literature search identified one small randomized controlled trial that compared Impella Recover LP 2.5 device to IABP for the treatment of cardiogenic shock, a meta-analysis of RCTs comparing percutaneous LVAD to IABP for the treatment of cardiogenic shock, and three other case series evaluating the feasibility and safety of the device. The meta-analysis (Cheng 2009) pooled the results of three trials; two evaluated the TandemHeart, and the third evaluated the Impella Recover 2.5 device. The RCT that compared Impella Recover LP 2.5 device to IABP for the treatment of cardiogenic shock was selected for critical appraisal. Seyfarth M, Sibbing D, Bauer I, A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol 2008; 52:1584-1588. See Evidence Table.

The use of percutaneous cardiac support systems in the treatment of End Stage Heart Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Artificial Hearts - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)

Ventricular Assistive Devices - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and

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	interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
04/07/2020	07/07/2020 [MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/06/2021

Revision History	Description
09/08/2016 (VAD)	Added the LCA A52967
03/12/2020 (VAD)	Added statement for medical director to consult with cardiology re Impella (PLVAD) as needed
04/07/2020	MPC approved to adopt KP National coverage policy. Combined Artificial Heart and Ventricular Assistive Devices criteria. Removed deleted codes 0051T, 0052T and 0053T.
07/07/2020	Added CPT codes 33981, 33982 and 33983
07/06/2021	Coding update, added new CPT code 33995

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Ambulatory Surgery Center (ASC) - Site of Care Policy

**Benton, Kitsap, Spokane, and Whatcom counties*

Effective October 1, 2023 - ***King and Thurston Counties*

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Background

Surgery may safely be performed in various settings. Some of the common settings used are an inpatient hospital or medical center, an off-campus outpatient hospital or medical center, an on-campus outpatient hospital or medical center, an ambulatory surgical center, or a doctor's office. Costs for surgical procedures may vary among these different settings. To encourage the use of the most safe and appropriate, cost-effective sites of care for certain medically necessary outpatient surgical procedures, prior authorization is required* to ensure the appropriate site of care for the surgical procedures linked below.

We will review the site of care for medical necessity for certain elective surgical procedures. Site of care is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.*

Policy

For Non-Medicare Members

This will be implemented using a phased approach, starting with Benton, Kitsap, Spokane, and Whatcom counties.

I. Certain planned surgical procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets **ANY of the following** criteria:
   - Advanced liver disease (MELD Score > 8)
   - Advance surgical planning determines an individual requires overnight recovery and care following a surgical procedure
   - Anticipated need for transfusion
   - Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect
   - Brittle Diabetes
   - Cardiac arrhythmia (symptomatic arrhythmia despite medication)
   - Chronic obstructive pulmonary disease (COPD) (FEV1 <50%)
   - Coronary artery disease ([CAD]/peripheral vascular disease [PVD]) (ongoing cardiac ischemia requiring medical management recently placed [within 1 year] drug eluting stent)
   - Developmental stage or cognitive status warranting use of a hospital outpatient department
   - End stage renal disease ([hyperkalemia above reference range]; peritoneal or hemodialysis)
   - History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event [< 3 months])
   - History of myocardial infarction (MI) (recent event [< 3 months])

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- Individuals with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia
- Age 15 or younger
- Ongoing evidence of myocardial ischemia
- Poorly Controlled asthma (FEV1 < 80% despite medical management)
- Pregnancy
- Prolonged surgery (> 3 hours)
- Resistant hypertension (Poorly Controlled)
- Severe valvular heart disease
- Sleep apnea (moderate to severe Obstructive Sleep Apnea (OSA)
- Uncompensated chronic heart failure (CHF) (NYHA class III or IV)

II. A planned surgical procedure performed in a hospital outpatient department is considered medically necessary if there is an inability to access an ambulatory surgical center for the procedure due to **ANY one of the following**:
- There is no geographically accessible ambulatory surgical center that has the necessary equipment for the procedure; or
- There is no geographically accessible ambulatory surgical center available at which the individual's physician has privileges; or
- An ASC's specific guideline regarding the individual's weight or health conditions that prevents the use of an ASC

When an elective surgery is requested at an inpatient hospital/medical center, this site may be considered medically necessary only when the patient has clinical conditions that places him or her at risk of complications. Examples include:
- Anesthesia risk
- Cardiovascular, liver, pulmonary, or renal risk
- Morbid obesity
- Pregnancy
- Bleeding disorder
- Anticipated need for transfusions

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific contract and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Gastroenterology: (**Benton, Kitsap, Spokane, Whatcom counties* **AND** ***King, and Thurston counties)*

Effective October 1, 2023

CPT® or HCPC Codes	Description
43191	Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)
43202	Esophagoscopy, flexible, transoral; with biopsy, single or multiple
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance

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43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43450	Dilation of esophagus, by unguided sound or bougie, single or multiple passes
43453	Dilation of esophagus, over guide wire
44360	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
44361	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with biopsy, single or multiple
44376	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)
44377	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with biopsy, single or multiple
44382	Ileoscopy, through stoma; with biopsy, single or multiple
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
44389	Colonoscopy through stoma; with biopsy, single or multiple
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45100	Biopsy of anorectal wall, anal approach (eg, congenital megacolon)
45171	Excision of rectal tumor, transanal approach; not including muscularis propria (ie, partial thickness)
45172	Excision of rectal tumor, transanal approach; including muscularis propria (ie, full thickness)
45190	Destruction of rectal tumor (eg, electrodesiccation, electrosurgery, laser ablation, laser resection, cryosurgery) transanal approach
45305	Proctosigmoidoscopy, rigid; with biopsy, single or multiple
45334	Sigmoidoscopy, flexible; with control of bleeding, any method
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance
45340	Sigmoidoscopy, flexible; with transendoscopic balloon dilation
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s)

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45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45379	Colonoscopy, flexible; with removal of foreign body(s)
45380	Colonoscopy, flexible; with biopsy, single or multiple
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance
45382	Colonoscopy, flexible; with control of bleeding, any method
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45386	Colonoscopy, flexible; with transendoscopic balloon dilation
45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
45390	Colonoscopy, flexible; with endoscopic mucosal resection
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures
45392	Colonoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)
G0105	Colorectal cancer screening; colonoscopy on individual at high risk
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk

General Surgery: *(*Benton, Kitsap, Spokane, and Whatcom counties)*

CPT® or HCPC Codes	Description
19000	Puncture aspiration of cyst of breast;
19001	Puncture aspiration of cyst of breast; each additional cyst (List separately in addition to code for primary procedure)
19020	Mastotomy with exploration or drainage of abscess, deep
19030	Injection procedure only for mammary ductogram or galactogram
19100	Biopsy of breast; percutaneous, needle core, not using imaging guidance (separate procedure)
19101	Biopsy of breast; open, incisional
19110	Nipple exploration, with or without excision of a solitary lactiferous duct or a papilloma lactiferous duct
19112	Excision of lactiferous duct fistula
19120	Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion (except 19300), open, male or female, 1 or more lesions
19125	Excision of breast lesion identified by preoperative placement of radiological marker, open; single lesion
19126	Excision of breast lesion identified by preoperative placement of radiological marker, open; each additional lesion separately identified by a preoperative radiological marker (List separately in addition to code for primary procedure)
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19303	Mastectomy, simple, complete
38520	Biopsy or excision of lymph node(s); open, deep cervical node(s) with excision scalene fat pad
38525	Biopsy or excision of lymph node(s); open, deep axillary node(s)
38530	Biopsy or excision of lymph node(s); open, internal mammary node(s)
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)
45500	Proctoplasty; for stenosis
45505	Proctoplasty; for prolapse of mucous membrane

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45520	Perirectal injection of sclerosing solution for prolapse
45541	Proctopexy (e.g., for prolapse); perineal approach
45560	Repair of rectocele (separate procedure)
45900	Reduction of procidentia (separate procedure) under anesthesia
45905	Dilation of anal sphincter (separate procedure) under anesthesia other than local
45910	Dilation of rectal stricture (separate procedure) under anesthesia other than local
45915	Removal of fecal impaction or foreign body (separate procedure) under anesthesia
45990	Anorectal exam, surgical, requiring anesthesia (general, spinal, or epidural), diagnostic
46020	Placement of seton
46030	Removal of anal seton, other marker
46040	Incision and drainage of ischiorectal and/or perirectal abscess (separate procedure)
46045	Incision and drainage of intramural, intramuscular, or submucosal abscess, transanal, under anesthesia
46050	Incision and drainage, perianal abscess, superficial
46060	Incision and drainage of ischiorectal or intramural abscess, with fistulectomy or fistulotomy, submuscular, with or without placement of seton
46080	Sphincterotomy, anal, division of sphincter (separate procedure)
46083	Incision of thrombosed hemorrhoid, external
46200	Fissurectomy, including sphincterotomy, when performed
46220	Excision of single external papilla or tag, anus
46221	Hemorrhoidectomy, internal, by rubber band ligation(s)
46230	Excision of multiple external papillae or tags, anus
46250	Hemorrhoidectomy, external, 2 or more columns/groups
46255	Hemorrhoidectomy, internal and external, single column/group
46257	Hemorrhoidectomy, internal and external, single column/group; with fissurectomy
46258	Hemorrhoidectomy, internal and external, single column/group; with fistulectomy, including fissurectomy, when performed
46260	Hemorrhoidectomy, internal and external, 2 or more columns/groups;
46261	Hemorrhoidectomy, internal and external, 2 or more columns/groups; with fissurectomy
46262	Hemorrhoidectomy, internal and external, 2 or more columns/groups; with fistulectomy, including fissurectomy, when performed
46270	Surgical treatment of anal fistula (fistulectomy/fistulotomy); subcutaneous
46275	Surgical treatment of anal fistula (fistulectomy/fistulotomy); inter-sphincteric
46280	Surgical treatment of anal fistula (fistulectomy/fistulotomy); trans sphincteric, suprasphincteric, extra sphincteric or multiple, including placement of seton, when performed
46285	Surgical treatment of anal fistula (fistulectomy/fistulotomy); second stage
46288	Closure of anal fistula with rectal advancement flap
46320	Excision of thrombosed hemorrhoid, external
46505	Chemodenervation of internal anal sphincter
46706	Repair of anal fistula with fibrin glue
46707	Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS])
46750	Sphincteroplasty, anal, for incontinence or prolapse; adult
46753	Graft (Thiersch operation) for rectal incontinence and/or prolapse
46754	Removal of Thiersch wire or suture, anal canal
46760	Sphincteroplasty, anal, for incontinence, adult; muscle transplant
46761	Sphincteroplasty, anal, for incontinence, adult; levator muscle imbrication (Park posterior anal repair)
46900	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; chemical
46910	Destruction of lesion(s), anus (e.g., condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; electrodesiccation
46916	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; cryosurgery
46917	Destruction of lesion(s), anus (e.g., condyloma, papilloma, molluscum contagiosum, herpetic

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	vesicle), simple; laser surgery
46922	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; surgical excision
46924	Destruction of lesion(s), anus (e.g., condyloma, papilloma, molluscum contagiosum, herpetic vesicle), extensive (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery)
46930	Destruction of internal hemorrhoid(s) by thermal energy (e.g., infrared coagulation, cautery, radiofrequency)
46940*	Curettage or cautery of anal fissure, including dilation of anal sphincter (separate procedure); initial
46942	Curettage or cautery of anal fissure, including dilation of anal sphincter (separate procedure); subsequent
46945	Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group
46946	Hemorrhoidectomy, internal, by ligation other than rubber band; 2 or more hemorrhoid columns/groups
46947	Hemorrhoidopexy (e.g., for prolapsing internal hemorrhoids) by stapling
46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed
47562	Laparoscopy, surgical; cholecystectomy
47563	Laparoscopy, surgical; cholecystectomy with cholangiography
47564	Laparoscopy, surgical; cholecystectomy with exploration of common duct
49505	Repair initial inguinal hernia, age 5 years or older; reducible
49507	Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated
49520	Repair recurrent inguinal hernia, any age; reducible
49521	Repair recurrent inguinal hernia, any age; incarcerated or strangulated
49525	Repair inguinal hernia, sliding, any age
49550	Repair initial femoral hernia, any age; reducible
49553	Repair initial femoral hernia, any age; incarcerated or strangulated
49555	Repair recurrent femoral hernia; reducible
49557	Repair recurrent femoral hernia; incarcerated or strangulated
49560	Repair initial incisional or ventral hernia; reducible
49561	Laparoscopy, surgical; repair recurrent inguinal hernia
49565	Repair recurrent incisional or ventral hernia; reducible
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated
49568	Implantation of mesh or other prosthesis for open incisional or ventral hernia repair or mesh for closure of debridement for necrotizing soft tissue infection (List separately in addition to code for the incisional or ventral hernia repair)
49570	Repair epigastric hernia (e.g., preperitoneal fat); reducible (separate procedure)
49572	Repair epigastric hernia (e.g., preperitoneal fat); incarcerated or strangulated
49585	Repair umbilical hernia, age 5 years or older; reducible
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated
49590	Repair spigelian hernia
49591	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible
49593	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible
49595	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible
49613	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible
49615	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other

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	prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible
49623	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic) (List separately in addition to code for primary procedure)
49650	Laparoscopy, surgical; repair initial inguinal hernia
49651	Laparoscopy, surgical; repair recurrent inguinal hernia
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated
49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible
49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated

Plastic surgery: *(*Benton, Kitsap, Spokane, and Whatcom counties)*

CPT® or HCPC Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14020	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10 sq cm or less
14021	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10.1 sq cm to 30.0 sq cm
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
14061	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
14302	Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
14350	Filleted finger or toe flap, including preparation of recipient site
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy

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19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)

Orthopedics/Podiatry: *(*Benton, Kitsap, Spokane, and Whatcom counties)*

CPT® or HCPC Codes	Description
20200	Biopsy, muscle; superficial
20205	Biopsy, muscle; deep
20206	Biopsy, muscle, percutaneous needle
20220	Biopsy, bone, trocar, or needle; superficial (e.g., ilium, sternum, spinous process, ribs)
20225	Biopsy, bone, trocar, or needle; deep (e.g., vertebral body, femur)
20240	Biopsy, bone, open; superficial (e.g., sternum, spinous process, rib, patella, olecranon process, calcaneus, tarsal, metatarsal, carpal, metacarpal, phalanx)
20245	Biopsy, bone, open; deep (e.g., humeral shaft, ischium, femoral shaft)
20924	Tendon graft, from a distance (eg, palmaris, toe extensor, plantaris)
23130	Acromioplasty or acromionectomy, partial, with or without coracoacromial ligament release
23140	Excision or curettage of bone cyst or benign tumor of clavicle or scapula
23145	Excision or curettage of bone cyst or benign tumor of clavicle or scapula; with autograft (includes obtaining graft)
23150	Excision or curettage of bone cyst or benign tumor of proximal humerus
23155	Excision or curettage of bone cyst or benign tumor of proximal humerus; with autograft (includes obtaining graft)
23156	Excision or curettage of bone cyst or benign tumor of proximal humerus; with allograft
23405	Tenotomy, shoulder area; single tendon
23406	Tenotomy, shoulder area; multiple tendons through same incision
23410	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; acute
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic
23415	Coracoacromial ligament release, with or without acromioplasty
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)
23430	Tenodesis of long tendon of biceps
23440	Resection or transplantation of long tendon of biceps
23450	Capsulorrhaphy, anterior; Putti-Platt procedure or Magnuson type operation
23455	Capsulorrhaphy, anterior; with labral repair (eg, Bankart procedure)
23460	Capsulorrhaphy, anterior, any type; with bone block
23462	Capsulorrhaphy, anterior, any type; with coracoid process transfer
23465	Capsulorrhaphy, glenohumeral joint, posterior, with or without bone block
23466	Capsulorrhaphy, glenohumeral joint, any type multi-directional instability
23480	Osteotomy, clavicle, with or without internal fixation
23485	Osteotomy, clavicle, with or without internal fixation; with bone graft for nonunion or malunion (includes obtaining graft and/or necessary fixation)
23700	Manipulation under anesthesia, shoulder joint, including application of fixation apparatus (dislocation excluded)
23930	Incision and drainage, upper arm or elbow area; deep abscess or hematoma
23931	Incision and drainage, upper arm or elbow area; bursa
23935	Incision, deep, with opening of bone cortex (eg, for osteomyelitis or bone abscess), humerus or elbow
24000	Arthrotomy, elbow, including exploration, drainage, or removal of foreign body
24006	Arthrotomy of the elbow, with capsular excision for capsular release (separate procedure)

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24100	Arthrotomy, elbow; with synovial biopsy only
24101	Arthrotomy, elbow; with joint exploration, with or without biopsy, with or without removal of loose or foreign body
24102	Arthrotomy, elbow; with synovectomy
24105	Excision, olecranon bursa
24110	Excision or curettage of bone cyst or benign tumor, humerus
24115	Excision or curettage of bone cyst or benign tumor, humerus; with autograft (includes obtaining graft)
24116	Excision or curettage of bone cyst or benign tumor, humerus; with allograft
24120	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process
24125	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with autograft (includes obtaining graft)
24126	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with allograft
24130	Excision, radial head
24134	Sequestrectomy (eg, for osteomyelitis or bone abscess), shaft or distal humerus
24136	Sequestrectomy (eg, for osteomyelitis or bone abscess), radial head or neck
24138	Sequestrectomy (eg, for osteomyelitis or bone abscess), olecranon process
24140	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), humerus
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), radial head or neck
24147	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), olecranon process
24149	Radical resection of capsule, soft tissue, and heterotopic bone, elbow, with contracture release (separate procedure)
24150	Radical resection of tumor, shaft or distal humerus
24152	Radical resection of tumor, radial head or neck
24155	Resection of elbow joint (arthrectomy)
24160	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and ulnar components
24164	Removal of prosthesis, includes debridement and synovectomy when performed; radial head
24200	Removal of foreign body, upper arm or elbow area; subcutaneous
24201	Removal of foreign body, upper arm or elbow area; deep (subfascial or intramuscular)
24220	Injection procedure for elbow arthrography
24300	Manipulation, elbow, under anesthesia
24301	Muscle or tendon transfer, any type, upper arm or elbow, single (excluding 24320-24331)
24305	Tendon lengthening, upper arm or elbow, each tendon
24310	Tenotomy, open, elbow to shoulder, each tendon
24330	Flexor-plasty, elbow (eg, Steindler type advancement);
24331	Flexor-plasty, elbow (eg, Steindler type advancement); with extensor advancement
24332	Tenolysis, triceps
24340	Tenodesis of biceps tendon at elbow (separate procedure)
24341	Repair, tendon or muscle, upper arm or elbow, each tendon or muscle, primary or secondary (excludes rotator cuff)
24342	Reinsertion of ruptured biceps or triceps tendon, distal, with or without tendon graft
24343	Repair lateral collateral ligament, elbow, with local tissue
24344	Reconstruction lateral collateral ligament, elbow, with tendon graft (includes harvesting of graft)
24345	Repair medial collateral ligament, elbow, with local tissue
24346	Reconstruction medial collateral ligament, elbow, with tendon graft (includes harvesting of graft)
24357	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); percutaneous
24358	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open
24359	Tenotomy, elbow, lateral or medial (eg, epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open with tendon repair or reattachment

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24360	Arthroplasty, elbow; with membrane (eg, fascial)
24361	Arthroplasty, elbow; with distal humeral prosthetic replacement
24362	Arthroplasty, elbow; with implant and fascia lata ligament reconstruction
24363	Arthroplasty, elbow; with distal humerus and proximal ulnar prosthetic replacement (eg, total elbow)
24365	Arthroplasty, radial head;
24366	Arthroplasty, radial head; with implant
24370	Revision of total elbow arthroplasty, including allograft when performed; humeral or ulnar component
24371	Revision of total elbow arthroplasty, including allograft when performed; humeral and ulnar component
24400	Osteotomy, humerus, with or without internal fixation
24410	Multiple osteotomies with realignment on intramedullary rod, humeral shaft (Sofield type procedure)
24420	Osteoplasty, humerus (eg, shortening or lengthening) (excluding 64876)
24430	Repair of nonunion or malunion, humerus; without graft (eg, compression technique)
24435	Repair of nonunion or malunion, humerus; with iliac or other autograft (includes obtaining graft)
24470	Hemiepiphyseal arrest (eg, cubitus varus or valgus, distal humerus)
24495	Decompression fasciotomy, forearm, with brachial artery exploration
24498	Prophylactic treatment (nailing, pinning, plating or wiring), with or without methylmethacrylate, humeral shaft
25000	Incision, extensor tendon sheath, wrist (eg, deQuervains disease)
25001	Incision, flexor tendon sheath, wrist (eg, flexor carpi radialis)
25085	Capsulotomy, wrist (e.g., contracture)
25100	Arthrotomy, wrist joint; with biopsy
25101	Arthrotomy, wrist joint; with joint exploration, with or without biopsy, with or without removal of loose or foreign body
25105	Arthrotomy, wrist joint; with synovectomy
25107	Arthrotomy, distal radioulnar joint including repair of triangular cartilage, complex
25109	Excision of tendon, forearm and/or wrist, flexor or extensor, each
25110	Excision, lesion of tendon sheath, forearm and/or wrist
25111	Excision, lesion of tendon sheath, forearm and/or wrist
25112	Excision of ganglion, wrist (dorsal or volar); recurrent
25115	Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); flexors
25116	Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); extensors, with or without transposition of dorsal retinaculum
25118	Synovectomy, extensor tendon sheath, wrist, single compartment
25119	Synovectomy, extensor tendon sheath, wrist, single compartment; with resection of distal ulna
25120	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process)
25125	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with autograft (includes obtaining graft)
25126	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with allograft
25130	Excision or curettage of bone cyst or benign tumor of carpal bones
25135	Excision or curettage of bone cyst or benign tumor of carpal bones; with autograft (includes obtaining graft)
25136	Excision or curettage of bone cyst or benign tumor of carpal bones; with allograft
25150	Partial excision (craterization, saucerization, or diaphysectomy) of bone (eg, for osteomyelitis); ulna
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); radius
25210	Carpectomy; 1 bone

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25215	Carpectomy; all bones of proximal row
25230	Radial styloidectomy (separate procedure)
25240	Excision distal ulna partial or complete (e.g., Darrach type or matched resection)
25260	Repair, tendon or muscle, flexor, forearm and/or wrist; primary, single, each tendon or muscle
25263	Repair, tendon or muscle, flexor, forearm and/or wrist; secondary, single, each tendon or muscle
25265	Repair, tendon or muscle, flexor, forearm and/or wrist; secondary, with free graft (includes obtaining graft), each tendon or muscle
25270	Repair, tendon or muscle, extensor, forearm and/or wrist; primary, single, each tendon or muscle
25272	Repair, tendon or muscle, extensor, forearm and/or wrist; secondary, single, each tendon or muscle
25274	Repair, tendon or muscle, extensor, forearm and/or wrist; secondary, with free graft (includes obtaining graft), each tendon or muscle
25275	Repair, tendon sheath, extensor, forearm and/or wrist, with free graft (includes obtaining graft) (e.g., for extensor carpi ulnaris subluxation)
25280	Lengthening or shortening of flexor or extensor tendon, forearm and/or wrist, single, each tendon
25290	Tenotomy, open, flexor or extensor tendon, forearm and/or wrist, single, each tendon
25295	Tenolysis, flexor or extensor tendon, forearm and/or wrist, single, each tendon
25300	Tenodesis at wrist; flexors of fingers
25301	Tenodesis at wrist; extensors of fingers
25310	Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); extensors, with or without transposition of dorsal retinaculum
25312	Tendon transplantation or transfer, flexor or extensor, forearm and/or wrist, single; with tendon graft(s) (includes obtaining graft), each tendon
25315	Flexor origin slide (eg, for cerebral palsy, Volkmann contracture), forearm and/or wrist;
25316	Flexor origin slide (eg, for cerebral palsy, Volkmann contracture), forearm and/or wrist; with tendon(s) transfer
25320	Capsulorrhaphy or reconstruction, wrist, open (eg, capsulodesis, ligament repair, tendon transfer or graft) (includes synovectomy, capsulotomy and open reduction) for carpal instability
25332	Arthroplasty, wrist, with or without interposition, with or without external or internal fixation
25335	Centralization of wrist on ulna (eg, radial club hand)
25337	Reconstruction for stabilization of unstable distal ulna or distal radioulnar joint, secondary by soft tissue stabilization (eg, tendon transfer, tendon graft or weave, or tenodesis) with or without open reduction of distal radioulnar joint
25350	Osteotomy, radius; distal third
25355	Osteotomy, radius; middle or proximal third
25360	Osteotomy; ulna
25365	Osteotomy; radius AND ulna
25370	Multiple osteotomies, with realignment on intramedullary rod (Sofield type procedure); radius OR ulna
25375	Multiple osteotomies, with realignment on intramedullary rod (Sofield type procedure); radius AND ulna
25390	Osteoplasty, radius OR ulna; shortening
25391	Osteoplasty, radius OR ulna; lengthening with autograft
25392	Osteoplasty, radius AND ulna; shortening (excluding 64876)
25393	Osteoplasty, radius AND ulna; lengthening with autograft
25394	Osteoplasty, carpal bone, shortening
25400	Repair of nonunion or malunion, radius OR ulna; without graft (eg, compression technique)
25405	Repair of nonunion or malunion, radius OR ulna; with autograft (includes obtaining graft)
25415	Repair of nonunion or malunion, radius AND ulna; without graft (eg, compression technique)
25420	Repair of nonunion or malunion, radius AND ulna; with autograft (includes obtaining graft)
25430	Insertion of vascular pedicle into carpal bone (eg, Hori procedure)
25431	Repair of nonunion of carpal bone (excluding carpal scaphoid (navicular)) (includes obtaining graft and necessary fixation), each bone

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25440	Repair of nonunion, scaphoid carpal (navicular) bone, with or without radial styloidectomy (includes obtaining graft and necessary fixation)
25441	Arthroplasty with prosthetic replacement; distal radius
25442	Arthroplasty with prosthetic replacement; distal ulna
25443	Arthroplasty with prosthetic replacement; scaphoid carpal (navicular)
25444	Arthroplasty with prosthetic replacement; lunate
25445	Arthroplasty with prosthetic replacement; trapezium
25446	Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)
25447	Arthroplasty, interposition, intercarpal or carpometacarpal joints
25449	Revision of arthroplasty, including removal of implant, wrist joint
25450	Epiphyseal arrest by epiphysiodesis or stapling; distal radius OR ulna
25455	Epiphyseal arrest by epiphysiodesis or stapling; distal radius AND ulna
25800	Arthrodesis, wrist; complete, without bone graft (includes radiocarpal and/or intercarpal and/or carpometacarpal joints)
25805	Arthrodesis, wrist; with sliding graft
25810	Arthrodesis, wrist; with iliac or other autograft (includes obtaining graft)
25820	Arthrodesis, wrist; limited, without bone graft (eg, intercarpal or radiocarpal)
25825	Arthrodesis, wrist; with autograft (includes obtaining graft)
25830	Arthrodesis, distal radioulnar joint with segmental resection of ulna, with or without bone graft (eg, Sauve-Kapandji procedure)
26010	Drainage of finger abscess; simple
26011	Drainage of finger abscess; complicated (e.g., felon)
26020	Drainage of tendon sheath, digit and/or palm, each
26040	Fasciotomy, palmar (eg, Dupuytren's contracture); percutaneous
26045	Fasciotomy, palmar (e.g., Dupuytren's contracture); open, partial
26055	Tendon sheath incision (eg, for trigger finger)
26070	Arthrotomy, with exploration, drainage, or removal of loose or foreign body; carpometacarpal joint
26075	Arthrotomy, with exploration, drainage, or removal of loose or foreign body; metacarpophalangeal joint, each
26080	Arthrotomy, with exploration, drainage, or removal of loose or foreign body; interphalangeal joint, each
26100	Arthrotomy with biopsy; carpometacarpal joint, each
26105	Arthrotomy with biopsy; metacarpophalangeal joint, each
26110	Arthrotomy with biopsy; interphalangeal joint, each
26111	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; 1.5 cm or greater
26113	Excision, tumor, soft tissue, or vascular malformation, of hand or finger, subfascial (e.g., intramuscular); 1.5 cm or greater
26115	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm
26116	Excision, tumor, soft tissue, or vascular malformation, of hand or finger, subfascial (e.g., intramuscular); less than 1.5 cm
26117	Radical resection of tumor (eg, sarcoma), soft tissue of hand or finger; less than 3 cm
26118	Radical resection of tumor (eg, sarcoma), soft tissue of hand or finger; 3 cm or greater
26121	Fasciectomy, palm only, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft)
26123	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft)
26125	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft); each additional digit (List separately in addition to code for primary procedure)
26160	Excision of lesion of tendon sheath or joint capsule (eg, cyst, mucous cyst, or ganglion), hand or finger
26170	Excision of tendon, palm, flexor or extensor, single, each tendon
26180	Excision of tendon, finger, flexor or extensor, each tendon

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26200	Excision or curettage of bone cyst or benign tumor of metacarpal
26205	Excision or curettage of bone cyst or benign tumor of metacarpal; with autograft (includes obtaining graft)
26210	Excision or curettage of bone cyst or benign tumor of proximal, middle, or distal phalanx of finger
26215	Excision or curettage of bone cyst or benign tumor of proximal, middle, or distal phalanx of finger; with autograft (includes obtaining graft)
26230	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis); metacarpal
26235	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis); proximal or middle phalanx of finger
26236	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); distal phalanx of finger
26320	Removal of implant from finger or hand
26350	Repair or advancement, flexor tendon, not in zone 2 digital flexor tendon sheath (eg, no man's land); primary or secondary without free graft, each tendon
26352	Repair or advancement, flexor tendon, not in zone 2 digital flexor tendon sheath (eg, no man's land); secondary with free graft (includes obtaining graft), each tendon
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); primary, without free graft, each tendon
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); secondary, without free graft, each tendon
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, with free graft (includes obtaining graft), each tendon
26370	Repair or advancement of profundus tendon, with intact superficialis tendon; primary, each tendon
26372	Repair or advancement of profundus tendon, with intact superficialis tendon; secondary with free graft (includes obtaining graft), each tendon
26373	Repair or advancement of profundus tendon, with intact superficialis tendon; secondary without free graft, each tendon
26392	Removal of synthetic rod and insertion of flexor tendon graft, hand or finger (includes obtaining graft), each rod
26410	Repair, extensor tendon, hand, primary or secondary; without free graft, each tendon
26412	Repair, extensor tendon, hand, primary or secondary; with free graft (includes obtaining graft), each tendon
26418	Repair, extensor tendon, finger, primary or secondary; without free graft, each tendon
26420	Repair, extensor tendon, finger, primary or secondary; with free graft (includes obtaining graft) each tendon
26426	Repair of extensor tendon, central slip, secondary (e.g., boutonniere deformity); using local tissue(s), including lateral band(s), each finger
26428	Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); with free graft (includes obtaining graft), each finger
26432	Closed treatment of distal extensor tendon insertion, with or without percutaneous pinning (e.g., mallet finger)
26433	Repair of extensor tendon, distal insertion, primary or secondary; without graft (e.g., mallet finger)
26434	Repair of extensor tendon, distal insertion, primary or secondary; with free graft (includes obtaining graft)
26437	Realignment of extensor tendon, hand, each tendon
26440	Tenolysis, flexor tendon; palm or finger, each tendon
26442	Tenolysis, flexor tendon; palm and finger, each tendon
26445	Tenolysis, extensor tendon, hand or finger, each tendon
26449	Tenolysis, complex, extensor tendon, finger, including forearm, each tendon
26450	Tenotomy, flexor, palm, open, each tendon
26455	Tenotomy, flexor, finger, open, each tendon
26460	Tenotomy, extensor, hand or finger, open, each tendon
26480	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without free graft, each tendon
26483	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; with free tendon graft

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	(includes obtaining graft), each tendon
26485	Transfer or transplant of tendon, palmar; without free tendon graft, each tendon
26489	Transfer or transplant of tendon, palmar; with free tendon graft (includes obtaining graft), each tendon
26500	Reconstruction of tendon pulley, each tendon; with local tissues (separate procedure)
26502	Reconstruction of tendon pulley, each tendon; with tendon or fascial graft (includes obtaining graft) (separate procedure)
26516	Capsulodesis, metacarpophalangeal joint; single digit
26517	Capsulodesis, metacarpophalangeal joint; 2 digits
26518	Capsulodesis, metacarpophalangeal joint; 3 or 4 digits
26520	Capsulectomy or capsulotomy; metacarpophalangeal joint, each joint
26525	Capsulectomy or capsulotomy; interphalangeal joint, each joint
26540	Repair of collateral ligament, metacarpophalangeal or interphalangeal joint
26541	Reconstruction, collateral ligament, metacarpophalangeal joint, single; with tendon or fascial graft (includes obtaining graft)
26542	Reconstruction, collateral ligament, metacarpophalangeal joint, single; with local tissue (e.g., adductor advancement)
26545	Reconstruction, collateral ligament, interphalangeal joint, single, including graft, each joint
26565	Osteotomy; metacarpal, each
26567	Osteotomy; phalanx of finger, each
26587	Reconstruction of polydactylous digit, soft tissue and bone
26590	Repair macrodactylia, each digit
26591	Repair, intrinsic muscles of hand, each muscle
26593	Release, intrinsic muscles of hand, each muscle
26596	Excision of constricting ring of finger, with multiple Z-plasties
26600	Closed treatment of metacarpal fracture, single; without manipulation, each bone
26605	Closed treatment of metacarpal fracture, single; with manipulation, each bone
26607	Closed treatment of metacarpal fracture, with manipulation, with external fixation, each bone
26608	Percutaneous skeletal fixation of metacarpal fracture, each bone
26615	Open treatment of metacarpal fracture, single, includes internal fixation, when performed, each bone
26641	Closed treatment of carpometacarpal dislocation, thumb, with manipulation
26645	Closed treatment of carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation
26650	Percutaneous skeletal fixation of carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation
26665	Open treatment of carpometacarpal fracture dislocation, thumb (Bennett fracture), includes internal fixation, when performed
26670	Closed treatment of carpometacarpal dislocation, other than thumb, with manipulation, each joint; without anesthesia
26675	Closed treatment of carpometacarpal dislocation, other than thumb, with manipulation, each joint; requiring anesthesia
26676	Percutaneous skeletal fixation of carpometacarpal dislocation, other than thumb, with manipulation, each joint
26685	Open treatment of carpometacarpal dislocation, other than thumb; includes internal fixation, when performed, each joint
26686	Open treatment of carpometacarpal dislocation, other than thumb; complex, multiple, or delayed reduction
26700	Closed treatment of metacarpophalangeal dislocation, single, with manipulation; without anesthesia
26705	Closed treatment of metacarpophalangeal dislocation, single, with manipulation; requiring anesthesia
26706	Percutaneous skeletal fixation of metacarpophalangeal dislocation, single, with manipulation
26715	Open treatment of metacarpophalangeal dislocation, single, includes internal fixation, when performed

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26720	Closed treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb; without manipulation, each
26725	Closed treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb; with manipulation, with or without skin or skeletal traction, each
26727	Percutaneous skeletal fixation of unstable phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with manipulation, each
26735	Open treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, includes internal fixation, when performed, each
26740	Closed treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint; without manipulation, each
26742	Closed treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint; with manipulation, each
26746	Open treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint, includes internal fixation, when performed, each
26750	Closed treatment of distal phalangeal fracture, finger or thumb; without manipulation, each
26755	Closed treatment of distal phalangeal fracture, finger or thumb; with manipulation, each
26756	Percutaneous skeletal fixation of distal phalangeal fracture, finger or thumb, each
26765	Open treatment of distal phalangeal fracture, finger or thumb, includes internal fixation, when performed, each
26770	Closed treatment of interphalangeal joint dislocation, single, with manipulation; without anesthesia
26775	Closed treatment of interphalangeal joint dislocation, single, with manipulation; requiring anesthesia
26776	Percutaneous skeletal fixation of interphalangeal joint dislocation, single, with manipulation
26785	Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed, single
26841	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation
26842	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation; with autograft (includes obtaining graft)
26843	Arthrodesis, carpometacarpal joint, digit, other than thumb, each;
26844	Arthrodesis, carpometacarpal joint, digit, other than thumb, each; with autograft (includes obtaining graft)
26850	Arthrodesis, metacarpophalangeal joint, with or without internal fixation
26852	Arthrodesis, metacarpophalangeal joint, with or without internal fixation; with autograft (includes obtaining graft)
26860	Arthrodesis, interphalangeal joint, with or without internal fixation
26861	Arthrodesis, interphalangeal joint, with or without internal fixation; each additional interphalangeal joint (List separately in addition to code for primary procedure)
26862	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft)
26863	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft), each additional joint (List separately in addition to code for primary procedure)
26910	Amputation, metacarpal, with finger or thumb (ray amputation), single, with or without interosseous transfer
26951	Amputation, finger or thumb, primary or secondary, any joint or phalanx, single, including neurectomies; with direct closure
26952	Amputation, finger or thumb, primary or secondary, any joint or phalanx, single, including neurectomies; with local advancement flaps (V-Y, hood)
27301	Incision and drainage, deep abscess, bursa, or hematoma, thigh or knee region
27310	Arthrotomy, knee, with exploration, drainage, or removal of foreign body (e.g., infection)
27323	Biopsy, soft tissue of thigh or knee area; superficial
27324	Biopsy, soft tissue of thigh or knee area; deep (subfascial or intramuscular)
27330	Arthrotomy, knee; with synovial biopsy only
27331	Arthrotomy, knee; including joint exploration, biopsy, or removal of loose or foreign bodies
27332	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial or lateral
27333	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial AND lateral
27334	Arthrotomy, with synovectomy, knee; anterior or posterior

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27335	Arthrotomy, with synovectomy, knee; anterior and posterior including popliteal area
27340	Excision, prepatellar bursa
27345	Excision of synovial cyst of popliteal space (e.g., Baker's cyst)
27347	Excision of lesion of meniscus or capsule (e.g., cyst, ganglion), knee
27350	Patellectomy or hemipatellectomy
27372	Removal of foreign body, deep, thigh region or knee area
27380	Suture of infrapatellar tendon; primary
27381	Suture of infrapatellar tendon; secondary reconstruction, including fascial or tendon graft
27385	Suture of quadriceps or hamstring muscle rupture; primary
27386	Suture of quadriceps or hamstring muscle rupture; secondary reconstruction, including fascial or tendon graft
27403	Arthrotomy with meniscus repair, knee
27405	Repair, primary, torn ligament and/or capsule, knee; collateral
27407	Repair, primary, torn ligament and/or capsule, knee; cruciate
27409	Repair, primary, torn ligament and/or capsule, knee; collateral and cruciate ligaments
27418	Anterior tibial tubercleplasty (e.g., Maquet type procedure)
27420	Reconstruction of dislocating patella; (eg, Hauser type procedure)
27422	Reconstruction of dislocating patella; with extensor realignment and/or muscle advancement or release (eg, Campbell, Goldwaite type procedure)
27424	Reconstruction of dislocating patella; with patellectomy
27427	Ligamentous reconstruction (augmentation), knee; extra-articular
27428	Ligamentous reconstruction (augmentation), knee; intra-articular (open)
27429	Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular
27570	Manipulation of knee joint under general anesthesia (includes application of traction or other fixation devices)
27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia
27606	Tenotomy, percutaneous, Achilles tendon (separate procedure); general anesthesia
27610	Arthrotomy, ankle, including exploration, drainage, or removal of foreign body
27612	Arthrotomy, posterior capsular release, ankle, with or without Achilles tendon lengthening
27620	Arthrotomy, ankle, with joint exploration, with or without biopsy, with or without removal of loose or foreign body
27625	Arthrotomy, with synovectomy, ankle;
27626	Arthrotomy, with synovectomy, ankle; including tenosynovectomy
27630	Excision of lesion of tendon sheath or capsule (eg, cyst or ganglion), leg and/or ankle
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon;
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)
27654	Repair, secondary, Achilles tendon, with or without graft
27656	Repair, fascial defect of leg
27658	Repair, flexor tendon, leg; primary, without graft, each tendon
27659	Repair, flexor tendon, leg; secondary, with or without graft, each tendon
27664	Repair, extensor tendon, leg; primary, without graft, each tendon
27665	Repair, extensor tendon, leg; secondary, with or without graft, each tendon
27675	Repair, dislocating peroneal tendons; without fibular osteotomy
27676	Repair, dislocating peroneal tendons; with fibular osteotomy
27680	Tenolysis, flexor or extensor tendon, leg and/or ankle; single, each tendon
27681	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision[s])
27685	Lengthening or shortening of tendon, leg or ankle; single tendon (separate procedure)
27686	Lengthening or shortening of tendon, leg or ankle; multiple tendons (through same incision), each
27687	Gastrocnemius recession (eg, Strayer procedure)
27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (eg, anterior tibial extensors into midfoot)

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27691	Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot)
27692	Transfer or transplant of single tendon (with muscle redirection or rerouting); each additional tendon (List separately in addition to code for primary procedure)
27695	Repair, primary, disrupted ligament, ankle; collateral
27696	Repair, primary, disrupted ligament, ankle; both collateral ligaments
27698	Repair, secondary, disrupted ligament, ankle, collateral (eg, Watson-Jones procedure)
27705	Osteotomy; tibia
27707	Osteotomy; fibula
27709	Osteotomy; tibia and fibula
27720	Repair of nonunion or malunion, tibia; without graft, (e.g., compression technique)
27722	Repair of nonunion or malunion, tibia; with sliding graft
27726	Repair of fibula nonunion and/or malunion with internal fixation
27756	Percutaneous skeletal fixation of tibial shaft fracture (with or without fibular fracture) (e.g., pins or screws)
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed
27814	Open treatment of bimalleolar ankle fracture (eg, lateral and medial malleoli, or lateral and posterior malleoli, or medial and posterior malleoli), includes internal fixation, when performed
27822	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip
27823	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; with fixation of posterior lip
27870	Arthrodesis, ankle, open
27871	Arthrodesis, tibiofibular joint, proximal or distal
28001	Incision and drainage, bursa, foot
28002	Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space
28003	Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot
28008	Fasciotomy, foot and/or toe
28010	Tenotomy, percutaneous, toe; single tendon
28011	Tenotomy, percutaneous, toe; multiple tendons
28020	Arthrotomy, including exploration, drainage, or removal of loose or foreign body; intertarsal or tarsometatarsal joint
28022	Arthrotomy, including exploration, drainage, or removal of loose or foreign body; metatarsophalangeal joint
28024	Arthrotomy, including exploration, drainage, or removal of loose or foreign body; interphalangeal joint
28035	Release, tarsal tunnel (posterior tibial nerve decompression)
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater
28041	Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); 1.5 cm or greater
28043	Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm
28045	Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); less than 1.5 cm
28046	Radical resection of tumor (eg, sarcoma), soft tissue of foot or toe; less than 3 cm
28047	Radical resection of tumor (e.g., sarcoma), soft tissue of foot or toe; 3 cm or greater
28055	Neurectomy, intrinsic musculature of foot
28060	Fasciectomy, plantar fascia; partial (separate procedure)
28062	Fasciectomy, plantar fascia; radical (separate procedure)
28072	Synovectomy; metatarsophalangeal joint, each
28080	Excision, interdigital (Morton) neuroma, single, each
28086	Synovectomy, tendon sheath, foot; flexor
28088	Synovectomy, tendon sheath, foot; extensor

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28090	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (eg, cyst or ganglion); foot
28092	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (e.g., cyst or ganglion); toe(s), each
28100	Excision or curettage of bone cyst or benign tumor, talus or calcaneus
28102	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with iliac or other autograft (includes obtaining graft)
28103	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with allograft
28104	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus
28106	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with iliac or other autograft (includes obtaining graft)
28107	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with allograft
28108	Excision or curettage of bone cyst or benign tumor, phalanges of foot
28110	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure)
28111	Ostectomy, complete excision; first metatarsal head
28112	Ostectomy, complete excision; other metatarsal head (second, third or fourth)
28113	Ostectomy, complete excision; fifth metatarsal head
28114	Ostectomy, complete excision; all metatarsal heads, with partial proximal phalangectomy, excluding first metatarsal (eg, Clayton type procedure)
28116	Ostectomy, excision of tarsal coalition
28118	Ostectomy, calcaneus
28119	Ostectomy, calcaneus; for spur, with or without plantar fascial release
28120	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); talus or calcaneus
28122	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (eg, osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus
28124	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); phalanx of toe
28126	Resection, partial or complete, phalangeal base, each toe
28130	Talectomy (astragalectomy)
28140	Metatarsectomy
28150	Phalangectomy, toe, each toe
28153	Resection, condyle(s), distal end of phalanx, each toe
28160	Hemi phalangectomy or interphalangeal joint excision, toe, proximal end of phalanx, each
28190	Removal of foreign body, foot; subcutaneous
28192	Removal of foreign body, foot; deep
28193	Removal of foreign body, foot; complicated
28200	Repair, tendon, flexor, foot; primary or secondary, without free graft, each tendon
28202	Repair, tendon, flexor, foot; secondary with free graft, each tendon (includes obtaining graft)
28208	Repair, tendon, extensor, foot; primary or secondary, each tendon
28210	Repair, tendon, extensor, foot; secondary with free graft, each tendon (includes obtaining graft)
28220	Tenolysis, flexor, foot; single tendon
28222	Tenolysis, flexor, foot; multiple tendons
28225	Tenolysis, extensor, foot; single tendon
28226	Tenolysis, extensor, foot; multiple tendons
28230	Tenotomy, open, tendon flexor; foot, single or multiple tendon(s) (separate procedure)
28232	Tenotomy, open, tendon flexor; toe, single tendon (separate procedure)
28234	Tenotomy, open, extensor, foot or toe, each tendon
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (eg, Kidner type procedure)
28250	Division of plantar fascia and muscle (e.g., Steindler stripping) (separate procedure)
28260	Capsulotomy, midfoot; medial release only (separate procedure)
28261	Capsulotomy, midfoot; with tendon lengthening

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28262	Capsulotomy, midfoot; extensive, including posterior talotibial capsulotomy and tendon(s) lengthening (eg, resistant clubfoot deformity)
28264	Capsulotomy, midtarsal (eg, Heyman type procedure)
28270	Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure)
28272	Capsulotomy; interphalangeal joint, each joint (separate procedure)
28280	Syndactylization, toes (e.g., webbing or Kelikian type procedure)
28285	Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)
28286	Correction, cock-up fifth toe, with plastic skin closure (e.g., Ruiz-Mora type procedure)
28288	Ostectomy, partial, exostectomy or condylectomy, metatarsal head, each metatarsal head
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
28292	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method
28295	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method
28296	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method
28297	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method
28299	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with double osteotomy, any method
28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation
28302	Osteotomy; talus
28304	Osteotomy, tarsal bones, other than calcaneus or talus;
28305	Osteotomy, tarsal bones, other than calcaneus or talus; with autograft (includes obtaining graft) (eg, Fowler type)
28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal
28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)
28308	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each
28309	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; multiple (eg, Swanson type cavus foot procedure)
28310	Osteotomy, shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure)
28312	Osteotomy, shortening, angular or rotational correction; other phalanges, any toe
28313	Reconstruction, angular deformity of toe, soft tissue procedures only (e.g., overlapping second toe, fifth toe, curly toes)
28315	Sesamoidectomy, first toe (separate procedure)
28320	Repair, nonunion or malunion; tarsal bones
28322	Repair, nonunion or malunion; metatarsal, with or without bone graft (includes obtaining graft)
28470	Closed treatment of metatarsal fracture; without manipulation, each
28476	Percutaneous skeletal fixation of metatarsal fracture, with manipulation, each
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each
28496	Percutaneous skeletal fixation of fracture great toe, phalanx or phalanges, with manipulation
28525	Open treatment of fracture, phalanx or phalanges, other than great toe, includes internal fixation, when performed, each
28666	Percutaneous skeletal fixation of interphalangeal joint dislocation, with manipulation
28675	Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed

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28705	Arthrodesis; pantalar
28715	Arthrodesis; triple
28725	Arthrodesis; subtalar
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)
28737	Arthrodesis, with tendon lengthening and advancement, midtarsal, tarsal navicular-cuneiform (eg, Miller type procedure)
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint
28750	Arthrodesis, great toe; metatarsophalangeal joint
28755	Arthrodesis, great toe; interphalangeal joint
28760	Arthrodesis, with extensor hallucis longus transfer to first metatarsal neck, great toe, interphalangeal joint (e.g., Jones type procedure)
28810	Amputation, metatarsal, with toe, single
28820	Amputation, toe; metatarsophalangeal joint
28825	Amputation, toe; interphalangeal joint
29805	Arthroscopy, shoulder, diagnostic, with or without synovial biopsy (separate procedure)
29806	Arthroscopy, shoulder, surgical; capsulorrhaphy
29807	Arthroscopy, shoulder, surgical; repair of SLAP lesion
29819	Arthroscopy, shoulder, surgical; with removal of loose body or foreign body
29820	Arthroscopy, shoulder, surgical; synovectomy, partial
29821	Arthroscopy, shoulder, surgical; synovectomy, complete
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (Mumford procedure)
29825	Arthroscopy, shoulder, surgical; with lysis and resection of adhesions, with or without manipulation
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (List separately in addition to code for primary procedure)
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair
29828	Arthroscopy, shoulder, surgical; biceps tenodesis
29830	Arthroscopy, elbow, diagnostic, with or without synovial biopsy (separate procedure)
29835	Arthroscopy, elbow, surgical; synovectomy, partial
29836	Arthroscopy, elbow, surgical; synovectomy, complete
29837	Arthroscopy, elbow, surgical; debridement, limited
29838	Arthroscopy, elbow, surgical; debridement, extensive
29840	Arthroscopy, wrist, diagnostic, with or without synovial biopsy (separate procedure)
29843	Arthroscopy, wrist, surgical; for infection, lavage and drainage
29844	Arthroscopy, wrist, surgical; synovectomy, partial
29845	Arthroscopy, wrist, surgical; synovectomy, complete
29846	Arthroscopy, wrist, surgical; excision and/or repair of triangular fibrocartilage and/or joint debridement
29847	Arthroscopy, wrist, surgical; internal fixation for fracture or instability
29848	Endoscopy, wrist, surgical, with release of transverse carpal ligament
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
29871	Arthroscopy, knee, surgical; for infection, lavage and drainage
29873	Arthroscopy, knee, surgical; with lateral release

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29874	Arthroscopy, knee, surgical; for removal of loose body or foreign body (eg, osteochondritis dissecans fragmentation, chondral fragmentation)
29875	Arthroscopy, knee, surgical; synovectomy, limited (eg, plica or shelf resection) (separate procedure)
29876	Arthroscopy, knee, surgical; synovectomy, major, 2 or more compartments (eg, medial or lateral)
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29880	Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed
29881	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29882	Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)
29883	Arthroscopy, knee, surgical; with meniscus repair (medial AND lateral)
29884	Arthroscopy, knee, surgical; with lysis of adhesions, with or without manipulation (separate procedure)
29885	Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
29886	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion
29887	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion with internal fixation
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction
29891	Arthroscopy, ankle, surgical, excision of osteochondral defect of talus and/or tibia, including drilling of the defect
29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)
29893	Endoscopic plantar fasciotomy
29894	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; with removal of loose body or foreign body
29895	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; synovectomy, partial
29900	Arthroscopy, metacarpophalangeal joint, diagnostic, includes synovial biopsy
29901	Arthroscopy, metacarpophalangeal joint, surgical; with debridement
29902	Arthroscopy, metacarpophalangeal joint, surgical; with reduction of displaced ulnar collateral ligament (eg, Stenar lesion)
29906	Arthroscopy, subtalar joint, surgical; with debridement
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
02/25/2021	03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	05/02/2023

Revision History	Description

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03/02/2021	MPC approved criteria for Ambulatory Surgery Center Site of Care. Requires 60-day notice; effective July 1, 2021.
04/13/2021	Updated policy effective date to August 1, 2021 with phased approach
05/12/2021	Updated 'site of service' terminology to 'site of care' throughout the policy.
07/27/2021	Updated policy effective date to September 1, 2021 with phased approach
12/15/2022	Moved the ASC list of codes to this criteria page for consolidation.
03/06/2023	Updated applicable codes to include new CPT codes effective 1/1/2023: 49591, 49593, 49595, 49613, 49615, 49617, 49621, 49623
05/02/2023	MPC approved an expansion of the ASC criteria and adoption of SOC restriction for Gastroenterology procedures. GI procedures is applicable to the following counties: **King and Thurston (new counties) and existing counties. This requires a 60-day notice, effective October 1, 2023.

MPC Medical Policy Committee

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Clinical Review Criteria
Axial Lumbar Interbody Fusion System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Axial Lumbar Interbody Fusion System*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this procedure is as safe as standard procedures and/or provides better long-term outcomes than current standard procedure.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Interbody fusion in the lumbar spine is performed to treat painful symptoms caused by instability of the vertebrae, such as spondylolisthesis, spinal stenosis, or degenerative disc disease. Traditional methods of spinal fusion include bone grafts or metal implants; however, insertion of these implants is not without risk. The technique requires excision of the problematic disc often coupled with decompression procedures, followed by instrumentation and bone grafting to provide stabilization and to promote a solid fusion. These procedures have the potential to destabilize the spine, cause significant morbidity and reduce the clinical effectiveness. Numerous open and minimally invasive techniques have been developed all with their advantages and disadvantages. The transaxial anterior lumbar interbody fusion was developed to capitalize on the presacral access route to the L5-S1 intervertebral space preventing the need for the surgeon to cut through paraspinous muscles and remove laminae and facet joints, potentially lessening postoperative patient pain and the likelihood of complications.

The Axial Lumber Interbody Fusion System (AxiaLIF®) (TranS1®, Inc., Wilmington, NC) is a minimally invasive approach to the L5-S1 disc space. It consists of techniques and surgical instruments for creating a presacral access route to perform percutaneous fusion of the L5-S1 or L4-S1 vertebral bodies. The procedure utilizes fluoroscopic guidance for a blunt guide introducer that is passed through a 15-20 mm incision lateral to the

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coccyx and advanced along the midline of the anterior surface of the sacrum. It was designed to mitigate soft tissue trauma during lumbar fusion surgery. This approach minimizes the need to cut through soft tissue lessening patient pain and the likelihood of complications. In addition, the procedure allows patients to be discharged from the hospital the day after surgery allowing quicker return to work.

The AxiaLIF system was cleared by the U.S. Food and Drug Administration (FDA) 510(k) process. According to the FDA 510(k) letter to the manufacturer, the system is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF is not intended to treat severe scoliosis, sever spondylolisthesis (grade 3 or 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 in conjunction with legally marked facet and pedicle screw system.

The AxiaLIF has not previously been reviewed by the Medical Technology and Assessment Committee (MTAC) and is currently being reviewed for decision-making guidance.

Medical Technology Assessment Committee (MTAC)

AxiaLIF

12/16/2013: MTAC REVIEW

Evidence Conclusion: *Efficacy* The literature search revealed five case series that report on outcomes associated with AxiaLIF. The largest, published in 2011, was a retrospective analysis of 156 patients from 4 clinical sites in the US. Ultimately, the mean pain and ODI scores improved by approximately 63% and 54% respectively (P<0.001) and the overall radiographic fusion rate at 2 years was 94%. The study did not report any adverse events. The patient population was reported to be homogenous, however, the variable nature and progression of the disease compromises the reliability of this claim. Limitations of this study include the retrospective analysis, industry funding as well as selection bias. Outcome measures were not all objective and relied on patient reporting. Only half of the patients were accounted for in the preoperative and postoperative ODI outcome (Tobler, Gerszten et al. 2011). Several smaller case series were also identified and are summarized in a table 1. Ultimately, all of the studies report similar results and conclusions but are subject to the bias of any retrospective series. Further limitations include a lack of control subjects, potential for selection bias as only one of the studies enrolled consecutive patients and unclear study objectives. All studies, with the exception of the publication by Patil and colleagues, received industry funding from TranS1 (Patil, Lindley et al. 2010; Gerszten, Tobler et al. 2012; Marchi, Oliveira et al. 2012). *Safety* Two publications addressed the safety of AxiaLIF with conflicting results. The first study was a 5-year surveillance study of 9,152 patients (Gundanna, Miller et al. 2011) and the second, a retrospective review of 68 patient records (Lindley, McCullough et al. 2011). Gundanna and colleagues reported minimal complications (1.3%) in their study while Lindley et al. reported high complication rates (23.5%). The observed adverse events across both the studies included pseudoarthrosis, superficial infection, sacral fracture, pelvic hematoma, failure of wound closure, and rectal perforation. Although both studies were designed to be systematic in their investigation, neither study had a control group for comparison and the results are dependent on either spontaneous reporting or the accuracy of medical records. In addition, both of the studies are subject to a variety of bias due to patient selection and industry funding.
Conclusion: There is insufficient evidence to determine the efficacy of AxiaLIF compared to standard fusion procedures. There is insufficient evidence to establish whether the AxiaLIF is as safe as standard fusion procedures.
Articles: Currently, there are no randomized control trials that compare the AxiaLIF with other approaches to lumbosacral interbody fusion. The literature related to the safety and efficacy is primarily comprised of case series.
The following studies were selected for review: Tobler WD, Gerszten PC, Bradley WD, Raley TJ, Nasca RJ and Block JE. Minimally invasive axial presacral L5-S1 interbody fusion. *Spine* 2011;**36**(20):E1296-E1301. See Evidence Table. Gerszten PC, Tobler W, et al. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. *Journal of Spinal Disorders & Techniques* 2012;**25**(2):E36-E40.See Evidence Table. Marchi L, Oliveira L, et al. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow up. *Journal of Neurosurgery: Spine* 2012;**17**(3):197-192. See Evidence Table. Patil S, Lindley E, et al. Clinical and radiological outcomes of axial lumbar interbody fusion. *Orthopedics* 2010;**33**(12). See Evidence Table Aryan H, Newman C, et al. Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. *Minimally Invasive Neurosurgery* 2008;**51**:225-230. See Evidence Table.

The use of AxiaLIF does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered Not Covered:

CPT® Codes	Description
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
03/04/2014	03/04/2014[MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC]	05/05/2020

[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	Removed deleted codes 0195T, 0196T and 0309T

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Clinical Review Criteria
Bone Anchored Hearing System (BAHA)

- BONEBRIDGE Bone Conduction Implant
- Osia®
- Vibrant Soundbridge
- Softband
- Adhear

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 16, section 100 – "Hearing Aids and Auditory Implants" and section 180 – "Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare."
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Effective until September 1, 2023

Kaiser Permanente has elected to use the Bone Anchored Hearing System (BAHS) (KP-0564 v2) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Effective September 1, 2023

Kaiser Permanente has elected to use the Bone Anchored Hearing System (BAHS) (KP-0564 09012023) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

Service	Criteria Used
Vibrant Soundbridge	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting these services, please send the following documentation to support medical necessity:

- Most recent audiogram/hearing test
- Most recent clinical notes from requesting provider &/or specialist (otolaryngology, ENT)

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Background

Vibrant Soundbridge System

The Vibrant Soundbridge System is an implantable alternative to standard hearing aids. It is intended for use in adults with moderate to severe sensorineural hearing loss, who desire an alternative to an acoustic hearing aid. Common limitations of conventional hearing aids are acoustic feedback, sound and voice distortion, and need for frequent servicing and maintenance (FDA documents, Sterkers et al., 2003; Luetje, 2002).

The Soundbridge system consists of a middle-ear implant known as the Vibrating Ossicular Prosthesis (VORP) and an external portion, the amplification system called the Audio Processor. The Audio Processor is about 1.2 inches in diameter and designed to be worn behind or above the ear. It contains a microphone that converts environmental sound to electrical signals. These signals are delivered to the VORP, causing the Floating Mass Transducer (FMT), one of its components, to vibrate. The vibration manually stimulates the auditory ossicles and is perceived by the patient as sound (manufacturer's documents).

Potential adverse effects of the Vibrant Soundbridge include the usual risks of major ear surgery and a possible decrease in residual hearing (FDA documents).

The Vibrant Soundbridge has been available commercially since February 1998 in Europe and received FDA approval in the US in August 2000. The FDA recommends that patients have experience with appropriately fitting conventional hearing aids before using the Vibrant Soundbridge.

Bone Anchored Hearing Aid (BAHA) (Entific Medical Systems)

The BAHA is an alternative device for hearing-impaired patients who are unable to wear traditional hearing aids. According to the manufacturer, the BAHA can be beneficial to individuals with chronic inflammation or infection of the ear canal, an incomplete ear canal e.g. congenital ear malformation and single-sided hearing loss. The BAHA is based on bone conduction technology, sound transmission without involvement of the skin and soft tissue and thus can be used by individuals with an impaired or diseased external or middle ear (Tjellstrom & Hakansson, 1995).

The BAHA device consists of an implant and an external sound processor attached to a subcutaneous abutment. The implant, a titanium fixture, is implanted behind the ear where it "osseointegrates" or bonds with the living bone. After healing from surgery, a percutaneous abutment is attached to the fixture. The sound processor "snaps" into the abutment. The sound processor, which transmits sound directly via the bone to the inner ear can be connected and disconnected at will (FDA and manufacturer's documents)

The BAHA was developed in Sweden in the 1980s. It was approved by the FDA in August 1996 and was introduced in the US market in January 1997. There are several different models, all of which were considered by the FDA to be Class II devices, substantially equivalent to air conduction hearing aids with digital sound processing.

Medical Technology Assessment Committee (MTAC)

Vibrant Soundbridge

06/06/2005: MTAC REVIEW

Evidence Conclusion: There are studies with pre- and post-implantation data, but no controlled studies on the efficacy of either the Vibrant Soundbridge or the BAHA. Data from case series suggest that patients who meet eligibility requirements may experience improvement and hearing from the Vibrant Soundbridge and BAHA. Lack of blinding and lack of a control group limit the validity of case series. The publications are further limited by small sample sizes and/or missing data.

Articles: *Vibrant Soundbridge*: Only case series were identified. Most were conducted in Europe where there is longer experience with the device compared to the U.S. Two studies were selected for review: The largest case series, a French study (n=125), and the strongest US study (n=54). The US study was the one used by the FDA to grant approval. *BAHA*: Only case series were identified, all with sample sizes <100. The two best-case series

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were reviewed. They were selected based on sample size and length of follow-up. There were two publications on one of the studies, so a total of three articles were reviewed. *The studies that were critically appraised are*: Sterkers O, Boucarra D, Labassi S. A middle ear implant, the Symphonix Vibrant Soundbridge: Retrospective study of the first 125 patients implanted in France. *Otol Neurotol* 2003; 24: 427-436. See Evidence Table Luetje CM, Brackman D, Balkany TJ et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. See Evidence Table Mylanus EA, van der Pouw KC, Snik AFM et al. Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. *Arch Otolaryngol Head Neck Surg* 1998; 124: 271-276. See Evidence Table Hol MKS, Snik AFM, Mylanus EAM et al. Long-term results of bone-anchored hearing aid recipients who had previously used air-conduction hearing aids. *Arch Otolaryngol Head Neck Surg* 2005; 131: 321-325. See Evidence Table Lustig LR, Arts A. Brackmann DE. Hearing rehabilitation using the BAHA bone-anchored hearing aid: Results in 40 patients. *Otol Neurotol* 2001; 22: 328-334. See Evidence Table

The use of Vibrant Soundbridge or the BAHA in the treatment of hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Bone anchored or transcutaneous bone-conduction hearing systems

Medicare –

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
HCPC Codes	**Description**
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only

Considered Not Medically Necessary:

CPT® Codes	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone

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Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
HCPC Codes	**Description**
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only

Vibrant Soundbridge - Considered Not Medically Necessary:

HCPC Codes	Description
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis

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Date Created	Review Dates	Date Last Revised
06/06/2005	09/07/2010[MDCRPC], 07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC],10/01/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	04/04/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
10/9/2018	Added Adhear to non-coverage statement
04/21/2020	Added applicable CPT codes: 69714, 69715, 69717, 69718
08/04/2020	MPC approved to adopt updates for Non-Medicare, adding clinical indications for BONEBRIDGE (MCG* KP-0564-see KP-0564 v2 eff 01.01.2021). Requires 60-day notice, effective date 01/01/2021.
12/08/2022	Added New CPT Codes applicable for MA and Non-MA.
04/04/2023	MPC approved modification to criteria to include OSIA and clarification to hearing thresholds.

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Clinical Review Criteria
Balloon Dilation of the Eustachian Tube

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Balloon Dilation of the Eustachian Tube*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Eustachian Tube Dilation

Unilateral or bilateral Eustachian tube balloon dilation (ETBD) is considered medically necessary once per lifetime for the treatment of chronic obstructive Eustachian tube dysfunction when **ALL** of the following criteria are met:

- Age 18 years or older
- Patient has had any of the following symptoms continuously for at least 12 months:
  - aural fullness
  - aural pressure
  - otalgia
  - hearing loss
  - autophony
- History of chronic ear disease or intolerance to barometric changes greater than 12 months
- The patient does not have any other causes of aural fullness such as:
  - Temporomandibular joint disorders
  - Extrinsic obstruction of the eustachian tube
  - Superior semicircular canal dehiscence
  - Endolymphatic hydrops
- Prior evaluation of the eustachian tube with nasal endoscopy
- Abnormal result of **BOTH** of the following prior to ETBD:
  - Tympanogram (Type B or C)
  - Tympanic membrane (i.e., retracted membrane, effusion, perforation) on exam
- If applicable, failure to respond to appropriate medical management of potential co-occurring conditions, such as:
  - Allergic rhinitis, rhinosinusitis - 4-6 weeks of a nasal steroid spray, if indicated
  - Laryngopharyngeal reflux - Proton pump inhibitor or antacid treatment

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- If patient has a history of tympanostomy tube placement, symptoms of Eustachian tube obstruction improved while tubes were patent, or the patient underwent myringotomy without tube placement with symptom relief

Eustachian tube balloon dilation (ETBD) is considered experimental, investigational or unproven for all other indications.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Eustachian Tube Role, ETD, & Prevalence, & Risk factors: (Anand et al., 2019; Fischer et al., 2020; Juszczak, Aubin-Pouliot, Sharon, & Loftus, 2019; Magro et al., 2021; Shan et al., 2019)
The eustachian tube (ET) is a ciliated epithelial-lined tube that covers the anterior wall of the middle ear and the nasopharynx. The ET has several roles including maintenance of middle ear physiology and function, pressure equalization across the tympanic membrane, clearance of secretions from the middle ear, and protection from pathogens and secretions from the oropharynx. An alteration of the opening or closing of the ET leads to ET dysfunction (ETD).
Categories of ETD vary from obstructive dysfunction to patulous dysfunction. Obstructive dysfunction is an insufficient opening of the ET. Patulous dysfunction is characterized by a patent valve (resulting in equalization of pressure between the middle ear and the nasopharynx).
The prevalence of ETD is estimated at 4.6% among adults in the United States and over 5% in the elderly population. Sinonasal risk factors include self-reported allergic rhinitis and persistent cold/flu.

Presentation & Treatment of ETD: (Swain, Janardan, & Mohanty, 2020)
Signs and symptoms of Eustachian tube dysfunctions consist of fullness of the ear, hearing difficulty, ear pain, tinnitus and vertigo. The medical treatments of ET dysfunction consist of antihistamines, nasal decongestants and oral or nasal steroids. If ETD is recalcitrant, Eustachian tuboplasty may be done. Balloon dilation of the Eustachian tube is a new surgical technique that has garnered interest.

Rationale
Existing treatments are not efficacious.

Description of the procedure (Magro et al., 2021; Meyer et al., 2018; Swain et al., 2020)
Balloon dilation of the ET (BDET) is a minimally invasive endoscopic procedure for ETD resistant to conservative treatment, in which a balloon is inflated into the Eustachian tube (ET). The procedure is generally performed under general anesthesia. Nevertheless, it can be done in office setting under local anesthesia. It can be unilateral or bilateral.
A balloon catheter is inserted, through the nose, into the ET under nasal endoscopy. The balloon is then inflated by filling in it up with saline to a pressure of 10 to 12 bars. The pressure is maintained for 2 minutes. Once the ET is dilated, the balloon is deflated and removed. The goal of the procedure is to dilate the cartilaginous portion of the ET without causing damage.

Medical Technology Assessment Committee (MTAC)

Balloon Dilation of the Eustachian Tube

Date: 10/11/2021

Evidence Conclusion:

- Low-quality evidence suggests that eustachian tube balloon dilation is more effective than medical treatment, on the short and long-term, in adult patients with eustachian tube dilation refractory to medical management.

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The procedure may be safe as no serious device-related complications are reported. However, more RCTs with longer follow-up are still needed.
- The evidence is insufficient to compare ETBD and tympanoplasty in patients with otitis media and severe ETD.

Articles: See Evidence Table

The use of Balloon Dilation of the Eustachian Tube does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPCS Codes	Description
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/27/2022	02/01/2022[MPC], 02/07/2023[MPC],	

[MPC] Medical Policy Committee

Revision History	Description
02/01/2022	MPC approved to adopt MTAC's recommendation of coverage and the clinical review criteria for this medical procedure. Requires 60-day notice, effective date 07/01/2022.

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Clinical Review Criteria
Bariatric Surgery

- Adjustable gastric banding, Laparoscopic or Open (Lap Band)
- Biliopancreatic Diversion with Duodenal Switch (Scopinaro Procedure)
- EndoGastric Solutions StomaphyX™ Endoluminal Fastener
- Gastric Bypass for GERD
- Gastric Electrical Stimulator
- Intragastric Balloons
- Mini-Gastric Bypass
- Roux-en-Y Gastric Bypass (RYGB)
- Single Anastomosis Duodeno-Ileal Bypass w/ Sleeve gastrectomy (SADI-S)
- Vertical Banded Gastroplasty (VBG)
- Vertical Sleeve Gastrectomy (VSG)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Billing and Coding: Bariatric Surgery Coverage (A53028)

For Non-Medicare Members (Adult & Pediatric/Adolescent)

Procedure	Criteria
Adjustable gastric banding, Laparoscopic or Open (Lap Band) -Not covered for Federal Plans Laparoscopic Vertical Sleeve Gastrectomy (VSG) as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity Roux-en-Y Gastric Bypass (RYGB) **Effective 03/01/2023** Biliopancreatic Diversion with Duodenal Switch* Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)*	**Effective until 03/01/2023** See Bariatric Surgery (KP-516 v2 eff 11.01.2021) MCG*. **Effective 03/01/2023** See Bariatric Surgery (KP-516 03012023) MCG*. *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access **If requesting this service, please send the following documentation to support medical necessity:** • Last 2 years of gastroenterology notes • Most recent clinical note from requesting provider

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*reserved for patients with a BMI >50	• Documentation of patient height, weight & comorbid conditions
EndoGastric Solutions StomaphyX™ Endoluminal Fastener Gastric Bypass for GERD Gastric Electrical Stimulation (GES) for Obesity	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist
Intragastric Balloon Device	MCG* A-0970 This is not covered per MCG **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

The following procedures are not covered (benefits are varied and need to be verified): Distal gastric bypass, Mini-gastric bypass

The vertical banded gastroplasty (VBG) is no longer a standard of care and is therefore considered not medically necessary and not covered.

Effective until 03/01/2023

Duodenal switch (Single-Anastomosis Duodenal Switch), Biliopancreatic Diversion with Duodenal Switch*
Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)* is currently under review. Please contact Review Services medical leadership for details.

CDC Adult Body Mass Index (BMI) Calculator View Chart
https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html
Percent of Excess Body Weight Loss Formula
(Initial Weight – Postop Weight)/ (Initial weight – Ideal Weight*) Ideal weight is defined by the weight corresponding to a BMI of 25 for the person in question.

***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

EndoGastric Solutions
Gastric Bypass for GERD

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Gastric Electrical Stimulator for Obesity
Intragastric Balloons
Laparoscopic Sleeve Gastrectomy
Vertical Sleeve Gastrectomy (VSG)

Background

The NIH has defined overweight as a BMI between 25 kg/m2 and 29.9 kg/m2, and obesity as a BMI of > 30 kg/m2. According to national survey data, an estimated one-third of adults in the United States are overweight. Overweight and obesity are associated with an increased risk of mortality. Individuals with a BMI > 30 have a 50-100% increased risk of premature death compared to individuals with a BMI between 20 and 25. In addition, overweight and obesity are associated with an increased risk of coronary heart disease, type 2 diabetes, hypertension, certain cancers and musculoskeletal disorders such as knee osteoarthritis (Surgeon General report: USPSTF).

Lifestyle changes, including diet, exercise, and behavior modification, are generally considered first-line therapy for overweight and obesity. Pharmacotherapy can be used as an adjunctive therapy when lifestyle changes alone are ineffective. Medical management of obesity has been found to be less effective with individuals who are morbidly obese (BMI > 35) than for those with lower BMI, particularly in terms of sustained weight loss. The NIH has stated that bariatric surgery is an option for patients with a BMI > 40 or a BMI > 35 with comorbid conditions, who have failed medical treatment (Fisher and Schauer, 2002; NIH, 1998).

There are two main strategies for surgically inducing weight loss, gastric restriction and intestinal malabsorption. Restrictive procedures mechanically reduce the size of the stomach. This limits the amount of food a patient can consume at a single meal and causes early satiety. Substantial dietary compliance is required, because individuals are still able to consume high-calorie liquids or soft foods. Malabsorption procedures involve bypassing a portion of the intestines which decreases the proportion of nutrients that are absorbed from food. Some types of surgeries use elements of both strategies (Fisher and Schauer, 2002; Southern California-RAND EBPC 2004).

Two currently accepted bariatric surgery methods are Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB). VBG is a restrictive procedure that uses staples to create a narrow gastric inlet or pouch and a non-adjustable band is placed around the new inlet to prevent enlargement. RYGB includes both restrictive and malabsorptive elements. The stomach is reduced to a small gastric pouch, and this pouch is connected to a segment of the jejunum, bypassing the duodenum and proximal small intestine. RYGB can be performed as open surgery or laparoscopically.

Adjustable gastric banding is a restrictive technique, using the Lap-Band System® (Inamed). A small gastric pouch is formed by laparoscopically placing a silicone ring (the Lap-Band) around the upper part of the stomach just below the gastro-esophageal junction. The band is connected via tubing to an access port that is secured beneath the skin of the abdomen. The band has a reservoir that is accessed percutaneously and filled with saline. The size of the band can be adjusted by adding or removing saline. The Lap-Band is removable, either laparoscopically or via an open procedure. In the clinical study presented by the manufacturer to the FDA, 60% of the band removal procedures were laparoscopic. The Lap-Band has been used in Europe and Australia since early 1990s and was approved by FDA in June 2001 (manufacturer's Web site).

Medical Technology Assessment Committee (MTAC)

Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)

2/10/1999: MTAC REVIEW

Evidence Conclusion: The published scientific evidence consists of several large case series and one randomized controlled trial from multiple institutions published over a 10-year period of time. Vertical Banded Gastroplasty (VBG) Data from 4 case series and 1 RCT totaling 403 patients undergoing VBG with 75-100% follow up at 3 years demonstrates between 15 and 31% weight loss. Reoperation or revisional surgery was required in 3% of patients in one series and 36% in another series. Mortality was 1-3% overall. Roux-en-Y (REY)- Data from 2 case series and 1 RCT totaling 532 patients in the REY groups with 60-86% follow up at 3 years demonstrates that Roux-en-Y gastric restrictive surgery results in between 33 and 35% weight loss. Reoperation or revisional surgery was required in 6% of patients in one series and not reported in the other series. Mortality was 1% overall.

Articles: MacLean, LD et al. *Surgery*, 1993;113:380-388. See Evidence Table. Sugerman, HJ, et al. 1989: *Am J Surg.*;157 93-100. See Evidence Table.

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Sjostrom CD, Peltonen M, Wedel H, Sjostrom L. Differentiated long-term effects of intentional weight loss on diabetes and hypertension. *Hypertension* 2000; 36: 20-25. See Evidence Table.

The use of gastric restrictive surgery (VBG or REY) meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/8/2006: MTAC REVIEW
Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)
Evidence Conclusion: There is some evidence that Lap-Band surgery is more effective than optimal non-surgical management for patients with BMI between 30-35 kg/m2 with co-morbidities. This evidence is not conclusive due to the size of the single RCT, and its limitations. Evidence from non-randomized studies suggests that gastric bypass surgery is more effective for weight loss than the Lap-Band technique for patients who meet standard eligibility criteria for bariatric surgery (BMI > 40 kg/m2 or > 35 kg/m2 with co-morbidities) and for the sub-set of patients with BMI > 50 kg/m2. Gastric surgery was not associated with more complications than the Lap-Band procedure, and studies generally found a higher reoperation rate after Lap-Band surgery. There may be residual confounding in the non-randomized studies. There are no randomized controlled trials comparing the safety and effectiveness of Lap-Band surgery to either gastric bypass or optimal non-surgical management for adults with BMI > 35 kg/m2. There is evidence from one randomized controlled trial that Lap-Band surgery is more effective for weight loss than a non-surgical intervention (i.e. supervised dieting, pharmacotherapy) for patients with BMI between 30-35 kg/m2 with co-morbidities (O'Brien et al., 2005). However, in the two years of follow-up 4 of the 39 patients who received the Lap-Band experienced prolapse of the posterior gastric wall. In addition, limitations of the study were that it was not blinded, follow-up was only two years, and the nonsurgical intervention was not well described beyond 6 months. The best evidence comparing the Lap-Band and Roux-en-Y gastric bypass comes from two non-randomized comparative studies (Weber et al., 2004; Cottam et al. 2006). Both matched patients who did and did not receive the Lap-Band according to age, sex and BMI. The Weber study included patients with BMI > 40 kg/m2 or BMI > 35 kg/m2 who had co-morbidities and the Cottam study did not specify eligibility criteria, but mean BMI was 47 kg/m2. Both studies found significantly more weight loss at 2-3 years and fewer co-morbidities in the group that underwent gastric bypass. In the Weber et al. study, the rate of reoperation was somewhat higher in the gastric bypass group than the Lap-Band group during the first 30 days (n=7 vs. n=1), but after 30 days the rate was higher in the Lap-Band group (n=26) than the gastric bypass group (n=4). The Cottam et al. study found a slightly higher rate of major reoperation in the gastric bypass group compared to the Lap-Band group (8% vs. 5%), but this difference was not statistically significant. A third non-randomized study compared the Lap-Band and laparoscopic Roux-en-Y gastric bypass in super morbidly obese patients (BMI > 50 kg/m2). Similar to the studies of patients with lower mean BMI, there was greater reduction in BMI and a higher proportion of excess weight loss in patients who received gastric bypass compared to the Lap-Band. There appeared to be a greater reduction in co-morbidities and fewer complications in the gastric bypass group, but numbers were too small to accurately compare the groups in these areas. Reoperations were necessary in 15% of the Lap-Band group and 6.5% of the gastric bypass group. In all of the non-randomized studies, there may be confounding variables, differences between groups that affect the outcome (such as differences in commitment to losing weight). A large case series conducted in Italy (n=1893) provides additional information on the safety of the Lap-Band technique. Reported post-operative mortality was 1 out of 200 procedures (0.5%) and was restricted to patients with preoperative cardiovascular complications. The most common post-operative complications were gastric pouch dilation (5%) and tube port complications (4%). The ideal study would be a randomized controlled trial comparing long-term outcomes of gastric surgery with the Lap-Band and commonly accepted bariatric surgery procedures or optimal non-surgical management. One randomized controlled trial was identified and critically appraised. It compared the Lap-Band to non-surgical treatment. Five non-randomized comparative studies were identified comparing the Lap-Band to gastric bypass. One study conducted in Sweden was excluded because it compared two case series of patients treated at different institutions. A second study was excluded because only preliminary findings were reported: there was 60% follow-up at 1 year and 15% at 2 years. The other three studies were critically appraised. A large case series from Italy (n=1863) was also reviewed to evaluate the long-term safety of Lap-Band surgery.
Articles: *Evidence tables were created for the following studies:* O'Brien PE, Dixon JB, Laurie C et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program. *Ann Intern Med* 2005; 144: 625-633. See Evidence Table. Weber M, Miller MK, Bucher T. Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity. *Ann Surg* 2004; 240: 975-983. See Evidence Table. Cottam DR, Atkinson J, Anderson A et al. A case-controlled matched-pair cohort study of laparoscopic Roux-en-Y gastric bypass and Lap-Band patients in a single US center with three-year follow-up. *Obesity Surg* 2006; 16: 534-540. See Evidence Table. Browne WB, Julliard K, Castro AE et al. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients. *Arch Surg* 2006; 141: 683-

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689. See Evidence Table. Angrisani L, Furbette F, Doldi SB et al. Lap-Band adjustable gastric banding system: The Italian experience with 1863 patients operated on over 6 years. *Surg Endosc* 2003; 17: 409-412. See Evidence Table.

The use of adjustable gastric banding and lap-band in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/15/2014: MTAC REVIEW
Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)
Evidence Conclusion: There is a lack of good quality RCTs with long-term follow-up that compared laparoscopic gastric banding versus Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy. The few published RCTs were small, with short follow-up duration, and methodological limitations. Colquitt and colleagues' 2014 systematic review and meta-analysis on surgery for morbid obesity was the last published update of previous Cochrane reviews and updates on that topic conducted by the same group of authors over the last decade. This last August 2014 update (Evidence table 1) included RCTs on bariatric surgery published through December 2013. The meta-analysis included 15 trials (N=1,180 participants) that compared different bariatric surgery procedures used for weight loss (seven additional trials compared surgery to non-surgical weight loss therapies). The meta-analysis had valid methodology and analysis, but the majority of the studies included had uncertain or high risk of bias. The overall results for the comparisons made among the three most commonly performed procedures were as follows: Laparoscopic gastric bypass (LRYGB) vs. laparoscopic adjustable gastric banding (LAGB)
The review found moderate quality evidence from 3 RCTs with uncertain risk of bias that LRYGB achieved significantly greater weight loss and BMI reductions up to 5 years after surgery vs. LAGB. Two trials reported longer duration of hospitalization with LRYGB, and one study showed that it was associated with larger number of late major complications vs. LAGB. On the other hand, one study showed that a large proportion of those undergoing LAGB required reoperation for band removal (the authors warned against generalizability of results of this study due to high drop-out rates). The evidence on QoL and co-morbidities was of very low quality. LAGB vs laparoscopic sleeve gastrectomy (LSG) One relatively small study (Himpens et al, 2006) with methodological limitations (reviewed earlier by MTAC) showed that reductions in weight and BMI were statistically significantly higher with LSG vs LABG. The study also showed that symptoms of GERD were resolved in a higher proportion among patients in the LSG group vs. LAGB (no tests of significance were provided). Open or LRYGB vs. LSG The RCTs included showed no statistically significant differences between the two procedures in the reductions in weight or BMI. Serious adverse events were reported in one trial and were higher in the LRYGB group. There were no statistically significant differences between the 2 procedures in their effect on comorbidities and complications except for one study that showed significantly more improvement in diabetes mellitus with LRYGB. The authors of the review concluded that the outcomes were similar between RYGB and LSG and that both procedures had better outcomes than LAGB. There was no good evidence from RCTs to determine whether any procedure was more effective than another in controlling comorbidities. The studies had relatively short-term follow-up durations, which was insufficient to study the long-term effects of the surgical procedures.
Wang et al, 2013 (Evidence table 2) conducted a meta-analysis of 11 randomised and non-randomized controlled studies (N=1,004 participants) that compared LAGB with LSG. The pooled results suggest that LSG is associated with greater excess with loss (EWL% mean difference -12.55 [95% CI, -15.66, -9.43] at 6 months and -4.97 [95% CI, -7.58, -2.36] at 12 months). LSG was also associated with better improvement in type 2 DM than LAGB (pooled OR of 0.34; 95 % CI 0.16-0.73). The meta-analysis combined the results of a small number of randomized and non-randomized studies with small sample sizes and short-term follow-up durations. The authors concluded that larger RCTs with long-term follow-up are needed to compare the efficacy of LSG, LAGB, and LRYGB.
Dogan and colleagues (2014) compared the safety and effectiveness of LAGB, LRYGB, and LSG in a matched retrospective cohort study involving 735 patients who underwent the procedures in two centers in the Netherlands between 2007 and 2010. The results showed that LRYGB was associated with a significantly higher excess weight loss compared to LSG in the first year after which there was no significant difference in weight loss between the two procedures. After 3 years of follow-up LAGB had a higher complication rate compared to the other two procedures. Revision surgery was needed in 21% of LAGB, and 9% of LSG underwent conversion to RYGB. The authors concluded that LRYGB is a safe and effective treatment in morbidly obese patients with good long-term outcomes. LSG was comparable to LRYGB regarding weight loss and complication rate; and that LAGB was inferior to both LRYGB and LSG. Arterburn, et al (2014) compared the short and long-term outcomes of LRYGB and LAGB in a retrospective cohort study of 7,457 adult patients who underwent laparoscopic bariatric surgery from January 2005 through December 2009 in 10 health care systems (including Kaiser Permanente) in the US. 1,507 underwent LAGB and 5,950 underwent RYGB. The primary outcomes were change in BMI,

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composite of 30-day rate of major adverse outcomes, subsequent hospitalization, and subsequent intervention. The results indicate that RYGB led to a significantly greater loss in BMI than LAGB (14.8 loss with RYGB vs. 8.0 LAGB, p<0.001). RYGB was associated with a higher rate of short-term complication, and long-term subsequent hospitalization. LAGB on the other hand was associated with a higher risk of long-term subsequent interventions procedures. The study was large and included a diverse group of patients but was retrospective and not randomized. Data were obtained from records which did not included all required information, and the subsequent interventions and hospitalizations may have been due to causes unrelated to the bariatric procedures. Trastulli et al (2013) conducted a systematic review to evaluate the safety and effectiveness of LSG in terms of weight loss, comorbidity remission, and efficacy for the management of patients with type 2 diabetes mellitus. The review included 15 RCTs, 6 of which compared LSG with LGB and 2 vs. LAGB. Three of these studies were judged by the authors to have good quality and the rest were of fair quality. The authors could not perform a meta-analysis due to the heterogeneity of the studies but performed some cumulative analyses when suitable. The results of these analyses indicate that the complication rate was 12.1% (range 10-32%) with LSG vs. a mean of 20.9% (range 10-26.4%) with LGB. Only two trials compared LSG with LAGB, one reported 0% hospital morbidity for both procedures, and the other (Himpens 2006) a total of 7 (17.5%) complications with LAGB (all were late) vs. 2 (5%) complications with SLG (all were postoperative). The percentage of excess weight loss (%EWL) ranged from 49% to 81% in the LSG group, 62.1% to 94.4% in the LGB group, and 28.7%-48% in the LAGB group) in a follow-up duration ranging from 3 months to 3 years. Type 2 DM remission ranged from 26.5% to 75% with LSG and 42%-93% with LGB. Buchwald and colleagues (2009) performed a systematic review and meta-analysis of 621 experimental and observational studies (N=136,134 participants) on bariatric surgery that were published in English between 1990- 2006, and that reported on the resolution of type 2 diabetes. Nineteen studies with 43 treatment arms and 11,175 patients reported on both weight loss and diabetes resolution separately for diabetic patients (N=4,070). The analysis indicated that overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion/duodenal switch, followed by gastric bypass, and least for banding procedures. Insulin levels declined significantly postoperatively, as did hemoglobin A1C and fasting glucose values. Conclusion: The limited published evidence comparing LAGB to LRYGB or LSG suggest that LAGB is not the most effective surgical procedure for the morbidly obese patients. The literature indicates that LAGB may have shorter operative time, shorter length of hospital stays, and lower rate of early complications; but it is also associated with higher rates of late complications and risk of surgical interventions compared to other bariatric surgery procedures. There is no good published quality evidence to date, to determine the comparative effectiveness of LAGB to LSG or LRYGB on the resolution of co-morbidities and improvement of health-related quality of life.

Articles: The literature search for studies published after the 2006 MTAC review, revealed over 500 publications, many of which were unrelated to the current review. Very few small randomized controlled trials compared the effects of one surgical bariatric procedure versus another. The search identified a recently updated Cochrane review (Colquitt et al, 2014) on surgery for weight loss in adults; a meta-analysis that compared LAGB with LSG (Wang et al, 2013), a multicenter retrospective matched cohort study (Dogan et al, 2014) that compared gastric bypass, LAGB and LSG in morbidly obese patients; three systematic reviews with no meta-analyses of RCTs on bariatric surgeries; a comparative effectiveness study of laparoscopic adjustable gastric banding vs. laparoscopic gastric bypass; as well as several cohort studies with no control or comparison groups that reported on short and long-term outcomes of gastric banding and LSG procedures. The two most recent meta-analyses were selected for critical appraisal.

Colquitt JL, Pickett K, Loveman E, et al. Surgery for weight loss in adults. Cochrane Database Syst Rev. 2014 Aug 8;8:CD003641. DOI: 10.1002/14651858.CD003641.pub 4. See Evidence Table 1

Wang S, Li P, Sun XF, et al. Comparison between laparoscopic sleeve gastrectomy and laparoscopic adjustable gastric banding for morbid obesity: a meta-analysis. Obes Surg. 2013 Jul; 23(7):980-986. See Evidence Table 2

The use of LAGB in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

EndoGastric Solutions Stomaphy X™ Endoluminal Fastener

BACKGROUND

Obesity Surgery the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system is a sterile, single-use device for use in transoral tissue approximation and ligation in the GI tract. The system consists of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants. The device is introduced into the body through the mouth under endoscopic visualization. Once inside the stomach, the stomach wall is suctioned into the tissue port on the StomaphyX™ creating a large plication. Non-resorbable polypropylene fasteners are then deployed across the fold to hold the tissue in place. Typically, 10 to 20 folds are required

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depending on the patient's anatomy. The pleats created in the stomach will reduce its size, which would potentially lead to early satiety and weight loss. According to the manufacturer, the StomaphyX™ procedure is incisionless, adjustable, and revisable. It is usually performed as an outpatient procedure, and is intended for individuals who want an alternative to invasive weight loss surgery, or those who have had previous gastric bypass surgery and are regaining weight. The EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system was cleared for marketing by the FDA in February 2007 for use in endoluminal trans-oral tissue approximation and ligation in the GI tract. The InScope™ Tissue Apposition System is a sterile, single patient used disposable suture system for approximating and securing soft tissue within the gastrointestinal tract. It is intended to perform suturing in conjunction with endoscopes having a working channel of 2.8 mm or larger. The system can be used to treat variety of defects endoscopically including ulcers and perforations (FDA Web site). The InScope™ Tissue Apposition System was cleared by the FDA for marketing in January 2007 to be used for the placement of sutures and approximation of soft tissue. GERD According to the Montreal Consensus, gastroesophageal reflux disease (GERD) is defined as a condition which develops when the reflux of stomach contents cause troublesome symptoms and/or complications. GERD is a mechanical disorder that is caused by a defective lower esophageal sphincter, a gastric emptying disorder, or failed esophageal peristalsis. Typical symptoms of GERD include heartburn and regurgitation; however, overtime reflux can cause ulceration, Barrett's esophagus, airway disease, and esophageal cancer. It is estimated that 40% of individuals in the United States suffer from GERD on a monthly basis. Current treatment options for GERD include long-term use of acid suppression medications or surgical intervention. While treatment with acid suppressing medications such as proton pump inhibitors and histamine 2-receptor blockers are effective, they do not treat the underlying mechanical disorder. Additionally, not all patients respond to these therapies (Zagol 2011, Stefanidid 2010). Surgery is another treatment option for patients with GERD. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), surgical therapy should be considered in patients with a diagnosis of reflux who (Stefanidid 2010): Have failed medical management (due to inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side-effects). Opt for surgery despite medical management (due to quality-of-life considerations, lifelong need for medication intake, expense of the medication, etc.). Have complications of GERD (e.g., Barrett's esophagus, peptic stricture). Have extra-esophageal manifestations (asthma, hoarseness, cough, chest pains, aspiration). There are a variety of surgical procedures used for the treatment of GERD. Currently, there is no consensus on the best procedure for all patients. The choice of procedure is often based on anatomic considerations and expertise; however, the laparoscopic Nissen fundoplication has emerged as one of the most widely used techniques. With fundoplication, the gastric fundus is wrapped around the lower end of the esophagus to reduce gastric reflux. The fundal wrap can be either total (360°) or partial (less than 360°). Studies suggest that approximately 90% of patients who undergo Nissen fundoplication achieve symptom relief. Side effects of this procedure include dysphagia, hyperflatulence, inability to belch, bloating, and postsurgery bowel symptoms (AGA 2008, Stefanidid 2010). Transoral incisionless fundoplication using the EsophyX device (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. This procedure attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. The EsophyX device is inserted transorally, under direct endoscopic visualization, into the stomach and is positioned at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The result is an omega shaped valve 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are less than 2 cm in size through the use of a built-in vacuum invaginator. As this procedure is incisionless and can often be performed on an outpatient basis it is an attractive alternative to conventional surgical procedures (Jafri 2009, Louis 2010). The EsophyX system had been cleared by the FDA for use in transoral tissue approximation, full-thickness plication and ligation in the gastrointestinal tract for the treatment of GERD in patients with symptomatic chronic GERD who require and respond to pharmacological therapy. This device may also be used to narrow the gastroesophageal junction and reduce hiatal hernia ≤2 cm in size in patients with symptomatic chronic GERD. The EsophyX system has not been previously reviewed by the Medical Technology Assessment Committee and is being review based on request from bariatric surgery and a member appeal.

04/09/2008: MTAC REVIEW
EndoGastric Solutions Stomaphy X™ Endoluminal Fastener
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the EndoGastric Solutions StomaphyX™ endoluminar fastener for weight loss. There is insufficient published evidence to determine the efficacy and safety of the InScope™ Tissue Apposition System for endoscopic gastric sutures.

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Articles: The literature search did not reveal any published studies, on the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system, or on the InScope™ Tissue Apposition System. Information about the systems was obtained from the FDA and the manufacturer's Web sites.

The use of endoluminar fasteners in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Vertical Sleeve Gastrectomy (VSG)

BACKGROUND

Obesity is a rapidly growing health problem in the United States and worldwide. According to data from the National Health and Nutrition Examination Survey (NHANES), over two thirds of the adults in the US are overweight or obese. Overweight is defined as Body Mass Index [BMI] between 25 and 29 kg/m2, and obesity is defined as BMI of 30.0 kg/m2 or higher. Obesity can be further subdivided into class 1: (BMI 30 to less than 35), class 2: (BMI 35 to less than 40), class 3: severe or morbid obesity (BMI of 40 or higher), and class IV: super obese or super morbid (BMI >50 kg/m2). Obesity leads to substantial morbidity, lower social functioning and quality of life, as well as premature mortality. It is associated with development and /or aggravation of many chronic conditions including cardiovascular diseases, hypertension, type 2 diabetes mellitus, sleep apnea, some forms of cancer, depression, and osteoarthritis (Duval 2006, Ogden 2006, Sturm 2007, Flegal 2012). Diet, behavioral modification, and exercise are the primary recommended treatments for obesity, but were found to have limited success among the morbidly obese. Drug therapy may be indicated for some, but has its side effects, and the majority regain the lost weight over time. Bariatric surgery is considered as an alternative therapy for morbidly obese individuals. Studies showed that bariatric surgery was more effective than behavioral and medical therapy, had long-term control of obesity, and improved comorbidities as type 2 diabetes. There are several surgical techniques for weight loss, but the Roux-en-Y gastric bypass (RYGB) and the adjustable gastric banding (AGB) are the two most commonly performed procedures across the world. However, surgery is a major intervention and may be associated with risk of complications and perioperative mortality. The morbidly obese individuals usually have a higher incidence of co-existing medical problems and are more likely to develop short and long-term complications after bariatric surgery (Karamanakos 2008, Almogy 2004, Fuks 2009). Sleeve gastrectomy (SG), also known as vertical sleeve gastrectomy (VSG), vertical gastrectomy (VG), greater curvature gastrectomy, parietal gastrectomy or vertical gastroplasty, was initially described in the late 1980s, as a first step procedure performed before RYGB or biliopancreatic diversion-duodenal switch in the super obese patients with severe comorbidities. It was intended to achieve a significant weight loss prior to performing a more restrictive and malabsorption operation among those at high surgical or anesthesiologic risk. After a period of initial weight loss, the surgical risk would be reduced, and the second definitive surgery could be performed. More recently, SG have been increasingly used as stand-alone operation for the morbidly obese patients due to its technical simplicity and short-term outcomes in weight loss (Lee 2007, Rubin 2008, Akkary 2008, Mellissas 2008, Keuper 2008, Kehagias 2011). Sleeve gastrectomy is a purely restrictive operation with no malabsorptive effects. It involves removing the fundus and greater curvature portion of the stomach leaving a narrow tubular stomach that is approximately the size and shape of a banana. It preserves the integrity of the pylorus and does not include intestinal bypass as part of the technique. The technique is simple, but some components of the surgery can result in serious complications if not performed correctly (Peterli 2009, Gill 2010, Brethauer 2011). There are several mechanisms contributing to the weight loss with SG; removing 80-90% of the stomach and leaving behind only a sleeve restricts the amount of the food that can be ingested and gives the sensation of fullness with minimal oral intake. Hormonal change represented by the decrease in the ghrelin level due to resection of the fundus may be another factor for the weight loss, as well as the accelerated gastric emptying, and the behavioral modification of the patients. The exact underlying mechanism is still unknown, and the long-term effects of the surgery are still under investigation (Rubin 2008, Akkary 2008, Moy 2008, Karamanakos 2008, Brethauer 2011). Sleeve gastrectomy has many potential advantages. Preservation of gastric function including the pylorus eliminates dumping, and being purely restrictive, SG does not result in malabsorption. Moreover, it can be performed laparoscopically (laparoscopic sleeve gastrectomy or LSG) even in the super-obese patients. SG does not require implantation of any artificial device or adjustments as the laparoscopic adjustable gastric band. It can also be performed in patients with disorders which preclude intestinal bypass e.g. anemia or Crohn's disease. However, the procedure is irreversible and has potential complications associated with the relatively long staple line such as bleeding and leakage. Leakage is the most concerning complication after SG and may result from the placement of the final staple line across the gastroesophageal junction or distal esophagus resulting in a staple line disruption. It may also result from mid-sleeve stenosis due to stenosis in the lumen or twisting or kinking of the sleeve at the incisura. Other reported complications associated with the sleeve gastrectomy include pulmonary embolism, subphrenic abscess, liver failure, stricture, wound infection, and need for reoperation. On the long-term, sleeve gastrectomy may potentially lead to gastroesophageal reflux disease due to an increase in

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the gastric pressure associated with the procedure (Moy 2008, Fuks 2009, Brethauer 2011). The First Report form the American College of Surgeons Bariatric Surgery Center Network indicates that obesity is a life-long disease, and thus short-term safety and efficacy of bariatric surgery should not be the deciding factor for selection of the procedure, and long-term follow-up beyond 1 year is needed; more importantly 5 years or longer. The report also notes that specifically longer-term assessment of the sleeve gastrectomy is critical as the gastric pouch enlargement over time may limit its ultimate effectiveness (Hutter 2011).

04/06/2009: MTAC REVIEW
Vertical Sleeve Gastrectomy (VSG)
Evidence Conclusion: The evidence consists of two RCTs (Himpens et al 2006, and Karamanakos et al (2008), and several case series. Himpens and colleagues compared laparoscopic sleeve gastrectomy to gastric banding in 80 patients with a median BMI 38 kg/m2 and Karamanakos and colleagues compared it with laparoscopic Roux-en-Y gastric bypass in 32 patients with mean BMI of 46 kg/m2. The longest follow-up duration reported was 3 years in Himpen's study. The two trials were randomized and controlled but had their limitations. The authors did not discuss specific inclusion criteria e.g. the BMI threshold and other characteristics. In addition, there was no standardized technique for performing sleeve gastrectomy, no standardized size or design for the gastric sleeve, and no optimal dilator size to create the lesser curvature conduit. All these variables could affect weight loss and make it difficult to compare sleeve gastrectomy with other established bariatric procedure. Himpen and colleagues found that the weight loss after 1 and 3 years was more significant with sleeve gastrectomy vs. gastric banding. However, the late weight loss after the two procedures was insufficient; it ranged from 1 to 48 kg with sleeve (median 29.5 kg), and 0 to 40 kg with gastric banding (median 17 kg). The number of reported adverse events associated with sleeve gastrectomy was small. However, some events were severe and required re-operations as intraperitoneal bleed, ischemia of the sleeve, anastomosis leak, and insufficient weight loss. Other reported complications of SG included pulmonary embolism, GERD, gastric erosion, gastric pain, vomiting, and others. Karamanakos and colleagues' trial showed no significant difference in the weight loss at 12 months between the two procedures. However, the study was too small, and had insufficient power to detect significant differences between the two study groups. In conclusion, there is insufficient published scientific literature to date to determine the long-term efficacy, safety, and durability of the weight loss associated with sleeve gastrectomy procedure as a stand-alone treatment option for obese patients. There is also insufficient evidence to determine the optimum BMI threshold where SG would be recommended or encouraged.
Articles: The search yielded over 130 articles. Many were reviews and opinion pieces. There were three randomized controlled trials; one compared SG with adjustable gastric banding, another compared it with Roux-en-Y gastric bypass, and the third compared two different techniques for sleeve gastrectomy. There were also a number of case series with different population sizes and follow-up durations. Only four were relatively large with sample sizes over 100, one was conducted in the US and three were conducted overseas. The US series (Lee et al 2007) had the largest sample size, longest follow-up duration, and non-randomized comparison groups.
The two RCTs that compared SG with alternative bariatric surgeries were selected for critical appraisal as well as the Lee et al's case series. The citations for the critically appraised studies are:
Himpens J, Dapri G, Cadiere GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy. Results after 1 and 3 years. Obesity Surgery 2006; 16:1450-1456. See Evidence Table Karamanakos SN, Vagenas K, Kalfarentzos F, et al. Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide –YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy. A prospective, double blind study. Ann Surg 2008; 247:401-410. See Evidence Table
Lee CM, Cirangle PT, Jossart GH. Vertical gastrectomy for morbid obesity in 216 patients: Report of two-year results. Surg Endosc 2007; 21:1810-1816. See Evidence Table

The use of Vertical Sleeve Gastrectomy for the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

2/11/2013: MTAC REVIEW
Vertical Sleeve Gastrectomy (VSG)
Evidence Conclusion: There is some evidence from very few small RCTs, and non-randomized prospective studies that laparoscopic sleeve gastrectomy performed as a stand-alone surgery, leads to short to mid-term significant weight loss, and improvement in comorbidities in obese patients. However, there is insufficient evidence to determine whether the weight loss and resolution of comorbidities will be sustained long-term. There is insufficient evidence to determine the long-term comparative effectiveness and safety of sleeve gastrectomy and Rou-en-Y gastric bypass or adjustable gastric banding for the treatment of obesity and obesity-related comorbidities. There is insufficient evidence to determine the long-term net health outcomes of laparoscopic sleeve gastrectomy. The studies that reported on long-term outcomes were small case series with no comparison

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or control group. Himpens and colleagues (2010) reported on the results of 6 years follow-up of 53 patients who underwent laparoscopic SG (different population from that in the RCT published by the same group of investigators in 2006). The results showed that after the sixth postoperative year weight gain was observed in 31 cases (75.6%). The mean BMI in this group of patients was 39.9± 5.9 at baseline, 26.6 ± 4.3 at 3 years, and 31.1 ± 6.2 at 6 years. New gastroesophageal reflux symptoms were also reported after 6 years; 18% of the patients in the stand-alone SG group reported occasional vomiting, and 23% reported frequent episodes of GERD. In another follow-up of a case series, D'Hondt and colleagues (2012) also reported a trend towards decrease in weight loss by time (median % excess weight loss [EWL] was 78.5% at 12 months, 72% at 24 months, and 54.4% at 72 months). When % EWL above 50% was considered, the total success rate of SG was 92.9% at 1 year, 89.5%, 87%, 85.7%, 64.3% and 54.5% after 2, 3, 4, 5, and 6 years respectively. There is also insufficient evidence to establish criteria for patient selection or an optimum BMI threshold where SG is recommended or encouraged.

Articles: The search for studies published after the 2009 MTAC review revealed one RCT comparing laparoscopic sleeve gastrectomy versus laparoscopic Roux-en-Y gastric bypass in patients with BMI <50 kg/m2, another very small RCT that compared the effects of the two procedures on the glucose metabolism, two non-randomized prospective comparative studies, and one case control study that compared the outcomes of SG to one or more other bariatric surgery. The literature search also revealed one network meta-analysis and two systematic reviews without meta-analyses that evaluated the different procedures for bariatric surgery, as well as a number of prospective and retrospective case series with or without comparison groups.

The two RCTs and two prospective comparative studies were selected for critical appraisal. The network meta-analysis was not selected for further critical appraisal as it compared changes of BMI levels with different bariatric surgeries vs. standard care and included only two earlier studies on SG. The following studies were critically appraised: Peterli R, Wölnerhanssen B, Peters T, et al. Improvement in glucose metabolism after bariatric surgery: comparison of laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy: a prospective randomized trial. Ann Surg. 2009; 50:234-241. See Evidence Table Kehagias I, Karamanakos SN, Argentou M, et al. Randomized clinical trial of laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the management of patients with BMI<50 kg/m2.Obes Surg. 2011;21:1650-1656. See Evidence Table Leyba JL, Aulestia N, Llopis SN. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the treatment of morbid obesity. A prospective study of 117 patients. Obes Surg 2011; 21:212-216. See Evidence Table Varela JE. Laparoscopic sleeve gastrectomy versus laparoscopic adjustable gastric banding for the treatment severe obesity in high risk patients. JSLS 2011; 15:486-491. See Evidence Table

The use of Vertical Sleeve Gastrectomy for the treatment of obesity does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity

BACKGROUND

Individuals with BMI >60 are considered to be "super obese." Super obesity is associated with an increased risk of multiple health problems including arthritis, breathing problems, cancer, depression, diabetes, heart disease, hypertension, venous disorders and death. In addition, surgical treatment for obesity, such as a Roux-en-Y gastric bypass, is believed to be more dangerous in super obese than less obese patients, particularly for individuals who carry their weight in the belly area. Laparoscopic sleeve gastrectomy (LSG) is a bariatric procedure that involves the laparoscopic removal of 70-80% of the left side of the stomach. This results in a stomach that is approximately the size and shape of a banana. LSG is technically simpler than other bariatric procedures including gastric bypass surgery, since it does not require re-routing of the intestines. In addition, the procedure does not require implantation of any artificial device as with other obesity treatments such as the Lap-Band. LSG is most commonly used as the first stage in a two-stage procedure. Patients may be able to lose 80 or more pounds after an LSG, reducing their BMI to the point that a Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch can be done more safely. The second operation is generally performed 8-12 months after the LSG. LSG is sometimes performed as a stand-alone procedure, but this application is not yet recognized by the American Society for Bariatric Surgery (ASDS). LSG has not been reviewed previously by MTAC.

04/02/2007: MTAC REVIEW

Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity

Evidence Conclusion: There is insufficient evidence on the safety and efficacy of laparoscopic sleeve gastrectomy for obesity. Only case series were available; there are no randomized controlled trials or cohort studies. The case series were generally small, and the largest series (Cottam et al., 2006) was compromised by a

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low follow-up rate. Follow-up data 12 months after the stage-one LSG were available for fewer than half of the treated patients. Mean weight loss in 46% of patients with follow-up data was 45± 17%.
Articles: The search yielded 6 case series; all but one included fewer than 50 patients. The only published case series with a sample size of >100 patients was critically appraised for MTAC: Cottam D, Qureshi FG, Mattar G et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. Surg Endosc 2006; 20: 859-863.

The use of laparoscopic sleeve gastrectomy in the treatment of severe morbid obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Electrical Stimulator for Obesity

BACKGROUND
Gastric electric stimulation is a new technique that has been proposed as a treatment for obesity. It involves the application of a small electrical current to the stomach through leads that are implanted in the muscular layer of the gastric wall. Although the exact mechanism of action is not fully understood, it is thought that electrical stimulation of the stomach wall can induce early satiety and reduce appetite. It may also have an effect on hormones related to satiety and/or appetite (Mizrahi 2012, Stamin 2012, Verdam 2012). Currently, no gastric electric stimulation devices are FDA approved for the treatment of obesity. This technology was previously reviewed by the Medical Technology Assessment Committee (MTAC) in 2001 for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. It did not meet MTAC criteria for this indication. It has not been previously reviewed for the treatment of obesity. It is being reviewed based on a request from Kaiser Permanente Bariatric Surgery.

2/11/2013: MTAC REVIEW
Gastric Electrical Stimulator for Obesity
Evidence Conclusion: A recent RCT that included 190 obese subjects evaluated the effects of gastric electric stimulation on weight loss. All patients underwent implantation with the gastric electric stimulator. Patients were instructed to consume a diet with a 500 kcal per day deficit and were required to attend monthly support group meetings. Patients in the treatment group had their devices activated. The devices for patients in the control group were kept inactive. After 12 months, there was no significant difference in the percent of excess weight lost between the treatment and the control group. The mean percent of excess weight loss was 11.7 in the treatment group and 11.8 in the control group (P=0.71). Adverse events included: endoscopy-detected gastric lumen lead penetration during the 2-lead implantation procedure (N=26), low battery between month 10 and month 12 (N=22), lead dislodgement (N=2), and pocket infection (N=1). There were no deaths or major complications. Medtronic/Transeuronix sponsored the study (Shikora 2009). An earlier study conducted by the same author also found no significant difference in the percent of excess weight loss between treatment (device on) and control (device off) subjects at 6 months; however, due to methodological limitations results from this study should be interpreted with caution (Shikora 2004). Conclusion: Evidence from a RCT suggests that there is no significant difference in the percent of excess weight lost between patients who received treatment with gastric electric stimulation plus a lifestyle intervention and patients who were treatment with lifestyle intervention alone.
Articles: The literature search revealed several small, case-series and two randomized controlled trials (RCTs) that evaluated the safety and efficacy of gastric electric stimulation for the treatment of obesity. The RCTs were selected for review. The following studies were selected for review: Shikora SA, Bergenstal R, Bessler M, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. Surg Obes Relat Dis 2009; 5:31-7. See Evidence Table Shikora SA. "What are the yanks doing?" the U.S. experience with implantable gastric stimulation (IGS) for the treatment of obesity - update on the ongoing clinical trials. Obes Surg 2004;14 Suppl 1: S40-8. See Evidence Table

The use of Gastric Electric Stimulation for the Treatment of Obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Bypass for GERD

BACKGROUND
Obesity is a rapidly growing health problem in the United States and worldwide. According to the National Health and Nutrition Examination Survey (NHANES), more than one third of the adults and almost 17% of the youths in the US are obese defined as Body Mass Index [BMI] 30.0 kg/m2 or higher. It is estimated that at least 5% of the total population are morbidly obese (i.e. with BMI >40 kg/m2). Obesity is associated with the development and /or aggravation of many chronic conditions including cardiovascular diseases, hypertension, type 2 diabetes mellitus, sleep apnea, some forms of cancer, depression, and osteoarthritis. Obesity may also be a predisposing factor for gastroesophageal reflux disease (GERD); obese patients are nearly three times as likely to experience GERD

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symptoms as those with normal BMI. However, researchers have found that the prevalence of GERD, even in the setting of severe obesity is <50%, which suggests that severe obesity itself is not sufficient to cause GERD. The mechanism by which obesity may increase gastroesophageal reflux is not fully understood, but several pathophysiologic mechanisms have been proposed to explain the association between the two conditions. Obese individuals may experience extrinsic gastric compression by surrounding adipose tissue leading to the increase in intragastric pressure and subsequent relaxation of the lower esophageal sphincter (LES), as well as anatomical disruption of the gastroesophageal junction. The latter may result in the formation of hiatal hernia which was found to be more prevalent in obese individuals than in those with normal weight (Ortega 2004, Nelson 2005, Duval 2006, Ogden 2012, Sturm 2007, Tai 2009, Prachand 2010, Flegal 2012).
The initial treatment of GERD symptoms involves lifestyle and dietary modification, which are often combined with acid inhibiting therapy. These generally alleviate GERD symptoms, but are usually unsuccessful in morbidly obese patients. If conservative measures fail, surgery is often considered as an alternative approach. Laparoscopic Nissen fundoplication has been the standard operation for these cases with medically refractory GERD. However, its use is controversial among obese patients due to conflicting results concerning its long-term effectiveness and sustainability. Fundoplication affects only the LES and lower gastroesophageal junction without addressing weight. Bariatric operations, which are intended primarily to induce weight loss in the morbidly obese, are considered as a potential alternative approach for treating GERD in obese patients. The success of these surgeries depends on the technique used. Restrictive techniques such as laparoscopic adjustable gastric banding and sleeve gastrectomy result in weight reduction by reducing the stomach volume leading to early satiety. However, some patients reported persistence or worsening acid reflux symptoms after these surgeries. Malabsorptive techniques such as jejuno-ileal bypass and biliopancreatic diversion result in weight reduction by functional shortening of the digestive tract and /or by diverting gastric juices. The Roux-en-Y gastric bypass (RYGB), a more technically complex operation, has both restrictive and malabsorptive properties and is described by some as a reliable procedure for treating severe GERD in obese individuals. It does not directly affect the cardio-esophageal competence but may prevent GERD through weight loss and physically altering the anatomy of the gastrointestinal tract and preventing acid reflux into the esophagus (Nelson 2005, El-Serag 2008, Ikramuddin 2008, De Groot 2009, Prachand 2010, Reavis 201).

2/11/2013: MTAC REVIEW
Gastric Bypass for GERD
Evidence Conclusion: There is insufficient published evidence from randomized controlled trials to determine the comparative effectiveness and safety of Roux-en-Y gastric bypass (RYGB) surgery and Nissen fundoplication for the treatment of GERD in obese patients. The methodological quality of the published studies is low due to non-randomization of the patients, small population sizes, differences in definitions of obesity and evaluation of GERD symptoms, lack of objective outcome assessment, as well as other inherent limitations of observational studies. In a non-randomized trial, Braghetto and colleagues (2012) evaluated postoperative results after fundoplication, RYGB, or a combination of the two procedures for the treatment of 139 obese patients with GERD and Barrett's esophagus. The authors did not explain why and how they selected the patients for each operation, and patients were not equally distributed among the different procedures. They noted however, that those with BMI >35 kg/m2 were selected for RYGB. Compared to the other two groups, patients in the RYGB had significantly higher BMI and weight. Patients underwent careful clinical assessment of symptoms and endoscopic/histological studies at baseline, and at 3-5 years after surgery. Manometric studies and 24-intra-esophageal pH studies were performed in all patients at baseline and among 116 (83%) after surgery. Overall the results of the study showed that the reflux symptoms and erosive esophagitis improved after all three surgeries compared to baseline. The improvement observed was significantly higher in the two approaches that included gastric bypass versus fundoplication alone. The gastric bypass surgery alone did not modify the lower esophageal sphincter (LES) pressure but led to the highest reduction in body weight and BMI. In an earlier very small (N=12) study with data obtained from a prospectively maintained database, Patterson and colleagues (2003) also showed that laparoscopic Roux-en-Y gastric bypass and laparoscopic Nissen Fundoplication were both effective in treating heartburn symptoms and acid reflux in obese patients. The LES resting pressure increased significantly after the fundoplication but not after the RYGB surgeries. Results from a number of other case series show that RYGB resulted in weight loss, improvement of GERD symptoms, regression of esophagitis, and reduction of number of antireflux medications used in obese patients with GERD. The studies did not evaluate the effect of lifestyle and dietary habits of the patients after the surgery, and do not provide sufficient evidence to determine the long-term benefits of gastric bypass in these obese patients with GERD.
Articles: The literature search did not reveal any randomized controlled trial that compared gastric bypass surgery to other standard medical or surgical treatment for severe GERD in obese patients. There was one non-randomized prospective study that compared outcomes of three different laparoscopic procedures for the treatment of obese patients with GERD and Barrette's esophagus, a very small study that compared bypass

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surgery to fundoplication, and another small study that compared vertical banded gastroplasty vs. Roux-en-Y gastric bypass in patients with GERD and morbid obesity. Other published studies on bypass surgery for GERD were all case series with population sizes ranging from less than ten to just over 200 patients. The study that included fundoplication as a comparative surgery as well as 4 relatively large and/or more recent case series were selected for critical appraisal. Braghetto I, Korn O, Csendes A, et al. Laparoscopic treatment of obese patients with gastroesophageal reflux disease and Barrett's esophagus: a prospective study. Obes Surg 2012; 22:764-772. See Evidence Table Frezza EE, Ikramuddin S, Gourash W, et al. Symptomatic improvement in gastroesophageal reflux disease (GERD) following laparoscopic Roux-en-Y gastric bypass. Surg Endosc 2002; 16:1027-1031. See Evidence Table Nelson LG, Gonzalez R, Haines K, et al. Amelioration of gastroesophageal reflux symptoms following Roux-en-Y gastric bypass for clinically significant obesity. Am Surg 2005; 71:950-953. See Evidence Table Ortega J, Escudero MD, Mora F, yet al. Outcome of esophageal function and 24-houir esophageal pH monitoring after vertical banded gastroplasty and Roux-en-Y gastric bypass. Obes Surg 2004; 14:1086-1094. See Evidence Table Tai CM, Lee YC, Wu MS, et al. The effect of Roux-en-Y gastric bypass on gastroesophageal reflux disease in morbidly obese Chinese patients. Obes Surg 2009; 19:565-570. See Evidence Table

The use of gastric bypass surgery for treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/20/2016: MTAC REVIEW
Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD)
Evidence Conclusion: The literature search did not identify any published randomized controlled trials to date, that compared gastric bypass surgery to Nissen fundoplication, or other standard medical or endoscopic procedures used for the treatment of severe GERD in morbidly obese patients. The studies published after the last MTAC reviews were all case series, and retrospective analyses of registered data in a database with no control or comparison groups. Due to their inherent biases, particularly selection bias; and lack of control groups, case series represent a level IV of evidence in the hierarchy of evidence. Case series cannot prove a cause and effect relationship but may only generate hypotheses for future research. Overall, the results the published case series suggest that gastric bypass leads to significant weight loss in obese patients, and is associated with improvement in GERD symptoms, and/or reduction of number of anti-reflux medications used by obese patients with severe GERD. These series generally relied on subjective outcomes, did not evaluate the effect of confounding factors, lifestyle and dietary habits of the patients after the surgery, and do not provide sufficient evidence to determine the long-term durability of the observed outcomes. Madalosso and colleagues, 2016 (Evidence table 1), recently published 3-years results of a prospective case series to assess the impact of Roux-en-Y gastric bypass (RYGB) on gastroesophageal reflux disease (GERD) in morbidly obese patients. The study did not compare gastric bypass to Nissen fundoplication, sham procedure, or any other surgical or medical therapy. In addition, the 39 months follow-up data were available for only 53 of the 94 (56%) patients recruited. The authors compared the postoperative outcomes to the baseline values and had the advantage of including objective measures. The overall results of the analysis suggest that RYGB surgery was associated with a significant weight loss, reduction in GERD symptoms, and decrease in esophageal acid exposure. These results have to interpreted with caution due to the nature of the study, potential selection bias, confounding, lack of a control group, and high dropout rate. Dupree, et al (2014) retrospectively analyzed data from the Bariatric Outcomes Longitudinal Database (BOLD)*, focusing on patients with pre-existing GERD. 33,876 patients underwent LRYGB, and 4,832 underwent LSG from 2007-2010. The results of the analysis showed that LRYGB was associated with complete resolution of GERD symptoms in 62.8% of the patients (symptoms were stable in 17.6% and worse in 2.2 %). For those who underwent LSG, 84.1% continued to have GERD symptoms, and 9.0% reported worsening of symptoms. Pallati and colleagues (2014) also used the same database (BOLD) to compare the efficacy of various bariatric procedures on the improvement of GERD symptoms, 36,938 patients out of 116,136 registered in the database from 2007–2009), had evidence of GERD before undergoing a bariatric surgery. After excluding patients undergoing concomitant hernia repair or fundoplication, 22,870 patients with 6 months follow-up were included in the analysis. 14,078 of these patients underwent RYGB, 8,207 LAGB, and 585 underwent LSG procedures. The analysis showed that GERD symptom score was significantly improved with the three surgeries, with the highest improvement reported with RYGB (56.5%) followed by AGB (46%) and SG (41%). Worsening of symptoms occurred in 2% of patients undergoing RYGB (4.6% with SG, and 1.2% with LAGB). The remainder of patients had no change in their GERD status. The study did not show any objective measure of GERD improvement. The results of Dupree et al and Pallati et al's analyses of data obtained from the Bariatric Outcomes Longitudinal Database should be interpreted cautiously. These were retrospective analyses influenced by the quality of the database and the extent of variables/patient characteristics it includes, such as

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alcohol consumption, cigarette smoking and other factors that have a potential impact on GERD. In addition, according to the authors the documented data on GERD was only based on the use of acid suppression medication with no objective data to confirm the gastroesophageal reflux e.g. 24-hour pH monitoring. Varban and colleagues (2015), retrospectively analyzed data from the Michigan Bariatric Surgery Collaborative (MBSC) registry to assess the use of acid-reducing medication (ARM) at one year after bariatric surgery in morbidly obese patients. Approximately 50% of the patients were reported to have GERD at baseline. 51% of those who underwent RYGB had GERD, and 40.6% of them were using an ARM at baseline, compared to 29.2% at 1-year after surgery. It was also reported that 19.2% of the patients not using ARM at baseline started using one after RYGB.

Conclusion:

- Due to the nature of the published studies, lack of comparison groups and objective outcome assessment, it is hard to determine whether the observed improvement of GERD symptoms were due to a direct effect of gastric bypass and reduction of abdominal pressure, or due to a placebo effect, masking of GERD by the change in diet after surgery, or undervaluation of the disease due to satisfaction with weight loss.
- There is insufficient published evidence to determine the comparative effectiveness and safety of gastric bypass surgery to Nissen fundoplication or other standard medical or endoscopic procedures used for the treatment of severe GERD in morbidly obese patients.
- There is insufficient published evidence to determine the long-term safety and efficacy of gastric bypass surgery in reducing GERD symptoms morbidly obese patients.
- There is insufficient published evidence to determine the effect gastric bypass surgery on the progression or regression of Barrett's esophagus in morbidly obese patients with GERD

Articles: The literature search did not reveal any randomized controlled trial that compared gastric bypass surgery to other standard medical or surgical treatment for severe GERD in obese patients with or without Barrett's esophagus. The empirical studies on gastric bypass surgery for patients with GERD were all observational studies that assessed the impact of RGYB on GERD in morbidly obese patients that underwent the surgery either as an initial operation or after a failed fundoplication surgery. The search also identified an analysis using a prospective database (Bariatric Outcomes Longitudinal Database) for patients who underwent bariatric surgery by a participant in the American Society of Metabolic and Bariatric surgery center of Excellence program; a recent meta-analysis that compared RYGB versus laparoscopic sleeve gastrectomy to treat morbid obesity-related comorbidities including GERD; and a number case series on the role of RYGB for failed antireflux surgery. The use of bypass surgery for a failed fundoplication as well as the comparison of different bariatric surgeries were outside the scope of the current review. The largest observational study with the longer follow-up duration was selected for critical appraisal. Madalosso CA, Gurski RR, Callegari-Jacques SM, et al. The Impact of Gastric Bypass Gastroesophageal Reflux Disease in Morbidly Obese Patients. Ann Surg. 2016 Jan; 263(1):110-116. See Evidence Table 1.

The use of Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Intragastric balloons for the treatment of obesity or morbid obesity

BACKGROUND

Obesity is a chronic disease that is strongly associated with numerous conditions including cardiovascular disease (heart failure, stroke, hypertension), diabetes mellitus, sleep apnea, cancers, osteoarthritis and disability [1]. The prevalence of obesity has been increasing and it is projected that, by the year of 2030, 20% of the world's adult population will be obese [1]. Obesity can be categorized based on body mass index (BMI). A body mass index (BMI) between 25 kg/m2 and 29 kg/m2 is considered overweight while obesity is defined as BMI greater than 30 kg/m2 [1]. Moderate and morbid obesity are defined as BMI between 30 to 39.9 kg/m2 and BMI >40 kg/m2 respectively [2]. The cause of obesity is multifactorial [3]. First, the chronic imbalance between energy intake and energy expense leads to obesity. Second, interactions between genetic, behaviors, social and environmental factors play a crucial role in the pathogenesis of obesity[3].

Management of obesity includes conservative therapy such as diet modification, physical exercise, psychosocial interventions, pharmacotherapy such as orlistat and bariatric surgery[4]. A study investigating the effect of diet on weight loss [5] showed that hypocaloric diet and exercise alone led to a non-sustainable weight reduction (5%). Similarly, pharmacotherapy results in additional benefits. Bariatric surgery seems to be an alternative method for long term management [6] but can be associated with adverse events. Despite the benefits of these approaches, some patients might not be able to lose weight or sustain weight loss.

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For patients who have failed weight reduction with diet and exercise alone, intragastric balloon (IGB) may be an alternative. Performed for the first time in 1980s [7], IGB is a minimally invasive procedure that diminishes the capacity of the stomach resulting in premature satiation and prolonged satiety and subsequently induces weight loss; Other mechanism resides in the regulation of hormone-mediated signal transduction [4, 8]. IGB insertion is a restrictive procedure in which a spherical, saline-filled balloon is endoscopically positioned in the stomach under mild sedation and left inflated for six months [9]. One or two balloons can be inserted and different fill volumes (400-700ml) and fill media have been described. These include air, fluid, combination of air and fluid. Some balloons can be swallowed and do not need to be endoscopically inserted.

Early designs were removed from the market due to severe complication such as migration resulting in intestinal obstruction but the introduction of the dual-balloon from ReShape Medical (San Clemente, CA) is believed to reduce the risks of obstruction and perforation. The ReShape Integrated Dual Balloon System (Reshape Dual Balloon) and ORBERA Intragastric Balloon System were approved by the Food and Drug Administration (FDA) in 2015.

03/21/2016: MTAC REVIEW
Intragastric balloons for the treatment of obesity or morbid obesity
Evidence Conclusion: Zheng et al., 2015 [4]: Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis (Evidence table 1) This meta-analysis aimed to confirm the safety and efficacy of intragastric balloon (IGB). The outcomes measured were weight loss, BMI, percent excess weight loss and safety. 11 RCTs were included after searching MEDLINE, EMBASE, CENTRAL plus other sources through December 2014. The quality of included studies was assessed, and weighted mean differences were determined from the analysis. Modest efficacy for intragastric balloon as a conjunction therapy to conservative therapy was achieved in six months group (SMG). The incidences of the adverse events were higher in the intervention group (IGB plus conservative therapy). The authors concluded that short-term efficacy for 6 months treatment of intragastric balloon in association with conservative therapy is clinically significant. However, the findings should be interpreted with cautious due to several limitations. Ponce et al., 2015 [10] The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity (Evidence table 2): This is a RCT, multicenter, sham controlled which aimed to investigate the safety and effectiveness of a dual balloon system plus diet and exercise in the treatment of obesity compared to diet and exercise alone. The study measured the percent excess weight loss (%EWL), the proportion of DUO patients achieving at Least a 25% EWL as primary outcomes. 326 patients were randomized to dual gastric balloon plus diet and exercise (Duo) or Sham endoscopy plus diet and exercise (Diet) and followed up for 48 weeks. The %EWL was greater in Duo arm compared to Diet arm. The response rate among DUO was 48.8 in the intention to Treat ($p<0.0001$). Improvements in comorbid conditions were observed. The authors concluded that the reshape duo balloon had an excellent safety profile and was significantly more effective than diet and exercise. However, the results should be interpreted with cautious due to many limitations. Other small sample size RCTs [11-14] with short follow-up duration and meta-analysis [15], suggested that IGB may be safe and effective on the short term. Conclusion: The results indicate that intragastric balloon in combination with diet and exercise may have a short-term effect in reducing weight in obese patients. The findings also indicate that intragastric balloon may be temporarily more effective than diet and exercise. However, the follow-up duration was insufficient to determine the safety and durability of the outcomes. There is insufficient data to determine whether intragastric balloon is safer and more effective than standard weight loss surgeries or pharmacotherapy. Intragastric balloon was reviewed by Interregional New Technology Committee (INTC) which concluded that “based on low-quality evidence of benefit as compared to conventional weight-loss management and lack of long-term evidence regarding safety and efficacy, it could not be concluded whether or not the benefit of intragastric balloon outweigh the harms at this time”.
Articles: The search identified a meta-analysis [4] and RCTs comparing IGB to diet and exercise and or sham balloon. However, the search did not identify RCTs making direct comparison between IGB and standard weight loss surgeries or pharmacotherapy. The following studies were selected for critical appraisal: Zheng, Y., M. Wang, et al. (2015). "Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis." Journal of translational medicine 13(1): 1-9. See Evidence Table 1. Ponce, J., G. Woodman, et al. (2015). "The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity." Surgery for Obesity and Related Diseases 11(4): 874-881. See Evidence Table 2.

The use of Intragastric balloons for the treatment of obesity or morbid obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Intragastric Balloons for Treatment of Obesity. Lansdale, PA: Hayes, Inc; 3/2018

Applicable Codes

Adjustable Gastric Banding--

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® /HCPC Codes	Description
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Biliopancreatic Diversion with Duodenal Switch (Scorpinaro Procedure)—
Single Anastomosis Duodeno-Ileal Bypass with sleeve gastrectomy (SADI-S)
reserved for patients with BMI >50

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)

Gastroplasty--

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Not Medically Necessary when criteria in the applicable policy statements listed above are met

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CPT® Codes	Description
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty

Vertical Sleeve Gastrectomy (VSG)--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty

Lap Band Port Revision--

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

Roux-en-Y Gastric Bypass (RYGB)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

Gastric Electrical Stimulation (GES) for Obesity--

Considered Not Medically Necessary:

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

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95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Intragastric Balloon--

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No Specific Codes – *often submitted as 43999 Unlisted procedure, stomach*	

Gastric Bypass for GERD--

Considered Not Medically Necessary:

CPT® Codes	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

EndoGastric Solutions StomaphyX™ Endoluminal Fastener—

Considered Not Medically Necessary:

CPT® Codes	Description
No Specific Codes – *often submitted as 43289 or 43499*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
02/01/1999	07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC], 03/5/2013[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC] 01/06/2015 [MPC], 05/05/2015 [MPC],	10/04/2022

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	03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC] , 09/04/2018[MPC], 09/03/2019[MPC] , 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2015	KP-516: Medical policy has been revised to highlight treatment for bariatric complications and repeat bariatric surgical procedure criteria.
09/01/2015	Revised Laparoscopic Sleeve Gastrectomy L34166 and L34157
04/05/2016	Added MTAC Review for Intragastric Balloons
06/20/2016	Added MTAC Review for Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD)
09/28/2017	Added Gastric Electrical Stimulation codes
11/02/2017	PEBB criteria updated
02/14/2017	Added non-covered procedures from CWQI
03/27/2018	Added LCA A53028
04/17/2018	Added Hayes review – Intragastric Balloons for Treatment of Obesity
10/06/2020	MPC approved the MCG 24th ed. guideline for Intragastric Balloon Device: A-0970
06/01/2021	MPC approved the updated recommendations to the current hybrid criteria for Bariatric Surgery to lower the qualifying age from 20 to 18 years or older. Requires 60-day notice, effective date 11/01/2021.
08/19/2021	Noted that PEBB is adopting Kaiser Permanente Commercial clinical review criteria for bariatric surgery procedures effective 01/01/2022.
09/07/2021	Removed reference to retired Noridian LCD L34157 as its content was added to LCA A53028 in 2016.
10/05/2021	MPC approved the removal of Vertical Banded Gastroplasty (VBG) from covered procedures. Requires 60-day notice, effective date 03/01/2022.
01/07/2022	Removed PEBB criteria from the commercial plan. PEBB will be using KP criteria effective 01/01/2022.
10/04/2022	MPC approved to adopt Adolescent indications for Bariatric Surgery. 60-day notice required. MPC approved coverage for Biliopancreatic Diversion with Duodenal Switch and Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S). 60-day notice required.

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KAISER PERMANENTE®

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Clinical Review Criteria
Basivertebral Nerve Ablation

- Intracept® Intraosseous Nerve Ablation System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Basivertebral Nerve Ablation"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Basivertebral nerve ablation (BVN), such as with the Intracept System (Relievant Medsystems Inc.), is intended to relieve chronic low back pain (CLBP) thought to be due to vertebrogenic causes by inhibiting the transmission of pain signals (Freburger et al., 2009).

The Intracept Procedure is a treatment option for patients who have not had adequate pain relief with conservative therapy. The minimally invasive procedure can be performed in the outpatient setting. Treatment-refractory CLBP and magnetic resonance imaging–detected Modic 1 or Modic 2 changes are listed as key indications by the manufacturer and were inclusion criteria in the identified studies. In the reviewed clinical studies, patients with symptomatic spinal stenosis, radiculopathy, disk protrusion, or spondylolisthesis were excluded.

The Intracept System consists of the Intracept Introducer Cannula, the Intracept Curved Cannula, the Intracept Radiofrequency Probe, and the Intracept Radiofrequency Generator. According to Relievant Medsystems Inc., the

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cannula is inserted via minimally invasive procedure under fluoroscopic guidance through the pedicle using a transpedicular approach. The Curved Cannula is then passed through the Introducer to create a channel to the trunk of the BVN. Next, the Radiofrequency Probe is inserted via the Curved Cannula and placed at the BVN. Bipolar radiofrequency (RF) energy is provided using the Radiofrequency Generator to accomplish the thermal ablation of the BVN. The RF destruction of the BVN is intended to stop the transmission of pain.

Insights

Clinical studies consistently indicate benefits in patient-oriented outcomes after the Intracept System was used to treat chronic low back pain (CLBP) believed to be due to vertebrogenic origin; however, a randomized controlled trial (RCT) did not convincingly indicate advantages over sham. A second RCT did find short-term treatment advantages over continued standard care; however, given the placebo response observed in the sham-controlled RCT, the findings of this open-label study should be interpreted carefully. Although 1 spine specialty society noted Intracept may be considered, no other guidance documents were identified and payer policies are generally unfavorable, possibly due to the lack of comparative research convincingly demonstrating advantages over treatment alternatives.

Reference

Hayes. Hayes Evolving Evidence Review. Intracept Intraosseous Nerve Ablation System (Relievant Medsystems) for Treatment of Adults with Low Back Pain. Dallas, TX: Hayes; July 9, 2020. Retrieved April 20, 2021 from https://evidence.hayesinc.com/report/eer.intraceptlbp4481.

Medical Technology Assessment Committee (MTAC)

Intraosseous Radiofrequency Basivertebral Nerve Ablation for the Treatment of Adults with Chronic Vertebrogenic Low Back Pain

06/24/2022: INTC Review

Evidence Conclusion: Low-certainty evidence from two RCTs, two open-label extensions, two prospective case series, and one post-hoc RCT analysis (Total N = 429 patients; 330 patients received Intracept and had data analyzed) demonstrate that the Intracept procedure improved function, pain, and QOL in adults with CLBP (≥6 months) with some patients showing durable and sustained improvements up to 5 years post-procedure. However, these improvements were not significantly different (either statistically or clinically) when compared to sham procedure at 3 months and up to 12 months. Statistically and clinically important differences in these outcomes favoring Intracept were found in one open-label RCT comparing Intracept June 24, 2022 | SCPMG Evidence-Based Medicine Services Page 3 of 35 KAISER PERMANENTE CONFIDENTIAL INFORMATION – internal use only, do not distribute outside of KP to standard care up to 3 months but given the context of no significant differences between Intracept and sham procedure at this timepoint, the results of this RCT must be interpreted with caution. Intracept appears to be relatively safe as no serious adverse events occurred during these clinical trials, but adverse events were not uncommon, with complication rates ranging from 2.7% to 25% among Intracepttreated patients across studies. Complications rates were similar between treatment and control arms in comparative RCTs. One of the most common AEs was postoperative leg pain due to a pedicle breach, often at levels L5 or S1. As with all interventional procedures, the experience of the operator and accurate patient selection will correlate with the safety of the procedure. More rigorous RCTs not funded and/or affiliated with the manufacturer and with longer-term comparative data are needed to validate any findings of benefit of the Intracept procedure over sham or standard care. Additionally, trials evaluating the comparative effectiveness of Intracept compared to other minimally invasive procedures are needed to determine its role among several available interventions for CLBP.

Articles: The Medical Technology Assessment Team (MTAT) reviewed the evidence on intraosseous radiofrequency basivertebral nerve ablation (i.e., Intracept®) for the treatment of chronic low back pain on June 24, 2022. Based on 2 RCTs of two different comparisons, 2 follow-up open-label extensions of these RCTs, 2 prospective case series, and 1 post-hoc RCT analysis, conclusions are limited by the overall low quantity and quality of the body of evidence.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC	Description

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Codes	
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)
C9752	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum
C9753	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure)

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Date Created	Date Reviewed	Date Last Revised
04/21/2021	05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved adoption of non-coverage policy for basivertebral nerve ablation. Requires 60-day notice, effective October 1, 2021.

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Clinical Review Criteria
Eating Disorders – Anorexia Nervosa

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Criteria

Inpatient Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa, Adult: Inpatient Care (B-001-IP) and Anorexia Nervosa, Child or Adolescent: Inpatient Care (B-016-IP) for medical necessity determinations.

Partial Hospitalization
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Partial Hospitalization Program (B-KP-001-PHP v2 eff 12.01.2021) for medical necessity determinations.

Intensive Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Intensive Outpatient Program (B-KP-001-IOP v2 eff 12.01.2021) for medical necessity determinations.

Acute Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Outpatient Care (B-KP-001-AOP v2 eff 12.01.2021) for medical necessity determinations.

Residential Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Residential Care (B-KP-001-RES v2 eff 12.01.2021) for medical necessity determinations.

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG (formerly Milliman) Care Guidelines for determining appropriate levels of care based on symptoms and functional

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impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Care Guidelines are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."
Inpatient anorexia nervosa services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient anorexia nervosa treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

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Date Created	Date Reviewed	Date Last Revised
6/30/2010	7/6/2010 MDCRPC, 5/3/2011 MDCRPC, 3/6/2012MDCRPC,1/08/2013MDCRPC, 11/05/2013MPC, 2/04/2014MPC, 12/02/2014MPC, 10/06/2015MPC, 10/04/2016MPC, 08/01/2017MPC, 06/05/2018MPC, 06/04/2019MPC, 06/02/2020MPC, 06/01/2021MPC , 06/07/2022MPC , 06/06/2023MPC	07/06/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
12/01/2015	Revised criteria to reflect GHC hybrid policy
03/31/2016	Removed 60-day notice
02/07/2017	MPC approved to adopt MCG 20th Ed. guidelines for Inpatient & Acute Outpatient Care; MPC approved to adopt hybrid (GHC/MCG) guidelines for Residential, Partial Hospital and Intensive Outpatient
09/05/2017	MPC approved to adopt KP-MCG hybrid criteria for all levels of care
06/02/2020	Removed diagnosis codes
07/06/2021	MPC approved to adopt MCG 25th Edition for Anorexia Nervosa, Adult: Inpatient Care (B-001-IP) and Anorexia Nervosa, Child or Adolescent: Inpatient Care (B-016-IP). MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Anorexia Nervosa: Partial Hospitalization Program (B-KP-001-PHP), Anorexia Nervosa: Intensive Outpatient Program (B-KP-001-IOP), Anorexia Nervosa: Outpatient Care (B-KP-001-AOP) and Anorexia Nervosa: Residential Care (B-KP-001-RES). Requires 60-day notice, effective date 12/01/2021.

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Clinical Review Criteria
Eating Disorder - Binge, Bulimia and Specified Eating Disorders

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Criteria

Inpatient Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Adult: Inpatient Care (B-005-IP) and Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Child or Adolescent: Inpatient Care (B-021-IP) for medical necessity determinations.

Partial Hospitalization
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Partial Hospital Program (B-KP-005-PHP) for medical necessity determinations.

Intensive Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Intensive Outpatient Program (B-KP-005-IOP) for medical necessity determinations.

Acute Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Outpatient Care (B-KP-005-AOP) for medical necessity determinations.

Residential Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Residential Care (B-KP-005-RES) for medical necessity determinations.

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

Definitions
Binge Eating
According to DSM 5:
An episode of binge eating is characterized by both of the following

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1. Eating, in a discrete period of time (e.g. usually less than a 2-hour period), an amount of food that is definitely larger than what most people would eat in a similar period of time under similar circumstances.
2. A sense of lack of control over eating during the episode (e.g. a feeling that one cannot stop eating or control what or how much one is eating).

The binge-eating episodes are associated with 3 (or more) of the following:

1. Eating much more rapidly than normal
2. Eating until feeling uncomfortably full
3. Eating large amounts of food when not feeling physically hungry
4. Eating alone because of feeling embarrassed by how much one is eating.
5. Feeling disgusted with oneself, depressed, or very guilty afterward.
   There is marked distress regarding binge eating.

The binging occurs, on average, at least once a week for 3 months, and is not associated with recurrent use of inappropriate compensatory behavior and does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

Overeating

According to DSM 5 - In Overeating, there is a consumption of excess food, with no engagement in inappropriate compensatory behavior and no excessive concern with body shape and weight characteristics that are seen in bulimia nervosa.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG (formerly Milliman) Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Care Guidelines are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Inpatient anorexia nervosa services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient anorexia nervosa treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	07/06/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

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MPC Medical Policy Committee

Revision History	Description
03/31/2016	Removed 60 day hold notice
02/07/2017	MPC approved to adopt hybrid (MCG/GHC) guidelines for all levels of care
12/05/2017	MPC approved to adopt hybrid (MCG/KP) guidelines for all levels of care
06/02/2020	Removed diagnosis codes
07/06/2021	MPC approved to adopt MCG 25th Edition for Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Adult: Inpatient Care (B-005-IP) and Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Child or Adolescent: Inpatient Care (B-021-IP). MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Partial Hospital Program (B-KP-005-PHP), Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Intensive Outpatient Program (B-KP-005-IOP), Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Outpatient Care (B-KP-005-AOP) and Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Residential Care (B-KP-005-RES). Requires 60-day notice, effective date 12/01/2021.

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Clinical Review Criteria
Eating Disorder – Unspecified

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Criteria

Inpatient Behavioral Health Level of Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders: Inpatient Behavioral Health Level of Care, Adult (B-904-IP) and Eating Disorders: Inpatient Behavioral Health Level of Care, Child or Adolescent (B-913-IP) for medical necessity determinations.

Partial Hospitalization
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Partial Hospital Behavioral Health Level of Care, Adult (B-KP-904-PHP) and Eating Disorders, Partial Hospital Behavioral Health Level of Care, Child or Adolescent (B-KP-913-PHP) for medical necessity determinations.

Intensive Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-904-IOP) and Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-913-IOP) for medical necessity determinations.

Acute Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Outpatient Behavioral Health Level of Care, Adult (B-KP-904-AOP) and Eating Disorders, Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-913-AOP) for medical necessity determinations.

Residential Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Residential Behavioral Health Level of Care, Adult (B-KP-904-RES) and Eating Disorders, Residential Behavioral Health Level of Care, Child or Adolescent (B-KP-913-RES) for medical necessity determinations.

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

Definitions
Binge Eating
According to DSM 5:
An episode of binge eating is characterized by both of the following:

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1. Eating, in a discrete period of time (e.g. usually less than a 2-hour period), an amount of food that is definitely larger than what most people would eat in a similar period of time under similar circumstances.
2. A sense of lack of control over-eating during the episode (e.g. a feeling that one cannot stop eating or control what or how much one is eating).

The binge-eating episodes are associated with 3 (or more) of the following:

1. Eating much more rapidly than normal
2. Eating until feeling uncomfortably full
3. Eating large amounts of food when not feeling physically hungry
4. Eating alone because of feeling embarrassed by how much one is eating.
5. Feeling disgusted with oneself, depressed, or very guilty afterward.

There is marked distress regarding binge eating.
The binging occurs, on average, at least once a week for 3 months, and is not associated with recurrent use of inappropriate compensatory behavior and does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

Overeating
According to DSM 5 - In Overeating, there is a consumption of excess food, with no engagement in inappropriate compensatory behavior and no excessive concern with body shape and weight characteristics that are seen in bulimia nervosa.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG (formerly Milliman) Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Care Guidelines are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."
Inpatient anorexia nervosa services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient anorexia nervosa treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
6/30/2010	7/6/2010 MDCRPC, 5/3/2011 MDCRPC, 3/6/2012MDCRPC,1/08/2013MDCRPC , 11/05/2013MPC , 2/04/2014MPC, 12/02/2014MPC, 10/06/2015MPC, 10/04/2016MPC, 08/01/2017MPC, 06/05/2018MPC, 06/04/2019MPC, 06/02/2020MPC, 06/01/2021MPC, 06/07/2022MPC ,	07/06/2021

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	06/06/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/02/2015	Changed documentation of GHC hybrid to MCG
12/01/2015	Revised criteria to reflect approval of MCG 19th Ed.
02/07/2017	MPC approved to adopt hybrid (MCG/GHC) guidelines for all levels of care
12/05/2017	MPC approved to adopt hybrid (MCG/KP) guidelines for all levels of care
06/02/2020	Removed diagnosis codes
07/06/2021	MPC approved to adopt MCG 25th Edition for Eating Disorders: Inpatient Behavioral Health Level of Care, Adult (B-904-IP) and Eating Disorders: Inpatient Behavioral Health Level of Care, Child or Adolescent (B-913-IP). MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Eating Disorders, Partial Hospital Behavioral Health Level of Care, Adult (B-KP-904-PHP) and Eating Disorders, Partial Hospital Behavioral Health Level of Care, Child or Adolescent (B-KP-913-PHP), Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-904-IOP) and Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-913-IOP), Eating Disorders, Outpatient Behavioral Health Level of Care, Adult (B-KP-904-AOP) and Eating Disorders, Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-913-AOP) and Eating Disorders, Residential Behavioral Health Level of Care, Adult (B-KP-904-RES) and Eating Disorders, Residential Behavioral Health Level of Care, Child or Adolescent (B-KP-913-RES). Requires 60-day notice, effective date 12/01/2021.

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Clinical Review Criteria
Mental Health – Inpatient Services

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 2 and Chapter 4.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Inpatient Behavioral Health Level of Care, Adult

Kaiser Permanente has elected to use the MCG* Inpatient Behavioral Health Level of Care, Adult (B-KP-901-IP) for medical necessity determinations.

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Inpatient Psychiatric services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

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Inpatient psychiatric treatment is utilized when it is the most effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Date Created	Date Reviewed	Date Last Revised
08/01/2006	05/07/2013[MPC] ,03/04/2014 [MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	07/11/2017

[MPC] Medical Policy Committee

Revision History	Description
01/06/2016	MPC approved to adopt 19th Edition MCG guidelines
09/06/2016	MPC approved to adopt 20th Edition MCG guidelines
07/11/2017	MPC approved to adopt 21st Edition MCG guidelines

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
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Clinical Review Criteria
Mental Health Services – Intensive Outpatient Services

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 – Covered Medical and Other Health Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the following MCG* guidelines for medical necessity determinations:

- Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-901-IOP v2 eff 12.01.2021)
- Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-902-IOP v2 eff 12.01.2021)

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

In January 2007, Kaiser Permanente Behavioral Health Service adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated annually.

Mental health outpatient services are provided or authorized with the overall goals of assessing and improving the member's symptoms and function. Also Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on

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an individual's social, medical, and/or occupational functioning."

Service authorization decisions also based on the member's contractually covered services and MCG Care Guidelines Behavioral Health criteria.

Applicable Codes

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/01/2016	11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/06/2021

[MPC] Medical Policy Committee

Revision History	Description
09/05/2017	MPC approved to adopt KP hybrid criteria
07/06/2021	MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-901-IOP) and Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-902-IOP). Requires 60-day notice, effective date 12/01/2021.

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Clinical Review Criteria
Neuropsychological Testing

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 of the coverage manual, 80.2 - Psychological Tests and Neuropsychological Tests.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Neuropsychological Testing (B-805-T) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Exclusions

Neuropsychological testing will not be authorized for any of the exclusions found in the member's contract, including learning disabilities.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of PCP or specialty notes that describe the members cognitive deficits

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The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2007, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning." The MCG Care Guidelines do not include any criteria regarding neuropsychological testing thus the need to develop these criteria. These criteria are based upon literature from the American Psychological Association as well as the Clinical Neuropsychological Society regarding standards for psychological testing.

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Explanation to Differentiate Psychological and Neuropsychological Testing

Psychological Testing

Psychological tests assess a range of mental abilities and attributes, including achievement, personality, cognitive, and behavioral functioning. They are used to address a variety of questions about people's functioning, diagnostic classification, co-morbidity, and choice of treatment approach. For example, personality tests and inventories evaluate the thoughts, emotions, attitudes, and behavioral traits that contribute to an individual's interpersonal functioning. The results of these tests determine an individual's personality strengths and weaknesses, and may identify certain disturbances in personality, or psychopathology. Basic assessment of memory and intellectual functioning is also part of psychological testing.

Psychological Testing is indicated in the following circumstances:

- Differential diagnosis of behavioral or psychiatric conditions when the member's history and symptomatology are not readily attributable to a particular psychiatric diagnosis and the questions to be answered by testing could not be resolved by a psychiatric/diagnostic interview, observation in therapy, or an assessment for level of care at a mental health or substance abuse facility; or
- Develop treatment recommendations after the member has been tried on various medications and/or psychotherapy, has not progressed in treatment, and continues to be symptomatic.
- A patient has had a recent mild traumatic brain injury (i.e. concussion) and a screening of his/her cognitive status is desired early on after the injury to answer more immediate questions about cognitive and emotional functioning as well as ability to return to accustomed life's activities at that time.
- There has been a recent change in patient's memory (i.e. within past six months) or changes in memory have been present for extended period of time and it is not significant or complex. Psychological testing can clarify /determine extent of memory and cognitive change and impact on functioning.
- Majority of Pre-surgical evaluations (spinal cord stimulator, complex spine surgery, bariatric surgery)

Neuropsychological Testing

Neuropsychological testing is a sub classification of psychological testing and is a well-established method for evaluating patients who demonstrate complex cognitive or behavioral abnormalities Areas of brain functioning that are typically assessed are basic motor and sensory-perceptual functions; attention, concentration, speed and efficiency of information processing; learning and memory functions; language and verbal intellectual functions; spatial, perceptual and nonverbal intellectual functions; reasoning and complex problem solving functions; and executive regulatory and monitoring functions. A Neuropsychological evaluation is both a neuro-diagnostic procedure, as well as the most in-depth and comprehensive way of identifying in individual's cognitive strengths and limitations.

Neuropsychological testing is indicated when:

- There is the presence of a significant cognitive deficit, mental status abnormality, behavioral change, or memory loss that requires quantification, monitoring of change, diagnostic clarification, differentiation of cause (e.g., organic cognitive vs. psychiatric disease) and determination of the patient's ability to function.
- There is the presence of a known neurological disease or condition (i.e. dementia, CVA, traumatic brain injury, multiple sclerosis, Parkinson's, etc.) and testing is needed to determine the impact of the disease or condition on brain functioning and the patient's ability to function in his or her personal situation. Patients with mild traumatic brain injury (TBI) should not be referred prior to 3 months post injury as the majority of mild TBI patients recover essentially back to baseline over the initial 3 months post injury period.
- There is a medically complex, not well understood case with memory and cognitive deficits as significant presenting concerns and/or barriers to effective functioning.
- Further assessment of a patient with persisting cognitive symptoms or complaints is needed where a range of previous workups including but not limited to a Neurology consult, brain imaging, Mini-mental State Examination (MMSE), a previous Clinical Psychological evaluation and so forth have been negative or non-contributory.
- As part of pre and post procedure evaluation for deep brain stimulation procedure for Parkinson's Disease

Summary

When to refer for psychological testing as compared to neuropsychological testing:

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- If the primary concern is differential diagnosis (is it bipolar. is it psychosis, is there a personality disorder present), refer for psychological testing
- Majority of pre-surgical evaluation refer for psychological testing.
- There is the presence of cognitive and/or memory concerns and it has not been present for extended period of time (i.e. greater than six months), and there is not the presence of other complicated medical conditions, refer for psychological testing.
- If cognitive, memory and behavioral concerns have been present for extended period of time, there are significant medical complications, and/or previous assessments (psychological evaluation, neurology consult) have been unable to clarify diagnosis or functioning status of patient, refer for neuropsychological testing.
- Pre-surgical evaluation for deep brain stimulation for Parkinson's Disease is referred for neuropsychological testing

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
96125	Standardized cognitive performance testing (eg, Ross Information Processing Assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
09/07/2006	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/02/2016	Removed LCD
04/05/2016	Adopted MCG 19th Edition
11/07/2017	Adopted MCG 21st Edition
09/04/2018	Adopted MCG 22nd Edition
07/31/2020	Added CPT code 96121
09/01/2020	Removed deleted CPT codes 96118-96120 and G0505; Added CPT codes 96136-96139 and 96146

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Clinical Review Criteria
Mental Health Services – Acute Outpatient

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Criteria

Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 – Covered Medical and Other Health Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare members

Kaiser Permanente has elected to use the following MCG* guidelines for medical necessity determinations:

- Outpatient Behavioral Health Level of Care, Adult (B-KP-901-AOP v2 eff 12.01.2021)
- Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-902-AOP v2 eff 12.01.2021)

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

The MCG guidelines will be used for determination of Initial Authorization of Service, Continued Authorization of Service, and for Discontinuation of Service.

Exclusions:
Outpatient mental health services may not be authorized or reimbursed if any of the contract exclusions are met.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

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Background

In January 2007, Kaiser Permanente Behavioral Health Service adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated annually.

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Mental health outpatient services are provided or authorized with the overall goals of assessing and improving the member's symptoms and function. Also, Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Service authorization decisions also based on the member's contractually covered services and MCG Care Guidelines Behavioral Health criteria.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
012/15/2006	09/04/2012[MPC],07/02/2013[MPC],05/06/2014[MPC],03/03/2015[MPC],01/05/2016[MPC], 11/01/2016[MPC], 07/10/2018 [MPC] ,07/09/2019 [MPC],07/07/2020 [MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/06/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Date of Revision	Revision History
11/01/2016	MPC approved to adopt MCG 20th Ed.: Acute Outpatient Behavioral Health Level of Care, Adult (B-901-AOP) and Acute Outpatient Behavioral Health Level of Care, Child or Adolescent (B-902- AOP)
09/05/2017	MPC approved to adopt KP hybrid criteria
07/06/2021	MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Outpatient Behavioral Health Level of Care, Adult (B-KP-901-AOP) and Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-902-AOP). Requires 60-day notice, effective date 12/01/2021.

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Date Sent: 6/28/23
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Clinical Review Criteria
Mental Health – Partial Hospitalization & Day Treatment

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 2 and Chapter 4.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Partial Hospital Behavioral Health Level of Care, Adult (B-KP-901-PHP) for medical necessity determinations.

Kaiser Permanente has elected to use the MCG* Partial Hospital Behavioral Health Level of Care, Child or Adolescent (B-KP-902-PHP) for medical necessity determinations.

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Exclusions:
Partial hospital mental health services will not be authorized if any of the exclusion criteria are met as referenced in the member's coverage contract.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

In January 2007, Kaiser Permanente Behavioral Health Service adopted and integrated into its clinical review criteria, the MCG for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Criteria are updated annually.

Mental health partial hospital services are provided or authorized with the overall goals of assessing and improving the member's symptoms and function. In addition, Kaiser Permanente Behavioral Health Services

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operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Partial hospitalization designates a structured, intensive, multidisciplinary treatment program that provides psychiatric, medical, and nursing care which meets the standards for licensure as a partial hospital program. The program is usually offered in an inpatient setting, but the patient goes home in the evening and on weekends. The program delivers a highly structured environment and 20 or more hours of treatment per week. Patients are expected to participate 5 to 7 days per week. Patient must be medically stable and live near treatment setting.

Service authorization decisions are also based on the member's contractually covered services and MCG Guidelines Behavioral Health criteria.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/14/06	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 02/04/2014[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	07/11/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/02/2016	Adopted MCG 19th Ed. guidelines
07/11/2017	Adopted MCG 21st Ed. guidelines

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Clinical Review Criteria
Mental Health – Residential Care

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 2 and Chapter 4.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

These criteria apply to members whose contract includes coverage for residential care.

Medical Necessity Criteria for Coverage of Admission:
Inpatient Mental Health Residential Admission for a mental health clinical disorder is medically necessary when MCG* Guidelines, current edition, Admission Guidelines for Residential Acute Behavioral Health Level of Care are met.
Residential Acute Behavioral Health Level of Care, Adult ORG: B-KP-901-RES (BHG)
Residential Acute Behavioral Health Level of Care, Child or Adolescent ORG: B-KP-902-RES (BHG)

Medical Necessity Criteria for Coverage of Continued Stay:
Continued Inpatient Mental Health Residential Stay for a mental health clinical disorder is medically necessary when MCG* Guidelines, current edition, Continued Care Guidelines for Residential Acute Behavioral Health Level of Care are met.
Residential Acute Behavioral Health Level of Care, Adult ORG: B-KP-901-RES (BHG)
Residential Acute Behavioral Health Level of Care, Child or Adolescent ORG: B-KP-902-RES (BHG)

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Exclusions:
Residential psychiatric services will not be authorized for any exclusion criteria referenced in a member's contract.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Residential care is intended for patients who need around-the-clock behavioral care but do not need the high level of physical security and frequency of psychiatric and nursing intervention that are available on an inpatient unit. Patients admitted to residential care are unlikely to need physical restraint or extensive nursing care. Psychiatrists typically round less often and nurses are generally on site for fewer hours each day than on an inpatient unit. However, the treatment team is generally composed of a similar mix of professionals as on an inpatient unit. Although it is sometimes assumed that residential care implies a longer length of stay than inpatient care, randomized controlled trials (RCTs) have shown that residential care is an efficacious short-term alternative to inpatient care for voluntary patients with urgent behavioral health conditions.

In January 2007, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Mental health, acute residential treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for mental health acute residential treatment, and with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively and safely in a less restrictive and disruptive level of care. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

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Date Created	Date Reviewed	Date Last Revised
09/11/2008	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	07/11/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/02/2016	Adopt MCG 19th Ed. guidelines
07/11/2017	Adopt MCG 21st Ed. guidelines

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Clinical Review Criteria
Psychological Testing

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	**Chapter 15 of the coverage manual, 80.2 - Psychological Tests and Neuropsychological Tests**
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Psychological Testing (B-807-T) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

In January 2007, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Explanation to Differentiate Psychological and Neuropsychological Testing

Psychological Testing

Psychological tests assess a range of mental abilities and attributes, including achievement, personality, cognitive, and behavioral functioning. They are used to address a variety of questions about people's functioning, diagnostic classification, co-morbidity, and choice of treatment approach. For example, personality tests and inventories evaluate the thoughts, emotions, attitudes, and behavioral traits that contribute to an individual's interpersonal functioning. The results of these tests determine an individual's personality strengths and

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weaknesses, and may identify certain disturbances in personality, or psychopathology. Basic assessment of memory and intellectual functioning is also part of psychological testing.

Psychological Testing is indicated in the following circumstances:

- Differential diagnosis of behavioral or psychiatric conditions when the member's history and symptomatology are not readily attributable to a particular psychiatric diagnosis and the questions to be answered by testing could not be resolved by a psychiatric/diagnostic interview, observation in therapy, or an assessment for level of care at a mental health or substance abuse facility; or
- Develop treatment recommendations after the member has been tried on various medications and/or psychotherapy, has not progressed in treatment, and continues to be symptomatic.
- A patient has had a recent mild traumatic brain injury (i.e. concussion) and a screening of his/her cognitive status is desired early on after the injury to answer more immediate questions about cognitive and emotional functioning as well as ability to return to accustomed life's activities at that time.
- There has been a recent change in patient's memory (i.e. within past six months) or changes in memory have been present for extended period of time and it is not significant or complex. Psychological testing can clarify /determine extent of memory and cognitive change and impact on functioning.
- Majority of Pre surgical evaluations (spinal cord stimulator, complex spine surgery, bariatric surgery)

Neuropsychological Testing

Neuropsychological testing is a sub classification of psychological testing and is a well-established method for evaluating patients who demonstrate complex cognitive or behavioral abnormalities Areas of brain functioning that are typically assessed are basic motor and sensory-perceptual functions; attention, concentration, speed and efficiency of information processing; learning and memory functions; language and verbal intellectual functions; spatial, perceptual and nonverbal intellectual functions; reasoning and complex problem solving functions; and executive regulatory and monitoring functions. A Neuropsychological evaluation is both a neuro-diagnostic procedure, as well as the most in-depth and comprehensive way of identifying in individual's cognitive strengths and limitations.

Neuropsychological testing is indicated when:

- There is the presence of a significant cognitive deficit, mental status abnormality, behavioral change, or memory loss that requires quantification, monitoring of change, diagnostic clarification, differentiation of cause (e.g., organic cognitive vs. psychiatric disease) and determination of the patient's ability to function.
- There is the presence of a known neurological disease or condition (i.e. dementia, CVA, traumatic brain injury, multiple sclerosis, Parkinson's, etc.) and testing is needed to determine the impact of the disease or condition on brain functioning and the patient's ability to function in his or her personal situation. Patients with mild traumatic brain injury (TBI) should not be referred prior to 3 months post injury as the majority of mild TBI patients recover essentially back to baseline over the initial 3 months post injury period.
- There is a medically complex, not well understood case with memory and cognitive deficits as significant presenting concerns and/or barriers to effective functioning.
- Further assessment of a patient with persisting cognitive symptoms or complaints is needed where a range of previous workups including but not limited to a Neurology consult, brain imaging, Mini-mental State Examination (MMSE), a previous Clinical Psychological evaluation and so forth have been negative or non-contributory.
- As part of pre and post procedure evaluation for deep brain stimulation procedure for Parkinson's Disease

Summary

When to refer for psychological testing as compared to neuropsychological testing:

- If the primary concern is differential diagnosis (is it bipolar. is it psychosis, is there a personality disorder present), refer for psychological testing.
- Majority of pre surgical evaluation, refer for psychological testing.
- There is the presence of cognitive and/or memory concerns and it has not been present for extended period of time (i.e. greater than six months), and there is not the presence of other complicated medical conditions, refer for psychological testing.
- If cognitive, memory and behavioral concerns have been present for extended period of time, there are significant medical complications, and/or previous assessments (psychological evaluation, neurology consult) have been unable to clarify diagnosis or functioning status of patient, refer for neuropsychological testing.
- Pre surgical evaluation for deep brain stimulation for Parkinson's Disease is referred for neuropsychological testing

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Creation Date	Review Dates	Date Last Revised
09/26/2006	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/02/2016	Adopted MCG 19th Ed. guidelines
12/06/2016	Adopted MCG 20th Ed. guidelines
10/03/2017	Adopted MCG 21st Ed. guidelines
08/07/2018	Adopted MCG 22nd Ed. guidelines
08/04/2020	Added CPT code 96130

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Clinical Review Criteria
Biofeedback

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Biofeedback Therapy (30.1).
Local Coverage Determinations (LCD)	3/14/2007 Noridian retired ***LCD Biofeedback Therapy Policy (L14443)***. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L14443 for determining medical necessity.
Local Coverage Article	None

For FEHB plans: See the member's contract for specific coverage details

For Non-Medicare Members

I. Biofeedback is covered for **ONE of the following**:
   A. Fecal Incontinence
   B. Tension or migraine headache if pharmacologic treatment inadequate or not indicated, by **1 or more** of the following:
      - Breast-feeding patient
      - History of long-term, frequent, or excessive use of analgesic or medications that can aggravate headache
      - Insufficient or no response to multiple pharmacologic treatment attempts
      - Intolerance of multiple pharmacologic treatment attempts
      - Patient attempting to become pregnant
      - Pregnant patient

II. The following indications for biofeedback are not medically necessary. There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
   - Abdominal pain, recurrent
   - Anxiety disorders
   - Arthritis
   - Asthma
   - Autism
   - Back pain
   - Bell's palsy

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- Bruxism and sleep bruxism
- Cardiovascular disorders
- Chronic fatigue
- Chronic pain
- Chronic obstructive pulmonary disease (COPD)
- Depression
- Epilepsy
- Facial palsy
- Fibromyalgia
- Hand hemiplegia
- Insomnia
- Knee pain
- Low back pain
- Low vision
- Lupus [systemic lupus erythematosus (SLE)]
- Motor function after stroke, injury, or lower limb surgery
- Movement disorders
- Myalgia or muscle pain
- Neck pain
- Orthostatic hypotension in patients with a spinal cord injury
- Post-traumatic stress disorder (PTSD)
- Raynaud's disease
- Side effects of cancer chemotherapy
- Temporomandibular joint disorders
- Tinnitus
- Urinary disorders
- Post-prostatectomy urinary dysfunction
- Urinary incontinence in adults
- Urinary retention
- Vesicoureteral reflux
- Voiding dysfunction
- Vestibulodynia, vulvodynia, vulvar vestibulitis

Biofeedback for the Treatment of Urinary Incontinence
See the Treatment of Urinary Incontinence criteria document

Neurofeedback for ADHD (EEG Biofeedback)
See the Neurofeedback criteria document

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Biofeedback is a technique designed to help individuals self-regulate certain physiological processes that are not normally considered to be under voluntary control or responses that are ordinarily easily regulated, but for which regulation has broken down due to trauma or disease. This is achieved through conveying audio and visual information about physiological processes such as blood pressure, heart rate, skin temperature, galvanic skin response (sweating), or muscle tension in real-time to raise awareness of physiological activities and train patients to control them. The goal of biofeedback is that eventually the patient will learn to control physiologic response without the aid of monitors (Kaiser 2011, Roditi 2011).

Different types of biofeedback include (Kaiser 2011, Magnusson 2008, Kapitza 2010):

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- Electroencephalography (EEG) biofeedback, which monitors the activity of brain waves linked to different mental states.
- Electrocardiography (EKG) biofeedback, which tracks the patient's heart rate.
- Electromyography (EMG) biofeedback, which uses sensors to measure tension in specific muscles.
- Galvanic skin response biofeedback, which uses sensors to signal anxiety based on the activity of a person's sweat glands and the amount of perspiration on the skin.
- Skin temperature biofeedback, which involves attaching sensors to the fingers or feet to indicate stress when the temperature is low.
- Respiratory biofeedback, which uses sensors to measure breathing.
- Postural biofeedback, which uses sensors to measure body motion.

Biofeedback has been used to treat a variety of medical conditions such as urinary incontinence, ADHD, headaches, anxiety, and back pain.

Evidence and Source Documents

Biofeedback for Anxiety Disorders
Biofeedback for Back Pain
Biofeedback for Migraine and Tension Headaches
Biofeedback for Treatment of Urinary Incontinence

Medical Technology Assessment Committee (MTAC)

Biofeedback for Anxiety Disorders

02/13/2012: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of generalized anxiety disorders.

Articles: The literature search revealed several studies evaluating biofeedback for the treatment of generalized anxiety disorder. All of the studies had small sample sizes and the majority were published more than 20 years ago. The newest study was a randomized controlled trial that evaluated the efficacy of a biofeedback enhanced virtual reality system. This study was not selected for review as the treatment group contained only 4 subjects (Gorini, 2010). Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of generalized anxiety disorders.

The use of biofeedback for anxiety disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Biofeedback for Chronic Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: The Kaiser review included four randomized controlled trials that ranged in size from 42 to 128 patients. Findings from these trials suggest that pain and disability improved with biofeedback, cognitive behavioral therapy (CBT), biofeedback plus CBT, placebo biofeedback, and rehabilitation; however, no significant differences were found between biofeedback and the other treatments. The body of evidence was limited by heterogeneity in the patient population, biofeedback protocols, and comparator treatments. Additionally, the studies were small with short follow-up periods. Biofeedback vs. CBT alone vs. waitlisted controls (Newton-John 1995) • N=44 • Type of biofeedback: Electromyography biofeedback (EMG). • Both the biofeedback and the CBT groups showed improvement in pain intensity, pain belief, and depression; however, there no significant differences between the two groups. There was no improvement in the waitlisted control group. Biofeedback plus CBT vs. CBT alone vs. waitlisted controls (Glombiewski 2010) • N=128 • Type of biofeedback: EMG • Both the combined group and the CBT alone group showed improvement in pain intensity compared to waitlisted control; however, there no significant differences between the two groups. Active biofeedback vs. placebo biofeedback (Kapitza 2010) • N=42 • Type of biofeedback: Respiratory biofeedback. • There was no significant difference in pain reduction between the two groups. Biofeedback plus rehabilitation vs. rehabilitation alone (Magnusson 2008) • N=47 • Type of biofeedback: Postural biofeedback. • Although the combined group showed improvements in pain, range of motion, and quality of life, the study did not report if they were statistically significantly different from the rehabilitation alone group. Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of chronic back pain.

Articles: The 2007 American College of Physicians and the American Pain Society (ACP/APS) guideline evaluated the evidence on biofeedback for chronic back pain. The studies evaluating this treatment were of poor quality and therefore they were unable to evaluate the net benefits of biofeedback. The conclusions of the ACP/APS guideline were supported by a 2009 BMJ clinical evidence review (Chou 2009). In 2011, the Kaiser Permanente Medical Technology Assessment Team (MTAT) also reviewed biofeedback for the treatment of

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chronic back pain. No additional studies were identified after the Kaiser review. The following technology assessments were selected for review: Kaiser Permanente TPMG New Medical Technologies. Biofeedback for chronic neck and low back pain. May 2011.

The use of biofeedback for back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Biofeedback for Migraine and Tension Type Headaches
02/13/2012: MTAC Review
Evidence Conclusion: A recent meta-analysis that included 94 RCTs and quasi-experimental studies evaluate the efficacy of different types of biofeedback for the treatment of migraine and tension-type headaches. Results from this analysis suggest that biofeedback was more effective than no treatment for headache reduction in patients with migraine headache (small effect size); however, there was no significant difference between biofeedback and placebo or relaxation. For patients with tension-type headache, biofeedback was significantly more effective than no treatment, placebo, and relaxation for headache reduction (small to medium effect size). There was no significant difference between biofeedback treatment modalities for the reduction of migraine headache pain (Nestouric 2008). A meta-analysis is only as good as the studies that it includes. The studies included in the meta-analysis had several limitations. • The majority of the studies included in the meta-analysis were small. The mean number of subjects per study was 40 for migraine studies and 45 for tension-type headache studies. • The type and number of sessions of biofeedback varied. • Several studies failed to describe basic treatment and patient characteristics. • Several studies used unstructured diagnostic systems. Conclusion: Migraine • Results from a recent meta-analysis suggest that biofeedback may be more effective than no treatment, but not placebo or relaxation for headache reduction. Tension-type headaches • Results from a recent meta-analysis suggest that biofeedback may be more effective than no treatment, placebo, and relaxation for headache reduction. • Another recent BMJ Clinical Evidence review found insufficient evidence to determine whether EMG biofeedback is effective for treating chronic tension-type headaches (Krishnan 2009).
Articles: Several meta-analyses and randomized controlled trials (RCTs) were identified that evaluated the efficacy of biofeedback for the treatment of migraine and tension-type headaches. The most recent meta-analysis was selected for review. An RCT published after the meta-analysis was also identified that evaluated the efficacy of a pain program that included education and training in pain theory plus EMG and temperature biofeedback compared to the pain program alone. This study was not selected for review due to methodological limitations (i.e., small sample size, high loss to follow-up, power not addressed, and baseline characteristics were not presented) (Mullally 2009). The following study was selected for review: Nestoriuc Y, Martin A, Rief W, Andrasik F. Biofeedback treatment for headache disorders: a comprehensive efficacy review. Appl Psychophysiology Biofeedback. 2008; 33:125-140. See Evidence Table.

The use of biofeedback for Migraine and Tension-type Headaches does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
HCPC	**Description**

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Codes	
E0746	Electromyography (EMG), biofeedback device

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Date Created	Date Reviewed	Date Last Revised
03/06/2012	03/06/2012[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 05/02/2017[MPC], 02/06/2018[MPC], 08/07/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	06/23/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/02/2017	Added indication to cover migraine headaches
07/18/2018	Added FEHB language
06/23/2020	Removed deleted CPT code 90911; Added CPT codes 90912 and 90913
12/02/2022	Added Retired LCD L14443

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Clinical Review Criteria
Bioimpedance Spectroscopy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Bioimpedance Spectroscopy***, for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Bioimpedance Spectroscopy (A-0667) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider

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Background

Lymphedema is a chronic progressive disorder of the lymphatic system characterized by interstitial accumulation of protein rich fluid. This occurs when lymphatic transport is reduced causing lymphatic stasis and subsequent protein accumulation within tissues. Accumulation of protein and fluid in the tissues triggers an inflammatory response and swelling that eventually leads to fibrosis. Primary lymphedema is rare and results from congenital anatomic abnormalities of the lymphatic system such as lymphatic hypoplasia or dysfunction of lymphatic valves. Secondary lymphedema on the other hand, is more common and may result from disease, trauma, surgery, or radiation therapy. In the United States, the most common cause of secondary lymphedema is malignancy and its related treatment, particularly in breast cancer patients treated with axillary surgery and/or

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radiation therapy (Warren 2007).

The proportion of women who develop breast cancer-related lymphedema (BCRL) is estimated to range from 3-15% for women who had sentinel node biopsy and up to 49% among those who underwent axillary lymph node dissection. This big variation in reported incidence of lymphedema is due to lack of a standardized assessment and differences in diagnostic criteria. Lymphedema may cause limb swelling, heaviness, pain, pitting of the skin, tightness, inflammation, reduced mobility, and impaired limb function (Taylor 2006, Smoot 2011).

Accurate assessment of lymphedema may facilitate earlier diagnosis and monitoring of treatment response. Physical assessment of BCRL is performed by comparing the affected versus the unaffected arm, or by comparing postoperative with preoperative measurements. Physical measurements used include limb circumferential assessment with a tape measure, and limb volume measurement using water displacement or optoelectrical perometry (also known as infrared volumetry). Circumferential measurement is the most common clinical assessment measure used. Limb circumference is used to calculate volume by assuming either cylindrical or truncated cone geometry. It thus indirectly measures the limb volume and may be confounded by changes in muscle and fat mass. In addition, it may be hard to use for the hand due to its irregular shape. Water volumetry or displacement, in which the limb is lowered in a water tank, has been considered by many as the reference method for determining limb volume. It is a reliable method and provides a way of including volumetric measurements of the hand or foot in the total limb volume measurements. However, water displacement cannot distinguish changes due to fat or muscle from extracellular fluid accumulation. The Perometer is an opto-electrical device that has a square frame in which the extended extremity is placed. The frame emits infrared light and slides up and down scanning the patient's extremity and recording cross sectional information every 3 mm. Limb volume is then calculated based on the assumption that the cross-section is an ellipse or circle. Many investigators consider perometry the modern gold standard for the assessment of limb volume. It is however, bulky in size, not available in most clinics, and cannot be used for bed- ridden patients. In more challenging cases radiologic imaging studies as lymphoscintigraphy, magnetic resonance imaging, or computerized tomography may be necessary to diagnose lymphedema (Sander 2002, Warren 2007, Jain 2010, Czerniec 2010, Smoot 2011).

While circumference and volume measures are reliable measures for changes in limb volume, they are not specific to lymphedema. Bioimpedance analysis (BIA) or bioimpedance spectroscopy (BIS) has been proposed as an alternate method to differentiate the extracellular fluid compartment from the total limb volume. It attempts at measuring lymph volume directly and detecting early increase in the extracellular fluid at a subclinical stage of lymphedema before it is manifests as a change limb volume.

BIS is a noninvasive procedure that uses skin electrodes to pass a low-level alternating current through the limb and measures the opposition or impedance to the flow of this current. Current flows along the path of least resistance through the body and thus follows tissues with the highest water content. Tissues as fat and bone act as insulators, while electrolyte body fluids conduct electrical current and as the fluid increases, impedance to current flow decreases, i.e. changes in impedance are inversely proportional to the volume of the extracellular fluid in the extremity the level of impedance is not only a function of the type of tissue, but also the frequency of the current. At low frequencies, cell membranes are non-conductive and current passes only through the extracellular fluid, while at high frequencies, the current passes through cell membranes in addition to the extra-and intracellular fluids. BIS thus gives a measure of electrical impedance and not volume (Warren 2007, Jain 2010, Czerniec 2010).

Medical Technology Assessment Committee (MTAC)

Bioimpedance Lymph Analysis

06/20/2011: MTAC REVIEW

Evidence Conclusion: The 2010 report prepared for the AHRQ assessed the diagnosis and treatment of secondary lymphedema in general, not specifically for cancer breast-related lymphedema. However, the reviewers indicated that most of the diagnostic studies involved patients with breast cancer. They noted that based on the evidence from the studied reviewed, there does not appear to be a gold standard for grading or measuring the severity of lymphedema. However, based on the extent of use and consistent evidence for reliability and validity, the reviewers of the AHRQ report recommend that measures of limb volume or circumference be considered the gold standard for diagnosing secondary lymphedema. They indicated that

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there was very little evidence to allow making conclusions about the reliability of bioimpedance lymph analysis (BIA) which was listed among other tests. BIA was found to have good validity when compared with tape measured circumference or perometry, but lower correlation coefficients than those for the circumference-displacement comparisons. The AHRQ report also indicated that the diagnostic testing studies do not provide sufficient evidence to determine whether any of the test methods would influence the choice of lymphedema treatment or patient outcome. Two more recent studies published after the AHRQ report and critically appraised for this MTAC review do not provide any additional evidence on the accuracy, validity or reliability of BIA, or on its impact on patient management or outcome.
Articles: The search revealed a recent comprehensive review on the diagnosis and treatment of secondary lymphedema prepared for the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment (TA) Program in May 2010. The literature search for this AHRQ report was made through January 2010. Two more recent studies that compared the accuracy and/or reliability of BIS to other physical measures used for the assessment of breast cancer-related lymphedema were critically appraised. Czerniec SA, Ward LC, Refshauge KM, et al Assessment of breast cancer-related arm lymphedema--comparison of physical measurement methods and self-report. *Cancer Invest.* 2010; 28:54-62. See Evidence Table. Smoot BJ, Wong JF, Dodd MJ. Comparison of diagnostic accuracy of clinical measures of breast cancer-related lymphedema: Area under the curve. *Arch Phys Med Rehabil*. 2011; 92:603-610. See Evidence Table.

The use of bioimpedance lymph analysis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
0358T	Bioelectrical impedance analysis whole body composition assessment, with interpretation and report
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

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Date Created	Date Reviewed	Date Last Revised
07/05/2011	07/05/2011[MPC], 05/01/2012[MPC], 03/05/2013[MPC], 01/07/201[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	01/07/2014

[MPC] Medical Policy Committee

Review History	Description

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Clinical Review Criteria
Blepharoplasty

- Blepharoptosis
- Brow Lift

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Blepharoplasty, Eyelid Surgery, and Brow Lift (L36286)
Local Coverage Article	Billing and Coding: Blepharoplasty, Eyelid Surgery, and Brow Lift (A57191)

For Non-Medicare Members

Blepharoplasty, blepharoptosis repair, or brow ptosis repair will be considered medically necessary when **ONE of the** following are met:

I. **Upper eyelid reconstructive blepharoplasty** is considered medically necessary and NOT cosmetic when **ONE of the following** is met:

A. Blepharoplasty for the following diagnoses may be considered medically necessary for an affected upper or lower lid without meeting visual loss criteria:
   1. Trichiasis
   2. Ectropion
   3. Entropion
   4. Exposure keratitis
   5. Painful blepharospasm refractory to medical management

B. In the absence of one of the conditions listed above **unilateral or bilateral upper lid** may be considered medically necessary for reconstructive purposes when the operative eye **meets ALL of the following** criteria:

1. Visual field less than 20° above central fixation – (untaped eye) OR limited to 10 to 15 degrees (untaped eye) laterally
2. Frontal or lateral photograph demonstrates visual field limitation consistent with the visual field examination, AND
3. Does not have unstable myasthenia gravis or a thyroid condition (No concerns about stability raised by Neurology for myasthenia gravis patients and normal thyroid lab if patient has pre-existing thyroid disease)
4. **ALL of following** information must be submitted:
   - Visual fields, including physician interpretation
   - MRD1 (marginal reflex distance) measurement
   - Documentation of clinically decreased vision
   - Lateral and full-face photographs

II. **Upper eyelid ptosis (blepharoptosis) repair** may be considered medically necessary for reconstructive purposes when the operative eye meets **ALL of the following** criteria:

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A. Documented complaints of interference with vision or visual field-related activities causing significant functional impairment (difficulty reading or driving due to eyelid position
B. Photographs demonstrate the eyelid at or below the upper edge of the pupil
C. Visual field less than 20° above central fixation
D. MRD1 (marginal reflex distance from pupil center to upper eyelid) of 2.0mm or less
E. Does not have unstable myasthenia gravis or a thyroid condition
F. **ALL of the following** information must be submitted
   - Visual fields, including physician interpretation
   - MRD1 (marginal reflex distance) measurement
   - Documentation of clinical decreased vision
   - Lateral and full-face photographs

III. **Brow ptosis repair** may be considered medically necessary for reconstructive purposes when **ALL of the following** criteria are met:
A. Photographs demonstrate the eyebrow is below the super orbital rim
B. Visual field less than 20° above central fixation
C. MRD1 of 2.0 mm or less
D. Cannot be corrected by upper lid blepharoplasty alone
E. Frontal or lateral photograph demonstrates visual field limitation consistent with the visual field examination, AND
F. Does not have unstable myasthenia gravis or a thyroid condition
G. **ALL of the following** information must be submitted:
   - Visual fields, including physician interpretation
   - MRD1 (marginal reflex distance) measurement
   - Documentation of clinically decreased vision
   - Lateral and full-face photographs

IV. **Blepharoplasty in anophthalmia** is considered medically necessary when the upper eyelid position interferes with the fit of eye prosthesis in the socket.

V. Blepharoplasty of the lower lids for excessive skin that does not correct a functional issue is considered **cosmetic** under the member benefit.

If requesting this service, please send the following documentation to support medical necessity:

- Signed clinical notes supporting a decrease in peripheral vision and/or upper field vision and excessive upper/lower lid skin
- Supporting pre-op lateral and full-face photographs
- Documented subjective patient complaints which justify functional surgery (vision, ptosis, etc.)
- Visual fields, including physician interpretation and recommendations (when applicable)
- MRD1 (marginal reflex distance) measurement (for blepharoptosis or brow ptosis repair)

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Background

This service is covered when it is medically indicated and determined not to be for cosmetic. The Medicare coverage language includes the identification of how to determine medical necessity. This is the language that has been adopted by Kaiser Permanente.

In order to determine coverage, the clinical history submitted by the requesting physician should include the reason for the surgery and the identification of the procedure to be done.

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Evidence and Source Documents

References:
Kaiser Permanente Coverage Contract Language
Medicare Coverage Manual /PROW Criteria

Medicare Part B News 180, March 2000, topic 1143 entry #5782, applicable to Washington State. And effective in March 2000 as of publish date.

Applicable Codes

Blepharoplasty – Medicare – Considered Not Medically Necessary:

CPT® Codes	Description
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad

Blepharoplasty – Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Blepharoplasty – Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Blepharoptosis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
67909	Reduction of overcorrection of ptosis

Repair of Brow ptosis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description

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67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

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Date Created	Date Reviewed	Date Last Revised
04/30/1998	05/04/2010[MDCRPC], 03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/27/2015	Added new LCD L35536
09/08/2015	Revised LCD to L36281, L34886, L35008
10/04/2016	Added indication: OR limited to 10 to 15 degrees (untapped eye) laterally
06/15/2019	Added indication: Does not have unstable myasthenia gravis or a thyroid condition (No concerns about stability raised by Neurology for myasthenia gravis patients and normal thyroid lab if patient has pre-existing thyroid disease)
07/07/2020	Added Medicare LCA (A57191)
08/04/2020	Added Medicare LCA (A57642); MPC approved to adopt updates to clinical criteria for non-Medicare, separating indications for blepharoplasty and blepharoptosis repair.

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Clinical Review Criteria
Osteogenic (Bone) Stimulators

- Non-invasive Electrical Stimulators
- Implantable Electric Stimulators
- Ultrasonic Stimulators

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Osteogenic Stimulators (150.2)
Local Coverage Determinations (LCD)	Osteogenesis Stimulators (L33796)
Local Coverage Article	Osteogenesis Stimulators (A52513)

For Non-Medicare Members

Electric Bone Growth Stimulators (Non-invasive and Implantable)
Kaiser Permanente has elected to use the Bone Growth Stimulators, Electrical and Electromagnetic (A-0565) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Ultrasonic Bone Growth Stimulators
Kaiser Permanente has elected to use the Bone Growth Stimulators, Ultrasonic (KP-0414) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Orthopedics/podiatry)
- Copies of last 12 months of x-rays of involved area

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Background

Electrical stimulation has been used as treatment for nonunion of fractures since the early 1950's with a reported success rate of 80-85%. New devices have made the use of this method of treatment more attractive. Bone Stimulators are covered in Kaiser Permanente plans that include coverage for durable medical equipment. The criteria for coverage had previously been part of the Durable Medical Equipment Formulary. The average contracted cost of the device is $3,000. Because of the renewed attention on this mode of treatment by Kaiser

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Permanente orthopedists, the referral management staff requested that clearer criteria be developed for reviewing coverage requests (1/97).

Fracture healing is a highly complex biological process. The healing process is delayed in approximately 10% of the 6 million fractures that occur annually in the United States. A portion of these delayed unions do not heal by 9 months after fracture and are categorized as non-unions (Hadjiargyrou,1998). There are two types of bone growth stimulators: electric and ultrasonic.

Electrical stimulation has been found to offer a reasonable means of treatment for nonunion that have failed to respond to previous bone grafting over an extended period of time. The effective use of electrical stimulation devices requires an understanding of the various principles and concepts employed by the four types of stimulators currently available. While the exact mechanism of electrically induced osteogenesis is uncertain, current theories indicate that several factors probably are involved, and more than one mechanism may be responsible.

Ultrasound, a form of mechanical energy that is transmitted through and into biological tissues, has a variety of diagnostic and therapeutic clinical applications. Research on the use of ultrasound to accelerate the healing of fractures has been done largely using animal models. For example, a study with rabbits found that bones exposed to ultrasound healed in about half the time as untreated bones. Data from animal models suggest that ultrasound may accelerate healing by increasing the blood flow at the fracture site (Rubin, 2001).

Exogen (Smith and Nephew) manufacturers a low-intensity ultrasound device for treating fractures, Sonic Accelerated Fracture Healing System (SAFHS). According to the manufacture, the SAFHS system is a portable, battery-operated device that produces ultrasonic waves of 30 milliwatts per cm^2 (comparable to ultrasound intensity levels used on sonograms for fetal monitoring). Patients apply the ultrasound waves directly to the fracture site.

The FDA approved the use of low-intensity ultrasound for fresh fractures in 1994 based on two randomized controlled trials and Exogen's registry data. In 2000, the FDA extended the use of ultrasound to treating established non-unions.

Medical Technology Assessment Committee (MTAC)

Ultrasonic Bone Stimulator

10/10/2001: MTAC REVIEW

Evidence Conclusion: *Fresh fractures:* Two of the RCTs (Heckman, Kristiansen) were conducted by some of the same investigators. Both found a significantly shorter time to healing for fractures in patients treated with an ultrasonic bone stimulator healed than those treated with a placebo device. Both studies had similar methodological flaws, the most serious of which was that neither study had a primary intention to treat analysis and about 30% of fractures were not included in the analysis. Both studies include a brief description of a secondary intention-to-treat analysis which found statistically significant differences between the ultrasonic bone stimulation and placebo groups; no point estimates, tables or figures were included to support these analyses. Both studies were funded by Exogen and included co-authored by an Exogen employee which could bias the study design and analysis. A third RCT was conducted by investigators without financial ties to Exogen. That study did not find a significant difference in time to radiographic healing between patients receiving ultrasonic bone stimulation versus placebo. This was a small study which may not have had sufficient statistical power to detect a difference if one existed. The threats to validity in the RCTs limit the ability to draw conclusions about the effect of ultrasonic bone stimulation on health outcomes among patients with fresh fractures. *Non-union fractures:* There were no published articles to evaluate the efficacy of ultrasound treatment to heal non-union fractures.
Articles: The search yielded 35 articles. Articles that were opinion pieces, editorials, reviews or on technical aspects of the treatment of fractures with ultrasound were not reviewed. There were 3 RCTs on the use of ultrasound with fresh fractures. Evidence tables were created for these 3 RCTs. There were no published articles on non-union fractures. There was one published abstract by Gebauer, but insufficient information was given in the abstract to evaluate it as evidence. *Citations for the RCTs reviewed*: Emami A, Petren-Mallmin M, Larsson S. No effect of low-intensity ultrasound on healing time of intramedullary fixed tibial fractures. J Orthop Trauma 1999; 13: 252-7. See Evidence Table. Kristiansen TK, Ryabi JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. J Bone Joint Surg 1997; 79-A: 961-73. See Evidence Table. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF. Acceleration of tibial fracture-healing by non-invasive low-intensity pulsed ultrasound. J Bone Joint Surg 1994; 76-A: 26-34. See Evidence Table

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The use of Ultrasonic Bone Stimulator for treatment of fresh and non-union fractures has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Electrical Bone Growth Stimulator:

CPT® or HCPC Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Ultrasonic Bone Growth Stimulator:

CPT® or HCPC Codes	Description
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Dates Reviewed	Date Last Revised
09/25/1997	06/01/2010[MDCRPC], [04]/05/2011[MDCRPC], [02]/07/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MPC],08/05/2014[MPC],06/02/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC] ,12/04/2018[MPC],12/03/2019[MPC],12/01/2020[MPC],12/07/2021[MPC], 12/06/2022[MPC]	01/08/2019

Revision History	Description
06/11/2015	CPT codes added
01/08/2019	MPC adopted hybrid criteria for Ultrasonic Bone Growth Stimulators (KP-0414)

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Clinical Review Criteria
Benign Prostatic Hyperplasia (BPH) Treatments

- Rezūm System for the Treatment of LUTS due to BPH
- Prostatic Urethral Lift (PUL or UroLift)
- Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Urolift: Local Coverage Article: Urolift (A54044)-RETIRED Noridian retired Local Coverage Article (LCA A54044). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on Kaiser Permanente commercial criteria or literature search.
Kaiser Permanente Medical Policy	Rezūm: Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Rezūm System for the Treatment of LUTS due to BPH," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
UroLift	Covers prostatic urethral lift (e.g., UroLift) as medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when **ALL of the following** criteria are met: A. age 50 or above B. prostate volume < 80 cc on ultrasound imaging C. no obstructive median lobe of the prostate identified on cystoscopy D. failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g.,

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	at least one drug trial from one of the following categories: alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist
Rezūm System for the Treatment of LUTS due to BPH	Water vapor thermal therapy (e.g., Rezūm System) is considered medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL of the following criteria are met: • age 50 years or above • estimated prostate volume ≥ 30 cm3 and ≤ 80 cm3 • failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g., at least one drug trial from one of the following categories: alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist
Prostate artery embolization for benign prostatic hyperplasia (BPH)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Benign prostatic hyperplasia (BPH), also known as prostate gland enlargement, is a common urologic condition that affects 14-30% of men 50 years of age or older. The enlarged prostate is often associated with progressive obstructive lower urinary tract symptoms (LUTS), which may impair the quality of life in older men. Common signs and symptoms of LUTS secondary to PBH include nocturia, frequent or urgent need to urinate, difficulty starting urination, weak urine stream or a stream that stops and starts, dribbling at the end of urination, and inability to completely empty the bladder. The severity of these symptoms varies among patients, but they tend to increase with age (Dixon 2016, Darson 2017, Helo 2017).

The treatment of LUTS depends on the patient's symptoms and level of bother. Therapeutic options include

- Watchful waiting (active surveillance) for patients with mild symptoms of LUTS secondary to BPH and for patients with moderate-to-severe symptoms who are not bothered by their symptoms and are not experiencing complications of BPH.
- Lifestyle modification is initially recommended for patients with bothersome LUTS that begin affecting their quality of life.

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- Drug therapy (e.g. alpha-blockers, 5-alpha-reductase inhibitors, muscarinic receptor antagonists and phosphodiesterase 5, inhibitors) is an appropriate and effective treatment for patients with bothersome, moderate to severe LUTS secondary to BPH.
- Surgical intervention is appropriate for patients with moderate-to-severe LUTS, acute urinary retention, or other complications due BPH. Surgery is the most invasive option for BPH management and is generally performed in patients will have failed medical therapy. However, some patients may wish to pursue the most effective therapy as a primary treatment if their symptoms are particularly bothersome (American Urological Association Guideline).

Transurethral resection of the prostate (TURP) and open simple prostatectomy are currently the gold standard surgical interventions. Both are highly effective and provide durable improvement in urinary functional outcomes. However, despite the refinements made in the operative technique, these invasive procedures are associated with perioperative complications and morbidity including bleeding, erectile and ejaculatory dysfunction, urethral stricture, urinary tract infection, and urinary incontinence (Chung 2018, Christidis 2017, Magistro 2017).

Several novel minimally invasive therapies have been developed, or are at different stages of development, with the aim of improving the patients' symptoms and avoiding the adverse outcomes of associated with the more invasive surgeries. Among these therapies are the UroLift System, intraprostatic injectables, temporary implantable nitinol device, image guided robotic waterjet ablation, transurethral microwave therapy (TUMT), convective water vapor energy (WAVE) ablation, prostatic artery embolization, and others. An ideal minimally invasive treatment would be an intervention that can be easily performed in the office or in an outpatient setting, leads to rapid and durable relief of symptoms, is associated with minimal morbidity and recovery time, and preserves the erectile and ejaculatory functions of the patient (Chung 2018, (Magistro 2017).

Rezūm System; NxThera, Inc. Maple Grove, MN) is a minimally invasive transurethral therapy that uses the stored thermal energy in water vapor (steam) to treat the extra prostate tissue that is causing symptoms. Tissue ablation with Rezūm System uses the thermodynamic principle of convection energy transfer in contrast to conductive heat transfer techniques used in the transurethral microwave therapy or transurethral needle ablation. The Rezūm system utilizes radiofrequency (RF) to generate wet thermal energy in the form of water vapor (steam). Once the vapor (103oC) is injected, it disperses through the tissue spaces and immediately changes to liquid releasing and delivering approximately 208 cal of thermal energy in 9 seconds. The target tissue temperature reaches 70o resulting in irreversible and near instantaneous cell death. No thermal effects occur outside the prostate or in the peripheral zone when a transition zone is targeted. In addition, as the vapor is wet thermal energy, there is no charring, desiccation, or carbonization of the treated tissue. The dead tissue will be eventually absorbed by the body through its natural healing response (Dixon 2016, Christidis 2017, Woo 2017 Magistro 2017).

The Rezūm System is composed of a generator containing a radiofrequency power supply to create water vapor from sterile water, and a single use transurethral delivery device that incorporates a standard 4 mm 30o rod lens allowing the procedure to be performed under direct cystoscopic visualization. The tip of the delivery device contains an 18-guage polyether ether ketone needle which has 12 small emitter holes spaced around its tip at 120o intervals to allow for circumferential dispersion of water vapor into the prostate tissue. (Darson 2017, Woo 2017).

The procedure is performed in the clinic or out-patient setting, under cystoscopic guidance and oral sedation. Radiofrequency energy is applied to a few drops of water (0.5ml) to create vapor inside a hand-held device. The patient is placed in the lithotomy position and the delivery device is inserted into the urethra; the total penetrating length of the vapor needle is fixed at 10.25mm. Its tip is visually positioned and inserted approximately 1cm distal to the bladder neck. Once the delivery system is within the prostate, the needle is deployed, and a 9-second burst of water vapor is injected into the prostatic tissue. This disperses rapidly and homogeneously through the tissue spaces and immediately condenses to water releasing the energy stored in the vapor into the cell membranes causing cell death and necrosis. The needle is retracted after each treatment and repositioned in 1cm increments distal from the previous site with the objective of creating adjacent overlapping lesions running parallel to the natural slope of the urethra. Usually 1-3 injections are needed for each lateral lobe and 1-2 injections for the median lobe. The total number of injections may vary according to size of the hypertrophied prostate tissue and the length of the urethra (McVary 2016, Woo 2017, Chung 2018).

Potential procedure-related side effects include acute urinary retention, failure of the procedure requiring secondary surgery, posttreatment dysuria, hematuria, frequency & urgency, hematospermia and urinary tract

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infection. According to the manufacturer, most of these events resolve within 3 weeks of the procedure, but there is a possibility that some may last longer.

Medical Technology Assessment Committee (MTAC)

Convection Radiofrequency Thermal Therapy with Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy

04/21/2018: MTAC REVIEW

Evidence Conclusion:

- There is no published evidence to determine the comparative efficacy and safety of convection radiofrequency thermal therapy with the Rezūm System and transurethral resection of the prostate (TURP), open simple prostatectomy, or other noninvasive intervention currently used in practice for relieving bothersome lower urinary tract symptoms secondary to benign prostatic hypertrophy.
- The published literature on Rezūm System consisted of one relatively small randomized sham- controlled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality.
- The published literature only provides low quality evidence suggesting that treatment with Rezūm System may improve LUTs secondary to BPH compared to sham therapy or no treatment.

Articles: The literature search for studies on the efficacy and safety of Rezūm system for the treatment LUTS secondary to BPH, identified one randomized sham-controlled trial that reported three years follow-up results in 4 publications (McVary 2015, 2016 & 2018, and Roehrborn 2017), as well as three pretest- posttest studies (one small pilot study with 2 years follow up results [Dixon 2012, and 2016] and two retrospective analyses [Darson 2017 and Mollengarden 2017]). All 4 studies were critically appraised. See Evidence Table 1.

The use of Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Rezūm for Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH)

03/04/2019: INTC REVIEW

Evidence Conclusion: There is insufficient evidence to draw a conclusion on use of Rezūm. The existing evidence is of insufficient quantity and quality.

Articles: The published literature on Rezūm System consisted of one relatively small randomized sham-controlled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality. Two indirect comparisons of Rezūm versus other medical therapy trial data were also reviewed.

The available published literature provided low quality evidence suggesting that treatment with Rezūm System may improve LUTs secondary to BPH compared to sham therapy or no treatment.

https://cl.kp.org/pkc/national/cpg/intc/topics/03_04_191.html

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)

03/21/2016: MTAC REVIEW

Evidence Conclusion: Conclusion from INTC review - "Urolift may be viable alternative to TURP for patients with LUTS secondary to BPH. Short-term data from low to moderate quality, industry-funded studies conclude that Urolift is effective and safe. The overall quality of the evidence is low to moderate. However, due to concerns regarding risk of bias in these studies, a definitive conclusion regarding the long-term safety and effectiveness of UroLift cannot be made from existing evidence. Additional, high quality studies with longer follow-up are needed to confirm preliminary findings".

Articles: Since the search did not identify new studies, and because INTC evidence review is recent, their review can be adopted. In addition, the search did not find studies comparing PUL to medical management. See Summary of RCTs.

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)
06/28/2017: MTAC REVIEW

Evidence Conclusion: One study (C Roehrborn et al., 2016) (See Evidence Table 1) assessed the long term (4 years) effectiveness and safety of PUL. PUL was compared to sham control. Characteristics of patients were similar. Patients were randomized to either PUL (N=140) or sham control (N=66) at 19 centers in North America and Australia and followed for 4 years. The authors reported that Urolift improved urinary symptoms, preserved sexual and ejaculatory function with minor adverse events. The authors indicated that durability of these effects needs to be confirmed at 5-year follow-up. The risk of bias is unclear for incomplete outcome data and the major limitation is the high attrition rate. The author of the previous study (Claus Roehrborn et al., 2017) (See Evidence Table 2) confirmed the durability of PUL effects in the 5-year follow-up study. Urinary symptoms (IPSS), BPHII, flow rate (Qmax), QoL, erectile and ejaculation functions were improved and /or preserved with minimal complications. Another abstract was reviewed (Henry Woo). Comparison was made between PUL and sham. This was a crossover study wherein 53 patients were enrolled. Patients were treated with sham, then crossover occurred, and patients were followed for 4 years. Compared to baseline, IPSS, QoL, and BPHII statistically improved at 45%, 49%, and 44% respectively (P<0.001). Flow rate (Qmax) also increased by 50% (P=0.01). Adverse events were mild. Level of evidence: In the first two studies, the risk of bias is unclear for incomplete outcome data and low in other domains of risk of bias assessment; no serious precision or directness issues were identified; findings were consistent; the quality of the study assessed by Modified Jadad Scale is high. The studies provide moderate evidence to support the use of PUL.

Conclusion:

- The long-term effectiveness and safety are based on three articles that compare PUL versus sham over 4 and 5 years. Compared to sham, moderate level of evidence indicates that PUL is effective and durable in patients with LUTS due to BPH on the long-term.
- The technology is also safe with minimal complications.

Articles: Three articles were reviewed: Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalis, D. (2016). Prospective, randomized, blinded study of Prostatic Urethral Lift (pul): four-year results. BJU Int, 117, 19-20. Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Te, A. (2017). PD27-01. 5 year prospective, randomized, controlled study results on the minimally invasive prostatic urethral lift (PUL). J Urol, 197(4), e511. Crossover study on the prostatic urethral lift (pul): 4-year results. Henry Woo, Sydney, Australia; Jack Barkin, Toronto, Canada; Damien Bolton, Heidelberg, Australia; Prem Rashid, Port Macquarie, Australia; Anthony Cantwell, Daytona Beach, FL; William Bogache, Myrtle Beach, SC; Stephen Richardson, Salt Lake City, UT; Ronald Tutrone, Baltimore, MD; James Fagelson, Englewood, CO; Peter Chin, Figtree, Australia

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostate artery embolization for benign prostatic hyperplasia (BPH)
10/14/2019: MTAC REVIEW

Evidence Conclusion:

- Low-quality evidence shows that prostatic artery embolization (PAE) may be less effective than TURP in terms of patient-reported and functional outcomes on the short-term.
- Low-quality evidence suggests that PAE may cause fewer complications than TURP, preserve erectile function, and decrease the duration of hospitalization. More RCTs with enough power and longer follow-up are warranted.
- There is insufficient evidence to compare PAE vs open prostatectomy.

Articles: PubMed search was conducted up to August 8, 2019 with the search terms prostate artery embolization. Other search terms included low urinary tract symptoms or LUTS, and benign prostatic hyperplasia or BPH. The search yielded 7 meta-analyses. Of these, four were retained (two meta-analyses with comparative studies and two with noncomparative studies). The other meta-analyses are included in other references because their findings are similar to that of the two meta-analyses of noncomparative studies retained.
In addition, the search yielded 8 RCTs. Of the 8 RCTs, none was retained (RCTs were either included in meta-analysis or were out of scope). Regarding nonrandomized studies, search yielded 18 studies, but none was included due to their inclusion in the meta-analyses of noncomparative studies. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Prostate artery embolization for benign prostatic hyperplasia (BPH) does not meet the *Kaiser*

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Permanente Medical Technology Assessment Criteria.

Applicable Codes

Urolift - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants

Rezūm –
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

Prostate Artery Embolization (PAE) - Considered Not Medically Necessary:

CPT® Codes	Description
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
ICD-10 Codes	**Description**
N35.010-N35.92	Urethral stricture
N40.0-N40.1	Enlarged prostate (EP)
N40.2-N40.3	Nodular prostate
C61	Malignant neoplasm of prostate

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised

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12/03/2019	12/03/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC]	10/06/2020

Revision History	Description
12/03/2019	Merged all BPH criteria (Urolift, Rezūm, PAE) into one document
12/03/2019	MPC approved non-coverage policy for Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)
05/05/2020	Added diagnosis codes N35.010-N35.92, N40.0-N40.3 and C61 (PAE); Added CPT code 53854 and removed 53899 (Rezum)
10/06/2020	MPC approved medical necessity criteria for Rezūm. Requires 60-day notice, effective date 3/1/2021.

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Clinical Review Criteria
Brachytherapy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	4/01/2016 Noridian retired Local Coverage Determination LCD Brachytherapy: Non-Intracoronary (L34065). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

1) Breast Cancer - Brachytherapy as an adjunct to whole breast radiation is covered when recommended by the treating practitioner. Patients eligible for brachytherapy as a sole treatment alternative to whole breast radiation therapy must meet **ALL of the following** criteria:

   A. Age ≥ 50*
   AND
   B. Diagnosis of unifocal invasive ductal cancer with **ALL** of the following:
      a. Tumor size ≤ 3cm
      b. Negative surgical margins at 2mm
      c. Negative nodal status

   OR

   C. Diagnosis of ductal carcinoma in situ (DCIS) with ALL of the following:
      a. Detected on screening
      b. Low to intermediate nuclear grade
      c. Tumor size ≤ 2.5 cm
      d. Resected with margins negative at ≥ 3 mm

*Age 40-49 meeting requirements above on a case by case basis.

Contraindicated for any of the following:

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A. age < 40
B. lobular disease
C. DCIS that does not meet the indications above
D. EIC
E. anatomic limitations or
F. angiolymphatic space invasion

2) High-Dose Rate Brachytherapy for Prostate Cancer
a) High-dose rate (temporary seed implantation) prostate brachytherapy may be considered medically necessary under the following conditions:
- When combined with external beam radiation as a "boost" or
- When used for early stage prostate disease as monotherapy.

Standard brachytherapy is covered without medical necessity review for:
Coronary Artery Brachytherapy, Intravascular Coronary Brachytherapy
Endobronchial Brachytherapy - Lung Cancer
High-Dose or Low-Dose Brachytherapy for Cervical and Endometrial Cancer
Prostate Cancer

Procedure	Criteria
AccuBoost peripheral breast brachytherapy Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background
Brachytherapy, also called internal radiation therapy, allows a physician to use a higher total dose of radiation to treat a smaller area and in a shorter time than is possible with external radiation treatment. Brachytherapy involves placing a radioactive material directly inside or next to the tumor. It has been proven to be very effective and safe, providing a good alternative to surgical removal of the prostate, breast, and cervix, while reducing the risk of certain long-term side effects.
There are two types of brachytherapy – temporary and permanent. In temporary brachytherapy, the radioactive material is placed inside or near a tumor for a specific amount of time and then withdrawn. Temporary brachytherapy can be administered at a low-dose rate (LDR) or high-dose rate (HDR).
Permanent brachytherapy, also called seed implantation, involves placing radioactive seeds or pellets (about the size of a grain of rice) in or near the tumor and leaving them there permanently. After several weeks or months, the radioactivity level of the implants eventually diminishes to nothing. The inactive seeds then remain in the body, with no lasting effect on the patient.

Evidence and Source Documents
Breast Cancer
Coronary Artery Brachytherapy, Intravascular Coronary Brachytherapy
Endobronchial Brachytherapy - Lung Cancer
High-Dose vs. Low-Dose Brachytherapy for Cervical and Endometrial Cancer
High-Dose Rate Brachytherapy for Prostate Cancer
Prostate Cancer
Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma

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Medical Technology Assessment Committee (MTAC)

Breast Cancer Brachytherapy

BACKGROUND

In the last two decades, the treatment of early-stage breast cancer has shifted from radical mastectomy to breast conserving therapy (BCT). This involves lumpectomy followed by whole breast external beam radiotherapy (WBRT). Several large randomized controlled trials with long-term follow-up showed that BCT has equivalent survival rates to the modified radical mastectomy among patients with early stage breast cancer. In addition, BCT has better cosmesis and less psychological and emotional trauma for women compared to mastectomy. Researchers believe that whole breast irradiation after lumpectomy reduces local breast recurrence by eliminating residual cancer at the surgical site, as well as occult areas of in-situ or infiltrating cancer in remote areas in the breast. The use of BCT is underutilized in the United States mainly due to the long course of conventional whole-breast radiation therapy, which is typically delivered daily 5 days per week for 5 to 7 weeks. This may be a problem for working women, elderly patients, or those living at a considerable distance from a treatment center. WBRT may also delay or be delayed by the initiation of systemic adjuvant chemotherapy. Investigators also found that treating the entire volume of the breast may deliver small radiation doses to the adjacent tissues leading to acute and chronic toxicity to the skin, heart, lung, and contralateral breast (Fisher 1995, 2002, Baglan 2001, Veronesi 2002, Chen 2007, Cuttino 2007). Recently, accelerated partial breast radiation therapy (APBI) has been proposed as an alternative approach to WBRT. APBI involves the treatment of the lumpectomy bed plus a 1-2 cm margin of breast tissue. This is based on the assumption that the microscopic tumor rarely extends 2 cm beyond the initial resection cavity when the margins are negative on final pathologic examination. Reducing the target allows the delivery of APBI and completing the treatment in less than one week. Several methods for delivering APBI were proposed and/or used. These approaches include multicatheter interstitial brachytherapy, balloon catheter brachytherapy, 3-D CRT (conformal radiation therapy) and intraoperative radiation therapy. These techniques are widely different in terms of radiation delivery, degree of invasiveness, length of treatment, and acceptance by radiation oncologists (Chen 2007, Chao 2007). Breast brachytherapy involves the placement of radioactive sources inside the breast to deliver a relatively high dose of radiation to the tissue immediately surrounding the lumpectomy site, and very little dose to the surrounding normal structure. The interstitial multicatheter system, the most common method used, involves the placement of a number of catheters into the breast to guide the radioactive materials to the intended area. Pellets of iridium-192 are then inserted into the catheters over the course of the treatment. The catheters are briefly connected to a dose-rate brachytherapy machine for internal radiation treatment, which takes about ten minutes each. After the course of treatment is completed the catheters are removed. The procedure requires significant technical expertise, and can be difficult and challenging (Chen 2007, Bovi 2007, Haley 2008, Kacso 2008). Balloon-based brachytherapy Several balloon-based brachytherapy devices were developed as an alternative to the interstitial multicatheter system to be more user-friendly to the clinician and more accessible and better tolerated by the patient. The MammoSite brachytherapy (MSB) system (Hologic, Marlborough, MA) was the first developed balloon-based brachytherapy device. It consists of a small balloon connected to an inflation channel and a catheter for the passage of a high dose rate brachytherapy dose (Iridium-1 92 [192Ir]. The device is implanted in the lumpectomy cavity during or following breast surgery. The balloon is inflated with sterile saline containing a small amount of radiographic contrast to a size that completely fills the cavity and ensures conformance of the tissue to the balloon. A computed tomography scan is obtained to assess the balloon conformance to the lumpectomy cavity and determine its symmetry, diameter, distance from skin, planning target volume, and the dose distribution. After treatment is completed in several days, the balloon is deflated, and the catheter is removed. The treatment with the MammoSite device generally delivers 34 Gy in 10 fractions (3.4 Gy /fraction twice daily with a minimum of 6 hours between the fractions on the same day). Investigators recommend the system for patients with ductal carcinoma in situ, invasive ductal carcinoma, and primary tumors with a diameter less than 3cm. It may not be suitable for patients with small breast or for tumors located in the upper inner quadrant because of the requirement for skin-to-cavity distances (Bensaleh 2009, Njeh 2010). Xoft Axxent® (Xoft, Inc., Fremont, CA) electronic brachytherapy is a modified form of balloon-based brachytherapy. Similar to MammoSite, Xoft Axxent consists of a balloon catheter that is percutaneously inserted into the lumpectomy cavity. The system uses 50 kiloVolt (kV) X-ray source (an electronic radiation source) rather than radioisotope, such as iridium-192 high dose rate (HDR) source. The x-ray source consists of a miniature x-ray tube that is inserted in the balloon catheter and delivers the radiation therapy to the patient. The system may be operated at variable currents and voltages to change the dose rate and penetration properties. The Xoft Axxent does not require a high-dose rate afterloader unit, or treatment in a shielded vault. Another potential advantage is the lower energy dose deposited in adjacent normal tissues, compared to other forms of balloon brachytherapy. It is unknown if these advantages would be outweighed by a potential harm of fat necrosis as a result of a significant dose inhomogeneity (Strauss 2009, Dickler 2009). SenoRx Contura device (SenoRx, Inc, Aliso Viejo, CA) differs from MammoSite in that it has multiple lumens for passage of 192Ir HDR source. In addition to the central lumen, the Contura balloon has 4

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surrounding channels to accommodate the HDR source. The surrounding channels have 5 mm offset around the central channel. The approach provides additional flexibility and has the potential of improving normal tissue sparing. The device includes a port which can be connected to suction to remove seroma fluid or air in an effort to improve conformity (Strauss 2009, Njeh 2010). Image guided radiation therapy: AccuBoost peripheral breast brachytherapy. The AccuBoost® peripheral breast brachytherapy system (Advanced Radiation Therapy of Billerica, MA) was developed to provide a means of delivering partial breast irradiation treatment regimen noninvasively under mammographic image guidance. The AccuBoost system consists of three main components: (1) A conventional mammography unit to immobilize the breast and localize the lumpectomy site. (2) Computed Radiography (CR) system to provide radiographic images of the lumpectomy cavity (and/or implanted fiducial markers) for cavity/ margin localization at the beginning of each fraction. The CR system can also record the exit dose distribution and provide information on the therapeutic dose. (3) AccuBoost Applicators: high dose rate (HDR) Ir192 brachytherapy source remote afterloading system to deliver brachytherapy in a peripheral noninvasive manner. The applicators are made from tungsten in the form of half-cylinders. The patient's breast is compressed to a thickness of 3-8 cm between two mammography paddles and imaged with a radiopaque coordinate grid. The radiation oncologist determines the isocenter coordinates and appropriate applicator size and shape based on the image. The collimating HDR 192Ir brachytherapy applicators are then applied on either side of the breast along a common axis and the brachytherapy dose delivered. The process is repeated along an orthogonal axis to distribute the entrance dose (Rivard 2009, Yang 2009, AccuBoost website). MammoSite, multi-lumen MammoSite, Axxent Electronic brachytherapy, and SenoRx Contura device are all FDA approved to deliver intracavity radiation to the surgical margins following lumpectomy for breast cancer. AccuBoost® system for delivering guided radiation therapy is also FDA approved.

06/12/2002: MTAC REVIEW
Breast Cancer Brachytherapy
Evidence Conclusion: The studies reviewed aimed at determining the equivalence between brachytherapy and external beam radiation, yet none of them was designed or analyzed in a fashion to study equivalence, which is a major threat to their validity. The authors set no equivalence boundary but took the lack of statistically significant difference between the two treatments as a proof of equivalence, which could lead to an erroneous judgment. Moreover, the studies were prospective, with a historical control group. The patients were not randomly assigned to the treatment group, and it is not discussed if they were consecutive, which may be a source of selection bias. The cohorts of women treated with brachytherapy were prospectively followed for a variable period of time (median 36 months in Vicini's study, and 74 months in King's study). The follow-up period was as short as a few months among some patients, and the dropout rate in the brachytherapy group was 82% after 5 years in Vicini's study. The reason for this high dropout rate was not discussed. In the two studies, data on the control group were obtained from retrospective chart reviews. Patients in the brachytherapy group received the treatment at either a low- or high-dose rate but were analyzed as one group. There were some differences in the baseline characteristics that were not adjusted for in the analysis of the results. The overall control and cosmetic outcomes of the brachytherapy as a sole treatment after lumpectomy were similar to that achieved by the external beam radiation therapy. However, these results cannot be generalized mainly due to the design of the study as well as the selection, observation and other biases in the studies. Randomized controlled studies with large sample size, power, and longer follow-up periods are needed to determine the long-term benefits and harms of brachytherapy used as a sole treatment after breast conservative therapy.
Articles: The search yielded 81 articles. Many were review articles, opinion pieces, or addressed brachytherapy as a boost, not a sole treatment after lumpectomy. The literature did not include any randomized controlled trials, or meta-analyses. There was a number of small case series with no control group, and two prospective studies that compared brachytherapy with external beam irradiation. These two studies were selected for critical appraisal. Vicini FA, Baglan KL, Kestin KL, et al. Accelerated treatment of breast cancer. *J Clin Oncol* 2001; 19:1993-2001. See Evidence Table. King TA, Bolton JS, Kuske RR, et al. Long-term results of wide field brachytherapy as the sole method of radiation therapy after segmental mastectomy for $T_{is, 1, 2}$ breast cancer. *Am J Surg* 2000; 180:299-304. See Evidence Table.

The use of brachytherapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/07/2005: MTAC REVIEW
Breast Cancer Brachytherapy
Evidence Conclusion: Brachytherapy as an adjunct or boost to whole breast radiation therapy:
The two randomized controlled trials reviewed (Polgar 2002, and Poortmans 2004) evaluated brachytherapy for early stage breast cancer with no or limited spread to the axillary lymph nodes. Both trials compared boost to no boost therapy after breast conserving surgery and whole breast external radiation therapy. Different techniques for the boost therapy were used (brachytherapy and electrons in Polgar's trial, and electrons, photon beams, and

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interstitial brachytherapy in Poortman's trial). The trials were not blinded, and the patients were randomized to boost or no boost treatment but were not randomized to the different boost techniques used. The latter was selected according to the physicians' preference. Poortman et al's trial was still ongoing, and in this publication the authors did not present a comparison between boost and no boost treatments but compared the outcomes of the different boost techniques used. Polgar et al reported a significant improvement with the boost vs. no boost treatment. The analysis provided however does not indicate that there was a statistically significant improvement as reported by the authors. The boost treatment was also found to be associated with an increased incidence of moderate to severe complications. Brachytherapy as a sole treatment alternative to whole breast radiation therapy. Vicini 2003, and Polgar 2004 were prospective cohort studies with a comparison group. Patients, however, were not randomly assigned to the treatment groups but matched to historical controls from the records or databases. The criteria used to assess the effect of the treatment included the degree of local control, disease free, relapse-free, and cancer free survival, as well as cosmetic outcome, and side effects. These two studies aimed at determining the similarity between brachytherapy and external beam radiation, yet none of them was designed or analyzed in a fashion to study equivalence, which is a major threat to their validity. The authors set no equivalence boundary but took the lack of statistically significant difference between the two treatments as a proof of equivalence, which could lead to an erroneous judgment. In conclusion, interstitial brachytherapy may be a promising treatment, but the studies reviewed do not provided sufficient evidence to conclude that it may be used as an alternative to whole breast radiation therapy after breast conserving surgery. Randomized controlled studies with large sample size, power, and longer follow-up periods are underway to determine the long-term benefits and harms of brachytherapy used as a sole treatment after breast conservative therapy.
Articles: The search revealed more than 200 articles. Many were reviews, editorials, or dealt with the technical aspects of the technology. There were several case series, retrospective studies, and small trials. Others compared mastectomy with external beam radiation therapy, and in one trial brachytherapy was compared to WBRT without breast lumpectomy. Studies were selected for review according to the following criteria: 1. Evaluating brachytherapy as an adjunct to whole breast radiation therapy or as a sole treatment after breast-conserving surgery, 2. Prospective design, and 3. Including a comparison or control group. Two large RCTs on the use of brachytherapy as a boost to WBRT were identified and critically appraised. Several studies on the use of brachytherapy as an alternative to WBRT were published after MTAC reviewed the technology in 2002. All evaluated brachytherapy for early stage breast cancer with no or limited spread to axillary lymph nodes. Harms et al (2002), Keisch et al (2003), Perera et al (2003), Richard et al (2004), and Shah et al (2004) studies were case series with no control or comparison groups. These studies mainly evaluated the safety of the treatment rather than efficacy. Only two of the identified studies (Vicini 2003 and Polgar 2004) included a comparison group and were selected for critical appraisal. *Evidence tables were created for the following studies: For the use of brachytherapy as an adjunct to whole breast radiation therapy:* Polgar C, Fodor J, Orosz Z, et al. Electron and high dose-rate brachytherapy boost in the conservative treatment of stage I-II breast cancer. First results of the Randomized Budapest Boost Trial. *Strahlenther Onkol* 2002; 178:1205-1211. See Evidence Table Poortmans P, Bartelink H, Horiot JC, et al. The influence of the boost technique on local control in breast conserving treatment in the EORTC "boost versus no boost randomized trial. *Radiother Oncol* 2004; 72:25-33. See Evidence Table *For the use of brachytherapy as a sole treatment alternative to whole breast radiation therapy:* Vicini F, Kestin L, Chen P, et al. Limited field radiation therapy in the management of early-stage breast cancer. *J Natl Cancer Inst* 2003; 95:1205-1211. See Evidence Table Polgar C, Major T, Fodor J, et al. High dose-rate brachytherapy alone versus whole breast radiotherapy with or without tumor bed boost after breast conserving surgery: seven-year results of a comparative study. *Intl J Radiat Oncol* 2004; 60:1173-1181 See Evidence Table

The use of brachytherapy as an adjunct or boost to whole breast radiation therapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of brachytherapy as a sole treatment alternative to whole breast radiation therapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/15/2011: MTAC REVIEW
Breast Cancer Brachytherapy
Evidence Conclusion: There is insufficient evidence to date to determine whether accelerated partial breast irradiation delivered by balloon-based brachytherapy or AccuBoost is safe and provides non-inferior or superior local tumor control and survival compared to conventional whole breast irradiation in patients with early stage breast cancer treated with breast conservative therapy. Polgar and colleagues' (2008) RCT, reviewed earlier, and Antonucci et al's study (evidence table 1) had several methodological flaws which limit generalization of their results. Large RCTs with long-term follow-up are needed to determine the equivalence or superiority of accelerated partial breast irradiation therapy to whole breast external beam radiation therapy. A phase 3 trial comparing APBI to whole breast irradiation in over 4,000 women with stage 0, I, or II breast cancer is underway. The trial is jointly conducted by the National Surgical

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Adjuvant breast and Bowel Project (NSABP) and the Radiation Therapy Oncology Group (RTOG). Patients in the APBI will be treated using one of three modalities: interstitial brachytherapy, MammoSite brachytherapy, or 3-D conformal EBRT. Outcome measures include overall survival, recurrence free survival, distant disease-free survival, toxicity, cosmesis, and convenience of the care. The primary aim of the trial is determining whether APBI would provide equivalent local breast control as WBRT in early stage breast cancer. Other ongoing trials include the Canadian RAPID trial which is recruiting over 2000 patients to be randomized to either whole breast irradiation or 3-D CRT, and an international phase III large trial supported by the European Brachytherapy Breast Cancer GEC-ESTRO Working Group. This trial will randomize 1170 women between WBRT and APBI using high-dose rate or pulsed-dose rate brachytherapy. The results of these, and a number of other ongoing trials, will provide data on the efficacy and toxicity of partial breast irradiation in the treatment of early stage breast cancer as compared to WBRT. They may also provide data on appropriate candidates for APBI and on the advantages and disadvantages of each method.
Articles: Objectives: To determine whether accelerated partial breast irradiation leads to non-inferior or superior local tumor control and survival compared to conventional whole breast irradiation, when used as an adjuvant therapy after lumpectomy in patients with early stage breast cancer. To determine whether the use of balloon-based brachytherapy systems is safe and effective for delivering adjuvant radiation therapy after lumpectomy in patients with early stage breast cancer. To determine whether the image guided radiation therapy using AccuBoost peripheral breast brachytherapy system is safe and effective for delivering adjuvant radiation therapy after lumpectomy in patients with early stage breast cancer. Screening of articles/selection: The search revealed around 150 articles on accelerated partial breast irradiation (ABPI). The majority of the published empirical studies were phase I/II trials with no comparison group, different sizes, and follow-up durations. There were no new randomized trials, published after the last review, on APBI therapy delivered by MammoSite, Axxent, Contura, or AccuBoost systems. The search identified a recently published interim analysis on the acute toxicity in a trial that compared conventional whole breast radiation with APBI plus IMRT, a nonrandomized study that examined the dosimetric advantage of Contura catheter vs. MammoSite, and a small case series of patients treated with Contura catheter. The literature search also revealed a report on four-year outcomes of a prospective study, with no control group, on the efficacy and toxicity of 3-D-CRT to deliver APBI, and a feasibility study with 11 patients treated with intraoperative radiation using the Axxent electronic brachytherapy system. No published clinical studies on AccuBoost system were identified. A recent analysis comparing APBI with WBRT was critically appraised. See Evidence Table**.** Antonucci JV, Wallace M, Goldstein NS, et al. Differences in patterns of failure in patients treated with accelerated partial breast irradiation versus whole-breast irradiation: a matched-pair analysis with 10-year follow-up. *Int J Radiat Oncol Biol Phys.* 2009;74:447-452. See Evidence Table.

The use of brachytherapy as an adjunct or boost to whole breast radiation therapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Coronary Artery Brachytherapy Intravascular Coronary Brachytherapy

BACKGROUND

Percutaneous transluminal coronary angioplasty (PTCA) is a widely used therapy for obstructive coronary artery disease. It is limited however by the high rate of restenosis which occurs in 30-60% of patients after a successful PTCA. The main mechanisms of restenosis include elastic recoil of the vessel, rapid platelet deposition, vascular remodeling and neointimal hyperplasia. Endovascular stents have been shown to reduce stenosis by preventing the elastic recoil and pathological remodeling. However, stents do not prevent the restenosis caused by neointimal hyperplasia, but rather initiate an inflammatory reaction that induces more proliferation than other coronary devices. An effective treatment of restenosis within the stent will be the suppression of this neointimal hyperplasia. Radiation therapy which is known for its antiproliferative effect has been proposed as a treatment for in-stent restenosis. Over the past six years, studies on the use of various techniques to apply intracoronary radiation which is known as intracoronary brachytherapy have been showing encouraging results. Brachytherapy uses a relatively large localized dose of beta or gamma radiation. It does not provide an immediate outcome. If effective, it reduces the rate of restenosis in the vessel in the target area. This effect can be measured by angiograms performed six months after the procedure. Brachytherapy requires a multidisciplinary team to deliver it including an interventionist cardiologist, a radiation oncologist, physicist and safety officer.

06/13/2001: MTAC REVIEW

Coronary Artery Brachytherapy Intravascular Coronary Brachytherapy

Evidence Conclusion: GAMMA-One (Leon et al), beta-WRIST (Waksman et al), SCRIPPS (Teirstein et al), and the START (In press) trials are four of the well-designed RCTs evaluating the use of brachytherapy in the management of in-stent restenosis. There are several other ongoing studies. These trials showed that patients

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with in-stent restenosis treated with brachytherapy needed less revascularization than those treated with PTCA or PTCA and stents without radiation. In two of the studies, intracoronary brachytherapy tended to increase the risk of late thrombus formation, but this was statistically insignificant. Although these trials reported that major cardiac events (MACE) were lower among patients who received brachytherapy, none of them had adequate power, or follow-up to detect the difference in myocardial infarction and death rates alone. Brachytherapy may also cause acute damage in the coronary arteries including aneurysm, pseudoaneurysm, arterial dissection, or rupture of the artery. None of these acute complications was reported in any of these trials. In addition, radiation may lead to a long-term damage on the surrounding tissue and have adverse effects on the clinical personnel. These long-term complications are unknown. The longest data available is the three-year follow-up in the SCRIPP trial (Teirstein et al). The nature of radiation needs a long-term follow-up.
Articles: The search yielded 79 articles. Many were just reviews and literature. There were eleven articles on randomized controlled studies, more than one publication for each of the major trials, GAMMA-one, beta-WRIST and SCRIPPS. The START trial was still in press. These major randomized controlled studies were evaluated in detail. *Evidence tables were created for the following studies:* Leon MB, Teirstein PS, Moses JW, et al. Localized Intracoronary Gamma-Radiation Therapy to Inhibit the Recurrence of Restenosis After Stenting. N Engl J Med 2001; 344: 250-256 See Evidence Table Teirstein PS, Massulo V, Jani S, Popma JJ, et al. Three-Year Clinical and Angiographic Follow-up After Intracoronary Radiation. Circulation 2000; 101: 360-365. See Evidence Table Waksman R, White L, Chan RC, et al. Intracoronary Gamma -Radiation Therapy After Angioplasty Inhibits Recurrence In Patients With In-Stent Restenosis. Circulation 2000; 101: 2165-2171 See Evidence Table
The use of Coronary Artery Brachytherapy for the treatment of restenosis of stent passes all *Kaiser Permanente Medical Technology Assessment Criteria.*

Endobronchial Brachytherapy - Lung Cancer

BACKGROUND
Among all types of malignancy, lung cancer is one of the most difficult to manage and is associated with the highest mortality rate. Its incidence is continuously increasing, with no improvement in mortality. 80-85% of the cases is non-small cell lung cancer (NSCLC). Squamous cell carcinoma and adenocarcinoma account for the majority of the NSCLC. Regardless of the histological type, surgery offers the best potential for cure. However, approximately 75% of the patients present with locally advanced non-resectable disease at the time of diagnosis. The treatment options for these patients are chemotherapy and / or external irradiation therapy, which have low survival rates, and high rates of local recurrence. Endobronchial brachytherapy (EBT or EBB) is an additional treatment increasingly used for centrally localized lung cancer. It can be used alone, or with the external radiation therapy (XRT) to boost the total dose of irradiation used. In earlier studies, it was used as a palliative treatment in case of endobronchial recurrence after XRT. In later studies it is used in combination with high-dose of XRT as a potential curative primary treatment in selected cases. With brachytherapy, radioactive sources usually iridium-192 are placed at the tumor site in the involved branch of the tracheobronchial tree. These will deliver a radiation dose that rapidly and progressively declines with the increasing distance from the source. Any adverse effects on normal tissue should be confined to the immediate vicinity of the bronchus, sparing the lung parenchyma and the esophagus. The procedure is done on outpatient basis. Bronchoscopy is performed under topical anesthesia to determine the field of treatment. A guidewire is then placed in the instrumentation channel of the endoscope, and the bronchoscope is removed. An after-loading catheter is passed on the guidewire, the guidewire is removed, and an applicator for placement of the radiation source is inserted in the catheter. Depending on the number of airway branches involved, 1 to 4 catheters may be placed. The position of the catheter is verified by fluoroscopy. The applicator is then connected to the iridium192 afterloading unit and the irradiation source advanced to the intended position under computer control. The application time ranges from 2 to 15 minutes depending on the dose, and length of the irradiated area. After removing the radioactive source, the catheters are removed, and the patient is observed for 30 minutes. High-dose brachytherapy may be delivered in fractionated doses by repeating the procedure at weekly or biweekly intervals, or twice a day until the entire dose is delivered. The dose varies individually and depends on the patient's clinical condition, history, and concurrent use of XRT. Endobronchial brachytherapy may be associated with acute complications. It could lead to fibrotic airway obstruction and may be linked to fatal hemoptysis depending on the dose, dose per fraction and the concurrent use of XRT.

08/08/2001: MTAC REVIEW
Endobronchial Brachytherapy - Lung Cancer
Evidence Conclusion: The RCTs reviewed were conducted to evaluate the effect of endobronchial brachytherapy either used alone, or in addition to external radiation therapy. Langendijk's study found a statistically significant benefit of adding EBT to XRT in treating atelectasis in patients with endobronchial obstruction in the main bronchus. Huber's study did not show any statistical difference between the two treatments. On the other hand, Stout's study found that external irradiation therapy, had a statistically significant better outcome than EBT (used alone) on the patients' survival and palliation of some symptoms. EBT was not found to be associated with a higher rate of fatal hemoptysis in all three trials. The studies had some limitations
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including likelihood of observation bias, incomplete data (all three RCTs), premature termination and lack of power (Langendijk). In conclusion, the efficacy and safety of endobronchial brachytherapy cannot be fully determined from the available evidence.
Articles: The search yielded 54 articles. Selection was based on study type. There were 3 articles on randomized control trials comparing the effect of external irradiation therapy (XRT) vs. endobronchial brachytherapy (EBT) / XRT + EBT, on patients with non-small cell lung cancer. Reviews, editorials and comments were reviewed, but no evidence tables were created. *The three RCTs selected for critical appraisal were:*
Huber RM, Fischer R, Hautmann H, et al. Does Additional Brachytherapy Improve the Effect of External Irradiation? A Prospective, Randomized Study in Central Lung Tumors. Int.J.Radiation Oncology Biol. Phys.1997: 38 (3): 533-540. See Evidence Table Langendijk H, Jong JD, Tjwa M, et al. External Irradiation Plus Endobronchial Brachytherapy in Inoperable Non-small Cell Lung Cancer: a Prospective Study. Radiotherapy and Oncology 2001; 58: 257-268 See Evidence Table Stout R, Barber P, Burt P, et al. Clinical and Quality of Life Outcomes in the First United Kingdom Randomized Trial of Endobronchial Brachytherapy Treatment of Inoperable non-small Cell Lung Cancer. Radiotherapy and Oncology 2000; 56: 323-327 See Evidence Table

The use of endobronchial brachytherapy in the treatment of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* 2 for effectiveness.

High-Dose Rate Brachytherapy for Prostate Cancer
BACKGROUND
Prostate cancer is one of the most common cancers, and the second leading cause of cancer death in men in the United States. The standard management options for localized disease included surgery, radiotherapy, and watchful waiting. However, the optimal treatment is not well defined. Both surgery and radiation therapy are reported to have equivalent outcomes, and each approach has its advantages and disadvantages. Researchers reported that for intermediate and high-risk disease, external beam radiation therapy (EBRT) is the standard treatment, and that there is a dose response for biochemical relapse-free survival. However, dose escalation to >70 Gy is associated with an increase in genitourinary and gastrointestinal side effects. Several techniques have been developed to deliver high doses of radiation to the prostate while sparing surrounding normal tissue. Among these are the three-dimensional conformal radiotherapy (3DCRT), intensity modulated radiation therapy (IMRT), photon therapy, and brachytherapy (Vordermark 2006, Hoskin 2007, Rades 2007). Prostate brachytherapy was introduced in the late 1980s after the development of transrectal ultrasonography and sophisticated treatment planning software. It can be performed as monotherapy or in conjunction with hormone therapy or EBRT. Monotherapy is usually reserved for low-risk cancer, and the combined therapies are used for high-risk disease (Nelson 2007). Interstitial brachytherapy can be delivered using permanent low-dose-rate (LDR) seed implants or temporary high-dose-rate (HDR) implants. The latter entails the temporary placement of higher energy radioactive sources in and near the tumor. An automated machine called an afterloader sequentially moves a high-intensity radioactive source to and from a set of catheters in and around the prostate to deliver a pre-determined radiation dose to the patient's tumor. Following treatment, the radioactive source is withdrawn. Both LDR and HDR have the advantage of conforming high doses of radiation according to the precisely localized target, rapid dose fall-off, and no target movement during treatment. The dose distribution of the LDR mainly depends on the position of the implanted seed, while the HDR uses a steeping source, usually iridium-192, and is thus able to vary both the position and /or dwell time of the source. This has the potential of better target volume coverage and a greater sparing of neighboring organs at risk (Chin 2006). Unlike LDR brachytherapy, HDR brachytherapy usually requires hospitalization of the patient. HDR brachytherapy is also associated with a number of acute and chronic side effects, including urinary urgency and frequency, dysuria, nocturia, urinary retention, urethral stricture, rectal irritation, and impotence.

06/06/2006: MTAC REVIEW
High-Dose Rate Brachytherapy for Prostate Cancer
Evidence Conclusion: There is insufficient evidence to draw conclusions about the effectiveness and safety of HDR brachytherapy monotherapy compared to an accepted treatment for prostate cancer.
There is some evidence that HDR brachytherapy plus EBRT results in better biochemical control than EBRT alone. Data are from 2 comparative studies, one randomized and one non-randomized; both studies have threats to validity. There is insufficient evidence to determine whether HDR brachytherapy added to EBRT improves disease-specific or overall survival. In the randomized controlled trial, there was no significant increase in overall survival with HDR brachytherapy plus EBRT; data were not reported for disease-specific mortality. In the non-randomized study, there was not a significant difference in disease-specific mortality. Overall survival was significantly higher in the combined treatment group when 5-year outcomes were modeled using Kaplan-Meier analysis—actual patient data on survival were not reported.
There is insufficient evidence on adverse effects associated with HDR brachytherapy plus EBRT. In the RCT, rates of adverse effects did not differ significantly between groups—however, these comparisons were likely
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underpowered. In the cohort study, adverse effects were only reported for the HDR brachytherapy plus EBRT group; 29% of patients developed impotence.
Articles: Note: Studies were identified using N California report but selection of articles for critical appraisal was re-done for the MTAC report. *HDR brachytherapy monotherapy:* There were no randomized controlled trials or non-randomized controlled trials that compared the safety and effectiveness of HDR brachytherapy monotherapy to a different treatment such as observation, surgery or EBRT. All of the studies were case series. Two publications from a single institution compared series of patients who received either HDR brachytherapy or LDR brachytherapy (Vargas et al., 2005 ; Grills et al., 2004). No studies were selected for critical appraisal since none compared HRD brachytherapy to another treatment for prostate cancer. *Combination therapy (HRD brachytherapy plus EBRT):* There was one randomized controlled trial comparing HRD brachytherapy plus EBRT to EBRT alone. There were also two nonrandomized comparison studies and nine case series. One of the non-randomized comparative studies (Jo et al., 2005) was a survey that only reported on quality of life, not clinical outcomes and thus this study was excluded from further review. The RCT (Sathya et al., 2005) and the other non-randomized comparison study (Kestin et al., 2000) were critically appraised. *The studies reviewed were:* Sathya JR, Davis IR, Julian JA et al. Randomized trial comparing iridium implant plus external-beam radiation therapy with external-beam radiation therapy alone in node-negative locally advanced cancer of the prostate. J Clin Oncol 2005; 23: 1192-1199. **See** Evidence Table Kestin LL, Martinez AA, Stromberg JS et al. Matched-pair analysis of conformal high-dose-rate brachytherapy boost versus external-beam radiation therapy alone for locally advanced prostate cancer. J Clin Oncol 2000; 18: 2869-2880. **See** Evidence Table

The use of High-dose rate brachytherapy in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/01/2007: MTAC REVIEW
High-Dose Rate Brachytherapy for Prostate Cancer
Evidence Conclusion: High-dose rate (HDR) brachytherapy for prostate cancer was previously reviewed by MTAC on 6/5/06. The report conclusion indicated that there was insufficient evidence to determine the effectiveness and safety of HDR brachytherapy monotherapy compared to an accepted treatment for prostate cancer. For the current review, the literature search revealed one more recent RCT conducted in the UK (Hoskin 2007), that compared external-beam radiation therapy (EBRT) given as a monotherapy vs. its combination with high-dose rate brachytherapy boost for the treatment of prostate cancer. The primary outcome was biochemical relapse free survival. The secondary outcomes were the overall and relapse-free survival, acute and late toxicity, and quality of life. The study had its advantages and limitations. It was randomized, controlled, had sufficient statistical power, high completeness rate, and analysis was based on intention to treat. However, the authors did not discuss blinding of the investigators to the patient allocation, the 55 Gy dose of external beam radiotherapy is considered suboptimal, and the technique of delivering the EBRT changed along the study. Moreover, the follow-up duration was relatively short, and the primary outcome was biochemical relapse free survival which is a surrogate outcome for overall survival. It is considered acceptable by some investigators, due to the long natural history of the disease. Overall, the results of the trial indicate that that the biochemical relapse-free survival was significantly higher among patients in the HDR brachytherapy in combination with external beam radiotherapy group versus those treated with external beam radiotherapy alone. The HDR brachytherapy was also associated with an improved quality of life, without any increase in toxicity. Soumarova and colleagues (2007) compared the acute genitourinary and gastrointestinal toxicity in 97 patients treated with external beam radiotherapy (3D conformal radiotherapy [CRT]) or 3D CRT combined with interstitial conformal HDR brachytherapy for the treatment of histologically verified localized carcinoma of the prostate. The study was prospective but non-randomized: 57 patients received 3D CRT and 40 patients were irradiated with 3D CRT+ HDR brachytherapy. The patients were followed by a radiation oncologist and urologist at 1-3 months intervals, and the acute genitourinary and gastrointestinal toxicities were evaluated using the RTOG criteria. The overall results of the study showed a lower incidence of acute gastrointestinal toxicity in HDR brachytherapy combination therapy group versus those in the 3D CRT monotherapy group. In conclusion the studies published to date do not provide sufficient evidence to determine the efficacy and safety of HDR brachytherapy in the treatment of histologically proven carcinoma of the prostate.
Articles: *HDR brachytherapy monotherapy:* The literature search did not reveal any randomized controlled trials or non-randomized controlled trials that compared the safety and effectiveness of HDR brachytherapy monotherapy to no, or a different mode of treatment as surgery or EBRT. All published studies on monotherapeutic brachytherapy for organ confined or locally advanced prostate cancer, were case series with variable sizes and duration of follow-up. None included a comparison or control group and thus were not critically appraised. *HDR brachytherapy in combination with external beam radiotherapy (EBRT):* There was one recent randomized controlled trial (Hoskin 2007) that compared HDR brachytherapy plus EBRT to EBRT alone, and a non-randomized controlled trial (Soumarova 2007) that compared the acute toxicity of EBRT with and without

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HDR brachytherapy, as well as several case series. The two studies were reviewed, Hoskin and colleagues RCT was presented in an evidence table.
Hoskin PJ, Motohashi K, Bownes P, et al. High dose rate brachytherapy in combination with external beam radiotherapy in the radical treatment of prostate cancer: initial results of a randomized phase three trial. Radiother Oncol 2007; May 24. See Evidence Table

The use of High-dose rate brachytherapy in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
High-Dose Rate Brachytherapy for Prostate Cancer
Evidence Conclusion: HDR brachytherapy as a monotherapy A recent retrospective cohort study combined data from two centers to evaluate the safety and efficacy of HDR brachytherapy compared to LDR brachytherapy for the treatment of prostate cancer. The primary outcome measures were biochemical control and rate of acute and chronic toxicities. There was no significant difference in biochemical control rates between the HDR brachytherapy and the LDR brachytherapy groups (88% vs. 89%, P=0.62). However, compared to patients treated with LDR brachytherapy, patients treated with HDR brachytherapy experienced significantly lower rates of acute and chronic dysuria, acute urinary frequency and urgency, and acute rectal pain. Results from this study should be interpreted with caution as there was no adjustment for confounding factors, treatment techniques evolved over the study period, the two centers had different treatment procedures, and approximately 29% of patients received neoadjuvant androgen deprivation (Martinez 2009). HDR brachytherapy combined with external beam radiation therapy. A retrospective cohort study that compared the efficacy of HDR brachytherapy in combination with 3D- conformal external beam radiation (3DCRT) with 3DCRT alone for the treatment of prostate cancer found no significant difference in biochemical control, overall survival, or cause-specific mortality between the treatment groups. As side effects were only reported for the combined group, it cannot be determined if patients in the combined group experienced more side effects compared to patients in the 3DCRT alone group (Zwahlen 2010). Conclusion: There is insufficient evidence to determine whether HDR brachytherapy given alone or in combination with EBRT is safe and effective for the treatment of prostate cancer.
Articles: The literature search did not reveal any randomized controlled trials that addressed the safety and efficacy of HDR brachytherapy. A retrospective cohort study was identified that evaluated the safety and efficacy of HDR brachytherapy given as a monotherapy compared to LDR brachytherapy was selected for review. There were several studies that evaluated the safety and efficacy of HDR brachytherapy combined with EBRT; however, the majority of these were case series. A recent study by Zwahlen and colleagues was selected for review as it was the only study with a control group. The following studies were critically appraised:
Martinez AA, Demanes J, Vargas C, et al. High-dose-rate prostate brachytherapy: An excellent accelerated hypofractionated treatment for favorable prostate cancer. *Am J Clin Oncol* 2009 November 30. See Evidence Table Zwahlen DR, Andrianopoulos N, Matheson B, et al. High-dose-rate brachytherapy in combination with conformal external beam radiotherapy in the treatment of prostate cancer. *Brachytherapy 2010;* 9:27-35. See Evidence Table

The use of High-dose rate brachytherapy in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

High-Dose vs. Low-Dose Brachytherapy for Cervical and Endometrial Cancer
BACKGROUND
The standard treatment for cervical cancer is external beam radiation therapy (EBRT) combined with intracavity brachytherapy. There is no accepted standard treatment for early endometrial cancer. However, brachytherapy is often used, alone or in combination with EBRT. Intravaginal brachytherapy is believed to be useful for endometrial cancer in part because the vaginal apex is a common site of endometrial cancer recurrence. Brachytherapy refers to internal or local irradiation. In intracavity brachytherapy, radioactive sources are placed in body cavities that are close to the tumor. The relative balance between the two types of radiation treatment (brachytherapy and EBRT) depends on the stage and volume of disease. Generally, as the tumor volume increases, EBRT is favored to achieve a larger volume of homogenous dose (Stitt, 1999). Low-dose rate (LDR) brachytherapy has been available longer and is still used more frequently than high-dose rate (HDR) brachytherapy. There are several potential advantages of HDR brachytherapy, including the ability to treat large clinical patient volume, the lack of need for general anesthesia or bed rest, the ability to individualize treatment, complete radiation protection for staff and the application of multiple fractions on an outpatient basis. Disadvantages of HDR brachytherapy are the higher costs of staffing, equipment and the changing of iridium source every three months. In addition, optimal fractionation schemes for HDR brachytherapy are yet to be well defined and long-term complications are unclear (Stitt, 1999). In a LDR brachytherapy session, instruments need to be in place for 2-3 days. Cervical cancer treatment involves two procedures, approximately one week apart. Radium was used originally, but now cesium-

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137 is used. In contrast, with HDR brachytherapy, a treatment session takes minutes. Multiple sessions are generally required; five is a common number for treating cervical cancer. For the treatment of endometrial cancer (brachytherapy alone or in combination with EBRT after a hysterectomy), two sessions of about 1 hour each are required. High-dose rate is generally accepted as being between 50-500 cGy/minute (Tewari & DiSaia, 2002; Hogberg et al., 1999).

06/11/2003: MTAC REVIEW
High-Dose vs. Low-Dose Brachytherapy for Cervical and Endometrial Cancer
Evidence Conclusion: Cervical cancer: With few exceptions, the studies reviewed did not find statistically significant differences in survival between patients receiving HDR and LDR brachytherapy for the treatment of cervical cancer. There were also no significant differences in adverse effects between the HDR and LDR groups. Although the studies suggest that the safety and effectiveness of the two treatments are similar, the studies were not designed as equivalence studies. The lack of a statistically significant finding could be due to a design flaw such as insufficient statistical power or bias. Neither of the RCTs discussed statistical power and both may have been underpowered to detect differences in survival and/or adverse effects between groups. This is particularly true because the results were reported separately by stage of disease which resulted in a smaller sample size for each comparison. The studies also had several threats to validity. Neither of the RCTs had adequate randomization (one allocated patients by birth month and the other alternated patient assignment to treatment group) which could introduce selection bias. In all three studies, there may have been baseline differences between groups that were not controlled for in the statistical analyses. The studies also differed in the extent of external beam radiation treatment the patients received. Endometrial cancer: There are no studies that specifically compare the safety and effectiveness of HDR and LDR brachytherapy for the treatment of endometrial cancer.
Articles: *Cervical cancer:* The search yielded 135 articles. Many of the studies were reviews, opinion pieces or dealt with technical aspects of the procedure. There were four studies that compared the outcomes of patients who received high-dose or low-dose brachytherapy. Two of the studies were randomized and two were non-randomized. The two randomized studies and the prospective non-randomized study were critically appraised:
Hareyama M, Sakata K, Oouchi A et al. High-dose versus low-dose-rate intracavity therapy for carcinoma of the uterine cervix. *Cancer* 2002; 94: 117-124. See Evidence Table
Teshima T, Inoue T, Ikeda H. High-dose rate and low-dose rate intracavity therapy for carcinoma of the uterine cervix. *Cancer* 1993; 72: 2409-2414. See Evidence Table
Endometrial cancer: The search yielded 36 articles. No randomized controlled trials were identified. There were no empirical studies comparing low-dose rate and high-dose rate brachytherapy. No articles were critically appraised.

The use of high-dose brachytherapy in the treatment of cervical and endometrial cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostate Cancer Brachytherapy
BACKGROUND
At the December 14, 1994 Committee on Medically Emerging Technologies the efficacy of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer was originally discussed. Dr. Blasko presented information on the 800 patients for which the procedure was performed. Only 252 of those patients had a minimum follow-up of two years. The conclusion of the committee was that there was inadequate follow-up data supporting the efficacy of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer. The question of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer was restated and evaluated at the January 16, 1997 Clinical Policy Committee Meeting. Committee members agreed that there was inadequate evidence to compare the benefits of the three active treatment options but that there was adequate evidence (large case series) to compare the complications of the three options. Among the three active treatment options, it was agreed that brachytherapy appeared to have the lowest rate of complications. Based on this information the Committee recommended to the Clinical Planning and Improvement Council and the Delivery System Operating Team that brachytherapy be added to the list of covered treatment options for localized prostate cancer. This recommendation was accompanied by the stipulation that educational material outlining the treatment options be developed for patient education in order that they can make an informed decision about their treatment course. Not all patients with Prostate Cancer are eligible candidates for Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer. Documentation of the screening criteria used to identification of the eligible candidates is the purpose of this document. In late 2001 the criteria were reviewed by Dr. Nico DeWette and updated based on the current practice and experience with Prostate Seed Implant and Combined Therapy

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12/14/1994: MTAC REVIEW
Prostate Cancer Brachytherapy
Evidence Conclusion: he conclusion of the committee was that there was inadequate follow-up data supporting the efficacy of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer.

01/16/1997: MTAC REVIEW
Prostate Cancer Brachytherapy
Evidence Conclusion: Committee members agreed that there was inadequate evidence to compare the benefits of the three active treatment options but that there was adequate evidence (large case series) to compare the complications of the three options. Among the three active treatment options, it was agreed that brachytherapy appeared to have the lowest rate of complications. Based on this information the Committee recommended to the Clinical Planning and Improvement Council and the Delivery System Operating Team that brachytherapy be added to the list of covered treatment options for localized prostate cancer. This recommendation was accompanied by the stipulation that educational material outlining the treatment options be developed for patient education in order that they can make an informed decision about their treatment course.

2001: MTAC REVIEW
Prostate Cancer Brachytherapy
Evidence Conclusion: In late 2001 the criteria were reviewed by Dr. Nico DeWette and updated based on the current practice and experience with Prostate Seed Implant and Combined Therapy.
Articles: Wennberg, John E., Assessing Therapies for Benign Prostatic Hypertrophy and Localized Prostate Cancer (PORT), Agency for Health Care policy and Research, Medical Outcomes and Guidelines Sourcebook, 273-288 Stock et al. Prostate Specific Antigen and Biopsy Results following Interactive Ultrasound Guided Transperineal Brachytherapy for Early Stage Prostate Carcinoma. Cancer. 1996, 77:2386-92
Wallner et al. Tumor Control and Morbidity Following Transperineal Iodine 125 Implantation for Stage T1/T2 Prostatic Carcinoma. Journal of Clinical Oncology. 1996, 14:449-53.
Kaye, Keith W., et al. Detailed Preliminary Analysis of ^{125}Iodine Implantation for Localized Prostate Cancer Using Percutaneous Approach. The Journal of Urology. March 1995. 153: 1020-1025.
Blasko, John C., et al., Brachytherapy and Organ Preservation in the Management of Carcinoma of the Prostate. Seminars in Radiation Oncology. 1993: 3(4), 240-249.

Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma
BACKGROUND
Gliomas are the most common primary tumors of the adult brain. Primary brain tumors are those that arise from brain tissue itself, rather than metastasizing to the brain from another location. One of the most commonly diagnosed types of glioma is glioblastoma multiforme (GBM) which is defined as a Grade 4 (high-grade) astrocytoma. High-grade tumors are by definition, rapidly growing and typically develop at a distinct focus in the brain and become more diffuse in their spread as they progress. Several therapies for high-grade glioblastomas are currently employed. No treatment has been shown to cure these tumors, most likely because tumor cells infiltrate into surrounding tissue and this tumor cell type has been shown to be moderately resistant to chemo and radiation therapy. Treatment for glioblastoma multiforme typically involves surgery to reduce the size of the tumor and external beam radiation therapy. External beam radiotherapy can be delivered using a standard x-ray machine or focused on a small area of three dimensionally localized tissue using stereotactic radiosurgery. Systematic chemotherapy is usually a third line treatment and. One proposed treatment for glioblastoma is the use of stereotactically implanted radioactive seeds (brachytherapy) at the site of the tumor. The potential advantage of brachytherapy is that it allows high dose radiation to be applied directly to the tumor site and may avoid radionecrosis caused by high doses of externally applied radiation and toxic effects of chemotherapy. Glioblastoma is typically associated with a fatal outcome. Brachytherapy for malignant brain tumors has been practiced since the early 1980s. Brachytherapy applied as a boost to external beam radiation therapy has become part of the initial treatment of patients with malignant gliomas. Previous reports on the use of brachytherapy for patients with malignant gliomas have suggested improved survival for some patients. The largest experience to date has been with temporary high-activity brachytherapy implants. However, temporary implants have certain disadvantages compared with permanently implanted seeds, including higher costs and the need for more rigorous radiation safety precautions during the period of implantation.

13/13/2000: MTAC REVIEW
Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1990-1999 using the terms: glioblastoma, brachytherapy and neoplasm recurrence. The published scientific evidence consists of 4 case series with no comparison group or comparison only to historical controls. Case series do not provide

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reliable information regarding efficacy as they are subject to bias because they lack control groups that allow elimination of confounding and selection bias. Publication bias can also influence whether negative results are reported in the literature. The studies reviewed in November 2000 have a number of limitations including a small sample size, potential selection bias, lack of a proper control group, and in one of the studies, the fact that different methods variables were used to compare groups of patients. Given these limitations, there is insufficient evidence to draw conclusions about the efficacy and safety of brachytherapy for patients with glioblastoma. It was noted that glioblastoma has the worst prognosis and shortest survival times of any type of primary brain tumor. All treatments serve only to extend survival, usually by a matter of 2-3 months usually at the cost of significant treatment related morbidity. Recent improvement in imaging techniques and more complete surgical resection makes it impossible to use historical control patients as valid comparisons with respect to clinical outcomes.
Articles: The search yielded 20 articles. 18 articles were not directly relevant or were review articles, letters, or case reports. Two (2) empirically relevant case series were identified (evidence tables attached). *The articles selected for critical appraisal include:* Patel et al. Permanent Iodine-125 interstitial implants for the treatment of recurrent glioblastoma multiforme. Neurosurgery 2000; 46:1123-1130. See Evidence Table
J Clin Oncol 1998;16:2202-12 entitled Iodine 131-labeled antitenascin monoclonal antibody 81C6 treatment of patients with recurrent malignant Gliomas: Phase I trial results. See Evidence Table
Shrieve, DC et al, *Neurosurgery*, 1995, 36:275-284 See Evidence Table
Halligan, JB et al, *Int J. Radiation Oncology Biol. Phys*. 1996, 35:541-547 See Evidence Table
Sneed, PK et al, *Seminars in Surgical Oncology*, 1997;13 See Evidence Table
Gaspar, LE, et al. Int J. Radiation Oncology Biol. Phys. 1999, 43:977-82 See Evidence Table
Gaspar, LE, et al. Int J. Radiation Oncology Biol. Phys. 1999, 43:977-82 See Evidence Table
Koot et al. Brachytherapy: Results of two different therapy strategies for patients with primary glioblastoma. Cancer 2000;88:2796-802. See Evidence Table

Radioactive Seeds for Treatment of Recurrent Malignant High-Grade Glioblastoma does not meet *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
19297	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)
19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance
20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure)
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
41019	Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application
58346	Insertion of Heyman capsules for clinical brachytherapy
61770	Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source
76965	Ultrasonic guidance for interstitial radioelement application
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote

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	afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
77750	Infusion or instillation of radioelement solution (includes 3-month follow-up care)
77761	Intracavitary radiation source application; simple
77762	Intracavitary radiation source application; intermediate
77763	Intracavitary radiation source application; complex
77768	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
77789	Surface application of low dose rate radionuclide source
77799	Unlisted procedure, clinical brachytherapy
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed
HCPC Codes	**Description**
G0458	Low dose rate (LDR) prostate brachytherapy services, composite rate

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
1998	06/01/2010[MDCRPC], 12/07/2010[MDCRPC], 09/06/2011[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 04/01/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	07/07/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of change
06/14/2016	Added retired LCD language
05/18/2015	Added AccuBoost to insufficient evidence table
09/08/2015	Revised LCD L34065
11/10/2015	Removed Electronic Brachytherapy for non-melanoma skin cancer. See separate criteria.
04/19/2016	Changed Medicare language as LCD 34065 was retired.
08/11/2016	Revised retired LCD language
06/02/2020	Removed deleted codes 77326, 77327, 77328, 77785, 77786, 77787, 0182T
06/24/2022	Remove codes 55875, 55876, 55920, 57155, 57156
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020.

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Clinical Review Criteria
Breast Implant Removal & Re-Implantation

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Criteria
For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Breast Reconstruction Following Mastectomy (140.2)
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Articles	Plastic Surgery (A57222)

For Non-Medicare Members
Breast implant removal is covered when **All of the following** criteria are met:
1. Breast implants were part of a reconstructive procedure meeting criteria for breast reconstructive surgery.
2. **One of the following** clinical symptoms are present:
   a. Infection related to implant
   b. Implant extrusion
   c. Ruptured implant
   d. Baker Classification* Class II to IV contracture
   e. Interference with diagnosis and/or treatment of breast cancer

Additionally, breast implant removal and subsequent re-implantation may be covered if the implants were placed for a diagnosis of breast cancer or other malignancy involving the breast if criteria are met - see Breast Reconstruction or Breast Prostheses following Mastectomy/Lumpectomy.

*Baker Classification:
Class I augmented breast feels as soft as a normal breast
Class II augmented breast is less soft, and implant can be palpated, but is not visible
Class III augmented breast is firm, palpable and the implant (or distortion) is visible
Class IV augmented breast is hard, painful, cold, tender, and distorted

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Breast implant removal is medically necessary under limited circumstances.

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Medical Technology Assessment Committee (MTAC)

Silicone Breast Implant Removal

09/11/1999: MTAC REVIEW

Evidence Conclusion: The committee reviewed the available data on the safety of silicone breast implants and concluded: There is no evidence linking silicone breast implants to cancer in women, the elective removal of existing implants is not recommended. There is concern and there may be a relationship between silicone breast implants and the development of connective tissue disease, although there is no epidemiological evidence Silicone breast implants can impede early detection of breast cancer in cases of cosmetic breast augmentation, but do not in cases of breast reconstruction following extractive surgery.

Articles: Committee reviewed the available data on the safety of silicone breast implants and concluded: There is no evidence linking silicone breast implants to cancer in women, the elective removal of existing implants is not recommended. There is concern and there may be a relationship between silicone breast implants and the development of connective tissue disease, although there is no epidemiological evidence. Silicone breast implants can impede early detection of breast cancer in cases of cosmetic breast augmentation, but do not in cases of breast reconstruction following extractive surgery. Capsular contracture does occur in many patients and patients should be advised, before implantation, that it is a possible side effect that is normal and not harmful to their health.

The use of silicone breast implant removal for prevention of breast cancer does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

2001: MTAC REVIEW

Silicone Breast Implant Removal

Evidence Conclusion: Evidence update outside of committee process that supported the 1999 outcome.

Articles: Intern Med J 2001 Mar31 (2):77-89 Women's health after plastic surgery.

Englert H, Joyner E, McGill N, Chambers P, Horner D, Hunt C, Makaroff J, O'Connor H, Russell N, March L. Westmead Hospital, Sydney, New South Wales, Australia. Laing TJ, Schottenfeld D, Lacey JV Jr, Gillespie BW, Garabrant DH, Cooper BC, Heeringa SG, Alcser KH, Mayes MD. Department of Internal Medicine, University of Michigan.

No meeting discussion.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
3/1999	10/5/2010[MDCRPC], 8/2/2011[MDCRPC], 4/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC] 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/17/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/01/2015	Revised LCD Local Coverage Determination (LCD): Non-Covered Services L34886 and L35008
12/19/2017	Added LCD 37020
04/06/2021	Updated LCA to Plastic Surgery (A57222)
04/18/2023	Updated LCA to Plastic Surgery (A57222)

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Clinical Review Criteria
Breast Pump

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Breast Pump*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

To qualify for a hospital grade breast, pump the member must meet **ONE of the following**:

- Direct breastfeeding is not possible because of a separation due to the prolonged or repeat hospitalization of either the infant or the mother.
- The infant has a medical condition or congenital anomaly that prevents effective breastfeeding.
- The mother has a medical condition or anatomical anomaly that prevents effective breastfeeding.

Hospital grade breast pump is not considered medically necessary after 12 months of age.

Kaiser Permanente will not cover rental of a heavy duty electrical/hospital grade breast pump when requested solely for convenience because it is considered not medically necessary. Purchase of a basic electric consumer pump (E0603) does not require medical necessity review.

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or specialist related to infant feeding issues.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Breast-fed infants have a lower risk of diarrhea and otitis media than bottle-fed infants during the first year of life. For premature infants, breast milk helps prevent infections, speeds recovery from respiratory distress syndrome, increases weight gain, protects against retinopathy, and facilitates cognitive and visual development.

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By contrast, the manual and electric breast pumps that are available commercially are not designed for reuse and are most commonly sold to mothers with normal infants who are working, traveling, or for other reasons not always home to breast-feed the baby. Standard electric breast pumps or manual breast pumps may be necessary to initiate breast feeding in the postpartum period, within the first eight weeks following delivery. Manual breast pumps are sufficient for continuation of breastfeeding following the postpartum period. Current recommendations from the American Academy of Pediatrics are to continue breastfeeding of infants through one year of age.

Women may be able to breastfeed adopted infants through induced lactation. The process involves nipple stimulation with use of an electric breast pump beginning about two months before the adoptive mother expects to begin breast-feeding. In addition, hormonal therapy, such as supplemental estrogen or progesterone, may be prescribed to mimic the effects of pregnancy. Typically, hormone therapy for induced lactation is discontinued shortly before breast-feeding begins. At that point, the infant's suckling is thought to stimulate and maintain milk production.

Authorized under provisions of the Patient Protection and Affordable Care Act, the U.S. Department of Health and Human Services (DHHS) released health plan coverage guidelines, developed by a committee of the Institute of Medicine, that require health insurance plans to cover breast pumps and certain other women's preventive services. New health plans and non-grandfathered plans and issuers are required to provide coverage consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

The Centers for Disease Control and Prevention (CDC, 2010) recommended that infected women in the United States refrain from breast-feeding to avoid post-natal transmission of HIV-1 to their infants through breast milk. These recommendations also should be followed by women receiving anti-retroviral therapy. Passage of anti-retroviral drugs into breast milk has been evaluated for only a few anti-retroviral drugs; ZDV, 3TC, and nevirapine have been detected in the breast milk of women.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E0604	Breast pump, hospital grade, electric (AC and/or DC), any type

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Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	10/04/2016

[MPC] Medical Policy Committee

Revision History	Description
10/04/2016	Added indication: Hospital grade breast pump is not considered medically necessary after 12 months of age

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KAISER PERMANENTE®

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Clinical Review Criteria

Breast Reconstruction or Breast Prostheses

- Following Mastectomy/Lumpectomy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Breast Reconstruction Following Mastectomy (140.2)
Local Coverage Determinations (LCD)	Plastic Surgery (L37020) External Breast Prothesis (L33317)
Local Coverage Articles	External Breast Prosthesis (A52478)

Effective until July 01, 2023

For Non-Medicare Members

For breast reconstruction or breast prosthesis following a mastectomy or lumpectomy member must qualify both in A and B:

A. **ONE of the following** must be met:
   1. Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity

   OR

   2. Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer

B. And must be **ONE of the following** procedures:
   1. **For the diseased**/ injured/affected breast must meet **ONE of the following**:
      a) Tissue/muscle reconstruction procedures (flaps)
      b) Capsulotomy
      c) Capsulectomy
      d) Implantation of tissue expander
      e) Implantation of U.S. Food and Drug Administration (FDA) approved internal breast prosthesis
      f) Areolar and nipple reconstruction
      g) Areolar and nipple tattooing
      h) Breast implant removal and subsequent re-implantation

   2. **For the non-diseased**/non-injured/unaffected/contralateral breast to produce symmetry in appearance must meet **ONE of the following**:
      a) Breast reduction by mammoplasty or mastopexy
      b) Augmentation mammoplasty
      c) Augmentation with implantation of FDA internal breast prosthesis when unaffected breast is smaller than the smallest available internal prosthesis

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d) Areolar and nipple reconstruction
e) Areolar and nipple tattooing
f) One reconstructive procedure to produce a symmetrical appearance
g) Breast implant removal and subsequent re-implantation performed to produce a symmetrical appearance when the original implant was in the unaffected breast prior to the disease in the affected breast.
h) Capsulotomy
i) Capsulectomy

The following products are covered for breast reconstruction when medically necessity criteria are met:
1. Alloderm
2. AlloMax
3. DermaMatrix
4. FlexHD
5. Neoform Dermis
6. Strattice tissue matrix
7. SurgiMend

Autologous fat injections for post-mastectomy breast reconstruction (autologous fat grafting, autologous fat transfer, breast fat grafting, lipoinjection, lipofilling)
A. Autologous fat injection coverage is covered only for breast reconstruction (dimpling and contouring), if medical necessity criteria for breast reconstruction is met.
B. Total breast reconstruction is not covered using the Brava system (autologous fat injection for complete reconstruction).

The following are <u>not covered</u>:
A. All other bioengineered skin substitutes other than listed above - see Wound Care criteria
B. Suction lipectomy or ultrasonically assisted suction lipectomy for correction of donor site asymmetry.
C. Reconstructive surgical revisions are for restoration and not for cosmetic. Ongoing surgery for treatment of natural changes due to age or weight changes is considered cosmetic and not covered.
D. Breast MRI is not covered for routine surveillance of silicone breast implants. The FDA made a recommendation (not a requirement) when they re-approved silicone implant use that members receive periodic breast MRIs. The FDA did not fund this screening. The choice of silicone vs saline is a patient preference and the use of MRI in this case cannot be described as medically necessary.

Pulsed electromagnetic field (PEMF) for pain reduction after breast reconstruction surgery
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies

External breast prostheses and bras - If the member has not undergone breast reconstruction, external breast prostheses and bras are covered after a medically necessary mastectomy or a lumpectomy, when surgery results in significant deformity.

- External prosthesis (one silicone every 2 years or one foam every 6 months) Post-mastectomy bras/forms, limited to 2 every 6 months. Replacements within this 6-month period are covered when medically necessary due to a change in the Member's condition.

Effective July 01, 2023

For Non-Medicare Members

For breast reconstruction or breast prosthesis following a mastectomy or lumpectomy member <u>must qualify both in A and B:</u>

A. **ONE of the following** must be met:
   1. Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity

   OR

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2. Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer

B. And must be **ONE of the following** procedures:
   1. **For the diseased**/ injured/affected breast must meet **ONE of the following**:
      a. Tissue/muscle reconstruction procedures (flaps)
      b. Capsulotomy
      c. Capsulectomy
      d. Implantation of tissue expander
      e. Implantation of U.S. Food and Drug Administration (FDA) approved internal breast prosthesis
      f. Areolar and nipple reconstruction
      g. Areolar and nipple tattooing
      h. Breast implant removal and subsequent re-implantation

   2. **For the non-diseased**/non-injured/unaffected/contralateral breast to produce symmetry in appearance must meet **ONE of the following**:
      a. Breast reduction by mammoplasty or mastopexy
      b. Augmentation mammoplasty
      c. Augmentation with implantation of FDA internal breast prosthesis when unaffected breast is smaller than the smallest available internal prosthesis
      d. Areolar and nipple reconstruction
      e. Areolar and nipple tattooing
      f. Breast implant removal and subsequent re-implantation performed to produce a symmetrical appearance when the original implant was in the unaffected breast prior to the disease in the affected breast.
      g. Capsulotomy
      h. Capsulectomy

The following products are covered for breast reconstruction when medically necessity criteria are met:
1. Alloderm
2. AlloMax
3. DermaMatrix
4. FlexHD
5. Neoform Dermis
6. Strattice tissue matrix
7. SurgiMend

Autologous fat injections for post-mastectomy breast reconstruction (autologous fat grafting, autologous fat transfer, breast fat grafting, lipoinjection, lipofilling)
A. Autologous fat injection coverage is covered only for breast reconstruction (dimpling and contouring), if medical necessity criteria for breast reconstruction is met.
B. Total breast reconstruction is not covered using the Brava system (autologous fat injection for complete reconstruction).

The following are <u>not covered</u>:
A. All other bioengineered skin substitutes other than listed above - see Wound Care criteria
B. Suction lipectomy or ultrasonically assisted suction lipectomy for correction of donor site asymmetry.
C. Reconstructive surgical revisions are for restoration and not for cosmetic. Ongoing surgery for treatment of natural changes due to age or weight changes is considered cosmetic and not covered.
D. Breast MRI is not covered for routine surveillance of silicone breast implants. The FDA made a recommendation (not a requirement) when they re-approved silicone implant use that members receive periodic breast MRIs. The FDA did not fund this screening. The choice of silicone vs saline is a patient preference and the use of MRI in this case cannot be described as medically necessary.

Pulsed electromagnetic field (PEMF) for pain reduction after breast reconstruction surgery
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies

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External breast prostheses and bras - If the member has not undergone breast reconstruction, external breast prostheses and bras are covered after a medically necessary mastectomy or a lumpectomy, when surgery results in significant deformity.

- External prosthesis (one silicone every 2 years or one foam every 6 months) Post-mastectomy bras/forms, limited to 2 every 6 months. Replacements within this 6-month period are covered when medically necessary due to a change in the Member's condition.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

While breast reconstructive surgery can be considered a cosmetic procedure, under both state and federal law, carriers must provide coverage for this type of surgery in certain clinical circumstances.

The Women's Health and Cancer Rights Act (WHCRA) of 1988 (also known as Janet's Law) is a federal law that requires Kaiser Permanente plans and carriers offering coverage in connection with group or individual plans to provide benefits for mastectomy-related services, including breast reconstruction surgery. WHCRA states that a Kaiser Permanente plan or carrier (in a manner determined in consultation with the attending physician and the patient), must provide coverage for:

- All stages of reconstruction of the breast on which the mastectomy has been performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- Prostheses and physical complications of mastectomy, including lymphedema.

U.S. Code – Title 29 Chapters - § 1185b, § 300gg-27, and § 300gg-52.

Washington state law also has provisions for the coverage of reconstructive surgery following a mastectomy. Both RCW 48.46.280 (HMOs) and RCW 48.330 (Health Care Service Contractors) require that carriers shall provide coverage for:

- Reconstructive breast surgery resulting from a mastectomy which resulted from disease, illness, or injury.
- All stages of one (1) reconstructive breast reduction on the non-diseased breast to make it equal in size with the diseased breast after definitive reconstructive surgery on the diseased breast has been performed.

In addition to the above statutes, guidance for interpretation of these state statutes is found in Carr v. Blue Cross of Washington and Alaska, 93 Wash. App. 941 (1999).

Kaiser Permanente has developed the criteria above with these laws as a guide.

Evidence and Source Documents

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction
BRAVA® Breast Expansion System
Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery
SERI® Surgical Scaffold for Breast Reconstruction

Medical Technology Assessment Committee (MTAC)

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction

BACKGROUND

Autologous fat transfer, also known as breast fat grafting (BFG), fat transplantation, lipofilling, or lipoinjection, is a process in which fat cells from one area of the body are transferred to another. Fat transfer was first performed by

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Neuber in 1893 for the correction of a depressed face scar, and two years later it was performed by Czerny for breast construction after excision of a large fibroadenoma. Since then, several surgeons have used free fat grafts for the reconstruction of breast defects. Autologous fat is considered an ideal injectable agent for soft tissue augmentation; it is easily available for most patients, easy to use, inexpensive, nontoxic, biocompatible, and potentially long lasting, and removable (Mu 2009, Fraser 2011, Bucky 2011). Breast fat grafting is a promising technique to correct contour deformities in breasts reconstructed with either prosthesis or autologous tissues. The value of the procedure is controversial due concerns about its safety and efficacy. The degree of reabsorption of the adipose tissue transplanted is unpredictable. The mechanism underlying the survival of dissected autologous fat after grafting is unknown but is believed to be dependent on revascularization of fat granules. The lipogenic activity may vary by donor site (e.g. abdomen, thigh, and flank), patient age, weight, smoking habits, co-morbidities, condition of recipient site (scarring, radiation, previous surgery) and other factors. One of the main concerns with autogenous fat grafting for the breast is the development of fat necrosis leading to liponecrotic cysts and microcalcifications that could be mistaken for cancerous calcifications. Compression of the breast tissue by the transferred fat may also make it difficult to identify subtle changes in architectural patterns seen with early breast cancer presentation. Another concern relates to the potential oncologic risks of breast fat grafting, as fat transfer into a previous breast-cancer area may potentially stimulate local recurrence. Other complications with autologous fat transfer include edema, hematoma, induration, infection, granuloma formation, oil cyst formation, fat liquefaction, sclerosis and resorption (Pulagam 2006, Mu 2009, Mizuno 2010, Fraser 2011, Bucky 2011, Rietjens 2011, Serra-Renom 2011). After gaining much popularity, the interest in autologous fat transfers waned in the 1950s and 1960s due to low rates of graft survival and the increased use of artificial material. The interest in autologous fat grafting for aesthetic and reconstructive purposes was renewed in the 1980s with the introduction of liposuction that provided a minimally invasive means of obtaining large amounts of adipose tissue in a semiliquid form. However, the procedure was again discontinued for some time due to concerns over post-operative calcifications and risk of obscuring developing malignant lesions. More recently, autologous fat transfer re-emerged after a number of surgeons introduced “lipomodelling” and used the technique alone or with in combination with other reconstructive procedures. Several harvesting and transplantation techniques have been developed and refined, yet no standard procedures have been adopted by all practitioners. There is no consensus on the ideal cannula, technique for harvesting, processing, or grafting the fat. Harvesting approaches include syringe aspiration and lipoaspiration. Once harvested, the fat is prepared for injection by one of several methods including: washing with physiological buffers, centrifugation for separating the cells from the debris, decantation, or concentrating it using cotton towels or other adsorbent media. For grafting, the fat is injected with a variety of delivery methods using sharp or blunt needles. It is reported that the fat “takes” if it is obtained using atraumatic methods, but it does not acquire the shape of the breast and remains flattened. It is difficult to remodel the grafted fat to acquire the desired cone shape. The procedure is not simple and should be performed by skilled and trained surgeons. It requires careful calculation of the amounts of fat injected at one time, number of injections needed, appropriate sites for injections, and proper administration of the transferred fat (Hyakusoku 2008, Mu 2009, Fraser 2011, Bucky 2011, Parrish 2010). In 1987, the American Society of Plastic and Reconstructive Surgeons (ASPRS) Ad-Hoc committee on New Procedures issued a position statement recommending that autologous fat transfer to the breast be prohibited due to its complications that may compromise breast cancer screening. In 2007, the ASPS and the American Society for Aesthetic Plastic Surgery (ASAPS) again determined that fat grafting for breast augmentation is not recommended due to the lack of clinical data on the efficacy and safety of the procedure, and also because it may interfere with the detection of breast cancer. In 2009, the ASPS Fat Graft Task Force took a more lenient position stating that, “Fat grafting may be considered for breast augmentation and correction of defects associated with medical conditions and previous breast surgeries.” This Task Force based the recommendation on low quality evidence from case series, and/or expert opinion and the gave it a B grade. They emphasized that the patients should be made aware of the potential risks and complications of the procedure and indicated that physicians should be cautious when considering high-risk patients (Gutowski 2009, Mizuno 2010).

08/15/2001: MTAC REVIEW

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction

Evidence Conclusion: The published studies are limited to case series and case reports which do not provide sufficient evidence to determine the efficacy, safety, and durability of autologous fat transfer for breast reconstruction after a mastectomy. The studies used different techniques, donor site, volume of fat transplant, as well as various outcome measures and follow-up durations. Most of the series included patients undergoing the procedure for breast augmentation, reconstructive surgery after mastectomy, as well as other indications. The largest published series of 880 patients over 10 years was reported by Delay, et al in 2009. The majority (83.4%) of the patient population underwent autologous fat grafting for breast reconstruction, the rest were for correction of congenital deformities, aesthetic breast surgeries, or to correct previous surgeries. The intervention was not compared to another procedure, and the study had several limitations including, but not limited to, lack of

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reporting inclusion/exclusion criteria, patient characteristics, and lack of clearly defined outcomes and reporting of duration or completeness of follow-up. The authors indicate that the procedure was successful to the patients and surgeons but did not clearly define success other than comparison of photographs. They reported that the incidence of fat necrosis was 15% for the first 50 patients and declined to 3% for the last 100 patients suggesting a surgical learning curve. The authors concluded, "None of the imaging results are likely to confuse the diagnosis of cancer for radiologists who are experienced in breast imaging. Oncologic follow-up (now at 10 years for our first patients) shows no increased risk of local recurrence or of development of a new cancer". Illouz and Sterodimas (2009), reported on a series of 820 consecutive patients who underwent autologous fat transplantation over 25 years. These included patients undergoing the procedure for breast reconstruction after a mastectomy, patients with congenital asymmetry, or women requesting breast augmentation. A total amount of fat transplanted in each breast ranged from 25-900 ml (mean 540 ml), and a mean of 3 sessions (range 1-5) were needed to achieve the desired results. The authors indicted that the majority of patients were satisfied with the results. They did not measure the longevity of the transplantation, did not discuss loss of follow-up, injected fat survival, or necrosis. They indicate that calcifications, cysts, and cancer were not apparent in the first year after the procedure and thought that they may not be directly associated with the procedure. Long-term follow-up data that ranged from 2-25 years (mean 113.3 years) were only available for 28% of the patients. In conclusion, data from published studies do not provide sufficient evidence to determine the components of a successful, consistent, durable, and safe autologous fat transplantation for breast reconstruction. The Breast Reconstruction and Augmentation with Brava Enhanced Autologous Fat Micro Grafting (BRAVA) trial is an ongoing nonrandomized study on fat grafting of the breast post-mastectomy as well as other indications.
Articles: Assessment objective: To determine the safety and efficacy of autologous fat grafting for post-mastectomy breast reconstruction. Screening of articles: The literature search revealed around 100 articles on autologous fat grafting for post-mastectomy breast reconstruction and/or augmentation. No published meta-analyses or randomized controlled trials were identified; only case series and case reports. The majority of the published literature was on breast augmentation. The two largest published series of patients who underwent autologous fat transplantation to the breast, mainly for reconstruction after mastectomy, were selected for critical appraisal. Delay E, Garson S, Tousson G, et al. Fat injection to the breast: technique, results, and indications based on 880 procedures over 10 years. *Aesthet Surg J.* 2009; 29:360-376.
See Evidence Table Illouz YG, Sterodimas A. Autologous fat transplantation to the breast: A personal technique with 25 years of experience Aesth *Plast Surg. 2009;33:706-715.* See Evidence Table

The use of autologous fat grafting does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

BRAVA® Breast Expansion System

10/21/2013: MTAC REVIEW

Evidence Conclusion: The developer of the Brava device (Brava LLC, Miami, Fla.) conducted a multicenter, prospective, magnetic resonance imaging-documented study to determine the safety and efficacy of single-stage large-volume autologous fat transfer to the breast treated with the Brava external breast expander. The population included 81 women between the ages of 17 and 63 years who desired breast augmentation. It is not clear from the study if patients seeking reconstruction following mastectomy were included or excluded (Khouri, Eisenmann-Klein et al. 2012). Currently, the evidence on the use of BRAVA® Breast Expansion System is limited and provided insufficient evidence to determine the safety and efficacy for use superficially in breast reconstruction surgery with autologous fat transfer. Conclusion: There is no evidence to permit conclusions concerning the safety and efficacy of the BRAVA Breast Expansion System used in breast reconstructive surgery with fat implants.
Articles: A search of PubMed and the National Institute of Health Clinical Trials records was completed for the period through September 2013 for studies on BRAVA® Breast Expansion System used for the treatment of patients following mastectomy for breast cancer. The search strategy used the terms *Brava, breast expansion, reconstructive surgery, fat implants, flap surgery* and *mastectomy* with variations. Articles were limited to those published in English language and enrolling human subjects. The search was supplemented by an examination of article bibliographies in addition to the PubMed *related* articles function. Screening of Articles: A literature search was conducted and revealed one publication (funded by the manufacturer) on the use of the Brava system plus autologous fat transfer in breast augmentation. There are no current publications on the use of the BRAVA Breast Expansion System in breast reconstruction. One ongoing clinical trial was discovered (Breast Reconstruction and Augmentation with the BRAVA Enhanced Autologous Fat Micro Grafting) with an estimated completion date of April 2014. No studies were selected for review.

The use of the BRAVA® Breast Expansion System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery

BACKGROUND

Pulsed electromagnetic field (PEMF) therapy, also known as electromagnetic therapy, uses an electromagnet to generate electric current, and nonthermal pulsed electromagnetic energy to deliver the current. PEMF utilize generators designed to create radiofrequency signals that are delivered through coils which do not come in direct contact with the skin. The electric current is generated in short bursts into in the injured tissue without the production of heat or interfering with nerve or muscle function. Unlike electrical stimulation, FEMF therapy does not involve the use of current, leads, or electrodes. The FEMF devices are noninvasive and can be applied over or as part of the dressing in the wound healing area directly following a procedure for the postoperative management of a surgical wound (Kinney 2005, Gupta 2009, Strauch 2009). The mechanism of action of PEMF on tissue growth and repair is not completely known. In vitro and animal research showed that PEMF can increase blood flow, enhance circulation, induces collagen synthesis, granulocyte infiltration, and inhibit growth of some wound pathogens. The literature also suggests that this modality of therapy can modify the inflammatory process, reduce edema, and enhance tissue repair. The effects of PEMF are immediate and are not limited by pharmacokinetics because the induced currents are instantaneously present when the coil is transmitting into the affected area (Kinney 2005, Gordon 2007, Strauch 2009). Electromagnetic therapy is currently being used in physical medicine, orthopedic and sports injuries, and other musculoskeletal conditions. PEMF therapy use is proposed for other conditions as the reduction of pain and edema after facial surgery, breast surgery, and abdominoplasty. Several trials are currently underway or planned to study the use of PEMF in several other fields of medicine (Kinney 2005, Gupta 2009).

06/18/2012: MTAC REVIEW

Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery

Evidence Conclusion: The two published trials on the use of pulsed electromagnetic field therapy (PEMF) to reduce pain and the use of pain medications after breast reconstruction surgery were small pilot studies with valid methodology. Both trials were randomized, blinded, used sham therapy as a control, and had sufficient power to detect statistically significant differences between PEMF and the sham therapy. Hedén and Pilla's trial randomized 42 women to receive bilateral active PEMF therapy, bilateral breast sham therapy, or one of the two therapies on each breast. The results of the study showed a significant difference between the active and sham therapies in the pain experienced and in the use of postoperative pain medication. Those who received PEMF on one breast and sham therapy on the other breast showed no significant differences between the two breasts or between them and the active treatment. This was attributed to the fact that the breast randomized to sham treatment received 40- 60% of signal amplitude delivered to the active treatment breast due to the propagation of PEMF signal from the coil application. Based on this observation, Rohde and colleagues (2009) randomized their study participants to receive either bilateral active therapy or bilateral sham therapy. The trial included 24 patients and reported outcomes for only 48 hours. Similar to Hedén and Pilla's results, women who received PEMF therapy experienced less pain and used fewer narcotics in the 48 postoperative hours. Conclusion: The overall results of the published small pilot studies show that PEMF therapy may reduce pain and use of pain medication after breast reconstruction surgery. Both trials noted that no adverse events were reported, but neither studied the effect of PEMF on the reduction of postoperative edema, or on the speed and quality of wound repair

Articles: The literature search revealed two relatively small randomized controlled trails that evaluated the use of PEMF therapy after breast reconstruction therapy. Both trials were critically appraised.

Hedén P and Pilla AA. Effects of pulsed electromagnetic fields on postoperative pain: A double-blind randomized pilot study in breast augmentation patients. Aesth Plast Surg.2008; 32:660-666. See Evidence Table

Rohde C, Chiang A, Adipoju O, et al. Effects of pulsed electromagnetic fields on interleukin-1β and postoperative pain: A double-blind, placebo-controlled, pilot study in breast reduction patients. Plast Reconst Surg.2010; 125:1620-1629. See Evidence Table

The use of Pulsed electromagnetic field (PEMF) therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

SERI® Surgical Scaffold for Breast Reconstruction

04/20/2015: MTAC REVIEW

Evidence Conclusion: There is a lack of published evidence on the use of SERI® Surgical Scaffold for breast reconstruction after mastectomy. The largest published study to date, SURE-001 (Fine et al, 2014, Evidence table 1) was a prospective observational study with no comparison or control group. It included 139 patients undergoing two-stage, implant-based breast reconstruction using SERI® Surgical Scaffold in multiple centers in the US. The study is planned to follow the patients for 2 years, but the published article reports the interim data for 71 patients followed for 1 year after surgery. The patients underwent tissue expander placement during stage one of

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reconstruction, with SERI® sutured into place for soft-tissue support of the lower-breast mound. Once expansion was complete with drain placement, the second stage of surgery was performed, where the expander was replaced with a permanent breast implant. The primary outcome of the study was the investigator satisfaction at 6 months. Other outcomes included the investigator satisfaction at 12 months after stage 1 surgery; ease to use of SERI®; visibility and palpability of SERI® through the skin at first postoperative visit, and during follow-up; patient satisfaction, and adverse events associated with the implant. The interim results of the study showed that the mean investigator satisfaction scores were 9.2 at 6 months where a score of 10 indicates being very satisfied with results. The mean patient satisfaction with the treated breast was 4.3 at 6 months and 4.5 at 12 months with a score of 5 signifying very satisfied with results. Adverse events occurred in 18 of the 71 patients with 1-year follow-up after stage I surgery, and most occurred within the first 6 months. Tissue necrosis occurred in 8.5% of the patients, seroma in 7%, hematoma in 7%, cellulitis in 4.2%; implant loss in 4.2%, capsular contracture in 1.4% and breast infection occurred in 1.4%. These results have to be interpreted with caution as the study was only observational with no control or comparison group and had a subjective primary outcome. The study was sponsored by Allergan, Inc. and all the investigators had financial ties to the manufacturer of SERI ®Surgical Scaffold. Conclusion: There is insufficient evidence to determine the efficacy and safety of SERI surgical scaffold in women undergoing breast reconstructive surgery after mastectomy.
Articles: The literature search did not reveal any randomized controlled trials that compared the use of SERI® Surgical Scaffold versus currently used practices or alternative material used for tissue support. To date, the published empirical studies consist of one prospective case series with 139 women undergoing breast reconstruction after mastectomy (SURE-001 study, Fine et al, 2014), a very small retrospective case series, and case reports on the use of SERI® for other indications as abdominoplasty and brachioplasty.
The prospective case series was selected for critical appraisal. Fine NA, Lehfeldt M, Gross JE, et al. SERI Surgical Scaffold, Prospective Clinical Trial of a Silk-Derived Biological Scaffold in Two-Stage Breast Reconstruction: 1-Year Data. Plast Reconstr Surg. 2015; 135(2):339-351. See Evidence Table 1

The use of the SERI® Surgical Scaffold for Breast Reconstruction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction; with latissimus dorsi flap
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap

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19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant
HCPC Codes	**Description**
C1789	Prosthesis, breast (implantable)
L8000	Breast prosthesis, mastectomy bra, without integrated breast prosthesis form, any size, any type
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8015	External breast prosthesis garment, with mastectomy form, post mastectomy
L8020	Breast prosthesis, mastectomy form
L8030	Breast prosthesis, silicone or equal, without integral adhesive
L8031	Breast prosthesis, silicone or equal, with integral adhesive
L8032	Nipple prosthesis, prefabricated, reusable, any type, each
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
L8035	Custom breast prosthesis, post mastectomy, molded to patient model
L8039	Breast prosthesis, not otherwise specified
L8600	Implantable breast prosthesis, silicone or equal

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Medicare – Considered Not Medically Necessary

HCPC Codes	Description
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/13/2011	08/02/2011[MDCRPC], 09/006/2011[MDCRPC], 06/05/2012[MDCRPC], 07/03/2012[MDCRPC], 08/07/2012[MDCRPC], 04/02/2013[MDCRPC], 11/05/2013[MPC], 12/03/2013[MPC], 09/02/2014[MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	02/07/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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06/02/2015	MPC approved MTAC recommendation of insufficient evidence for Seri Surgical Scaffolding for Breast Reconstruction
09/01/2015	Added language per that external prosthesis and bras are covered “before, during and after” surgery per WHCRA regs
11/2/2015	Aligned external prosthesis language with contract policy
03/08/2018	Added Plastic Surgery LCD
4/14/2020	Added non-covered statement for routine surveillance of silicone breast implants
07/31/2020	Added CPT codes 15769, 15771 and 15772
04/06/2021	Updated applicable codes
02/07/2023	MPC approved to adopt the modified changes to remove the indication for *one reconstructive procedure to produce a symmetrical appearance*. Requires 60-Day notice, effective 07/01/2023.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Bronchial Thermoplasty for Treatment of Severe Bronchial Asthma

- Alair Bronchial Thermoplasty System

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**Bronchial Thermoplasty for Treatment of Severe Bronchial Asthma**" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* (A-0634) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (pulmonary/allergy)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Asthma is an increasingly prevalent disease that affects over 20 million people in the United States. It is estimated that 15 -20% of asthma patients have a severe condition despite receiving the new effective therapies. Asthma is characterized by chronic inflammation of the airways, airway wall edema, bronchial hyper responsiveness, and remodeling of the airways that include increased airway smooth muscle mass. Each of these factors alone or in combination can result in recurrent episodes of wheezing, coughing, chest tightness, and breathlessness (Castro 2010, Cox 2011).

Although inflammation of the airways is a main feature of asthma, researchers believe that the contraction of the

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excess airway smooth muscles, in response to various asthma triggers, is the main cause of airway constriction and restricted airflow leading to breathing difficulty during asthma attacks. This led to a hypothesis that decreasing the mass and /or contractility of airway smooth muscle would reduce airway bronchoconstriction and ameliorate the symptoms of asthma. Based on this hypothesis, investigators suggested that the application of thermal energy to the airway wall, termed bronchial thermoplasty, can reduce the bronchoconstrictor response in asthma (Cox 2007, Pavord 2007, Wechsler 2008).

Bronchial Thermoplasty (BT) is a device-based approach for severe persistent asthma that involves the application of controlled heat from a radiofrequency (RF) source to the airway wall resulting in a prolonged reduction in airway smooth muscle mass. The Alair System (Asthmatx Inc., Sunnyvale, CA) is the first device designed to use RF to selectively reduce the amount of excess airway smooth muscle in airways distal to the main stem bronchi down to 3 mm in diameter. The Alair system consists of the Alair RF catheter that has an expandable electrode array on the tip, and the Alair RF controller which supplies energy via the catheter to heat the airway wall. The catheter is deployed under direct vision through a compatible flexible bronchoscope, which is navigated to the first target treatment site, typically the most distal airway in the targeted lobe. Once the bronchoscope is inserted in the airways, the catheter is passed through the bronchoscope and its electrode array expanded such that all its sides are in contact with the airway wall. The bronchoscopist steps on a footswitch attached to the RF controller for approximately 10 seconds. This delivers low-power, temperature-controlled RF thermal energy to the treated airway. A single activation of the catheter delivers RF energy over a distance of approximately 5 mm. The catheter is then repositioned so that other adjacent areas of the airways may be treated, following a mapped treatment plan, and avoiding overlap. All visible and reachable airways 3-10 mm in diameter that are distal to the main stem bronchi are treated with a series of contiguous activations. A systematic approach from distal to proximal, working methodologically from airway to airway across the lung being treated is recommended to ensure that all accessible airways are carefully identified and treated only once. BT is performed under conscious sedation in an outpatient setting, and the procedure takes 30-45 minutes to complete. The treatment is administered in three sessions approximately 3 weeks apart. A different region of the lung is treated during each session: one lower lobe in session 1; the second lower lobe in session 2; and both upper lobes in session 3. Depending on the patient size and anatomy, a range of approximately 60-100 energy cycles are performed (Duhamel 2010, Wechsler 2008, Castro 2010).

Patients are selected for BT by an asthma specialist and an experienced bronchoscopist and should not considered for the procedure if they have acute respiratory infection, known coagulopathy, active respiratory infection, or with asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) 14 days before the procedure (Duhamel 2010).

This Alair Bronchial Thermoplasty system received marketing clearance from the U.S. Food and Drug Administration (FDA) in April 2010 for the control of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. The FDA approved the system based on data from AIR2 trial and is requiring a five-year post-approval study of the device to study its long-term safety and effectiveness. The FDA list of potential adverse events associated with the use of the device includes: upper respiratory tract infection, throat irritation, pharyngolaryngeal pain, rhinitis, nasopharyngitis, asthma (multiple symptoms), sinusitis, wheezing, dyspnea, airway bleeding, cough, laryngospasm, bronchospasm, bronchitis, excess mucus production, chest discomfort, increased airway reactivity, atelectasis, hemoptysis, bronchial stenosis, bronchiectasis, pneumothorax, and others.

Medical Technology Assessment Committee (MTAC)

Bronchial Thermoplasty

04/18/2011: MTAC REVIEW

Evidence Conclusion: The Asthma Intervention Research (AIR) trial examined the efficacy of BT in patients with moderate to severe asthma while AIR2 and Research in Severe Asthma (RISA) trials studied the efficacy of the procedure in patients with symptomatic severe asthma despite the use of high doses of inhaled corticosteroids (ICS) and long acting β_2 adrenergic agonists (LABA). AIR and RISA trials compared BT in addition to usual care with standard medications versus usual care alone and had no sham control. The AIR2 trial compared the BT to sham therapy, which was an advantage of the trial as it addressed the concern about the placebo effect of bronchial thermoplasty in the control of severe asthma. All three trials were supported by Asthmatx Inc., the manufacturer of Alair Bronchial Thermoplasty System, and the authors had financial ties to the industry and other pharmaceutical companies. The AIR trial conducted by Cox and colleagues (Evidence Table 1) enrolled 112 patients aged 18 to 65 years with moderate to severe asthma symptoms despite receiving combined therapy with ICS and LABA, and in whom the withdrawal of LABAs resulted in a worsening of asthma control. Eligible patients were randomly allocated to a treatment group that received BT in addition to the standard therapy, or to a control group that only received the standard treatment. Initially the patients were followed up for 12 months after which they were invited to participate in

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a 4-year safety study. The primary outcome for the first 12 months was the difference between the BT group and the controls in the change in rate of mild exacerbation between baseline and later time points. The trial results showed a significant difference between the BT group and the controls in the change of mild exacerbations rate from baseline to three months and 12 months. No such significant difference between the two treatment groups was observed for severe exacerbations. The 5-year follow-up of 80% of patients in the BT group showed no increase in rate of hospitalization or emergency department visits for respiratory symptoms in years 2 to 5 compared to year one. The AIR2 trial by Castro and colleagues (Evidence Table 2) enrolled 288 highly selected patients with severe symptomatic asthma despite treatment with high doses of ICS and LABA. They were randomized in a 2:1 ratio to receive BT or sham therapy in which the controls underwent three bronchoscopies and sham thermoplasty treatment that duplicated the BT procedure except for the delivery of radiofrequency energy. Patients were followed-up for 12 months and the primary outcome was improvement in Asthma Quality of Life Questionnaire (AQLQ) at 6, 9, and 12 months. Both the BT and sham therapy groups experienced a large improvement in the AQLQ that lasted for 12 months. The absolute difference between the two groups was statistically significant but was too small and might not be clinically relevant. Other secondary outcomes including the Asthma Control Questionnaire (ACQ) score, symptom scores, airflow, airway hyper responsiveness, and rescue medication use showed a trend towards more improvement with BT over sham treatment, but none was statistically significant. The authors did not study the effect of BT on step-down of maintenance asthma medications, which according to the national guidelines is the main goal in the long-term management. Both AIR and AIR2 trials show that BT therapy temporarily aggravated asthma symptoms and increased the risk of adverse events some of which required hospitalization.

Articles: The literature search revealed around 30 articles on bronchial thermoplasty. The majority were review articles, editorials, and correspondences. Three RCTs conducted by the same group of authors were identified (AIR, AIR2, and RISA trials). RISA trial was too small (N=32), AIR trial had a 5-year follow-up, and AIR2 trial had a sham comparison group. Both AIR and AIR2 trials were selected for critical appraisal. Castro M, Rubin AS, Laviolette M, et al for the AIR2 trial Study group Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. *Am J Respir Crit Care Med,* 2010;18:116-124. See Evidence Table. Cox G, Thompson NC, Rubin AS, et al for the AIR trial Study group. Asthma control during the year after bronchial thermoplasty. *N Engl J Med.* 2007;356:1327-1337 See Evidence Table. Thomson NC, Rubin AS, Niven RM, et al. Long term (5 Year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med*. 2011;1: 8.

The use of Bronchial Thermoplasty does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

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Date Created	Date Reviewed	Date Last Revised
05/04/2011	Added to annual review because of Medicare changes 05/01/2014[MPC], 05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
04/07/2016	Removed Medicare coverage language
08/04/2020	Added Kaiser Permanente Medical Policy statement under Medicare section

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Scintimammography

- Breast Scintigraphy
- Breast-Specific Gamma Imaging (BSGI)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **Scintimammography** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Scintimammography (A-0071) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider and/or specialist (general surgery, oncology)
- Most recent imaging reports

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Mammography is the standard tool used for breast cancer imaging. Community screening programs have found that mammography has an overall sensitivity of 75% and a specificity of 92%. The sensitivity of mammography in randomized trials is in the range of 68-88% (Elmore 2005). However, mammography is less sensitive in women younger than 50 and in women with dense breasts (Brem 2008; Killela 2009). Breast-specific gamma imaging (BSGI) is intended for use when post-mammography evaluation is indicated. Other technologies currently used for post-mammography evaluation include ultrasound and magnetic resonance imaging (MRI). Each of these technologies has its advantages and limitations. Ultrasound is well tolerated, it does not use ionizing radiation or require intravenous contrast administration, and it is able to identify small non-palpable masses in dense breast tissue; however, it is time consuming to perform and increases the risk of false-positive results (Le-Petross 2011). MRI of the breast offers high sensitivity (93-100%), but it has a low specificity (65-79%), which leads to a high

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number of false-positive results (Zhou 2009). Additionally, MRI is not suitable for all patients; women with pacemakers, who are claustrophobic, and who cannot lie prone for the required length of the exam may not be suitable candidates for MRI (Ferrara 2010).

Imaging modalities can be roughly classified as either anatomical imaging or functional imaging. Anatomical imaging techniques, such as mammography and MRI, identify structural abnormalities in the body. Functional imaging techniques, such as BSGI, illustrate a physiological behavior. Functional imaging evaluates the metabolic activity of breast lesions through uptake of radioactive tracers. To conduct BSGI, patients are given an intravenous injection with a small dose of a tracing agent (Technicium Tc99m) that emits gamma rays. The tracer is absorbed by the cells in the body. Cancer cells absorb more of the tracing agent due to their higher metabolic activity and increased blood supply. Thus, cancerous areas show up as “hot spots” on BSGI imaging. When used for screening, functional imaging techniques have an advantage over anatomical imaging techniques because they can usually reliably differentiate between an active tumor and scar tissue (Ferrara 2010). BSGI is not without limitations; it is limited by its inability to reliably image cancers smaller than 1 cm. The sensitivity of BSGI is also low (35%-65%). The advent of high-resolution breast-specific gamma cameras is thought to have increased the sensitivity of BSGI and its ability to detect cancers smaller than 1 cm (Brem 2008).

BSGI uses a specialized high-resolution, small field-of-view gamma camera. The cameras are compact and maneuverable, and they can be placed close to the chest to image deep within the breast. Two camera manufacturers were identified. One camera is the Dilon 6800 made by Dilon Technologies of Newport News, VA. An earlier version of this camera, the Dilon 2000, was approved by the FDA in 1999, but the Dilon 6800 was not identified in the FDA database. The second technology is the LumaGem camera developed by Gamma Medica. A version of the LumaGem scintillation camera was cleared by the FDA in 2000. As with the Dilon camera, the breast-specific model described on the manufacturer’s Web site, the LumaGem 3200S, was not identified in the FDA database (Ferrara 2010).

Medical Technology Assessment Committee (MTAC)

Breast Specific Gamma Imaging

02/05/2007: MTAC REVIEW

Evidence Conclusion: No published studies were identified that compared the diagnostic accuracy of breast-specific gamma cameras and standard techniques for post-mammographic imaging such as MRI and ultrasound. In addition, there were no studies that evaluated change in clinical practice if the breast-specific gamma camera were used instead of, or in addition to, MRI or ultrasound. Two studies (Brem et al., 2005; Coover et al., 2004) were evaluated that examined the ability of a breast-specific gamma camera to identify cancers in high-risk women not identified by mammography or physical examination. Both studies were small and had industry funding, and only one included an independent blind comparison of the gamma cameras findings to a reference standard for all patients (Brem et al., 2005). The reference standard in the Brem study was biopsy of positive findings and one-year follow-up for negative cases. In the Brem study, there were 14 false-positives (specificity=85%) and 2 true positives (sensitivity=100%) in 94 women. The confidence interval for sensitivity was very wide due to the small sample size (the 95% CI varied from 22% to 100%) so it is difficult to draw conclusions about accuracy from this study. The Coover study, which was weaker methodologically, identified 3 cancers with the breast-specific gamma camera in 37 women who had had negative mammograms. Although results from these studies are promising, additional appropriately designed studies with a larger number of women are needed to evaluate the accuracy of the breast-specific gamma cameras.

Articles: One published study with the Dilon 6800 camera was identified (Brem et al., 2005). This study included 94 patients and was critically appraised. An earlier study by the same lead author (Brem RF) evaluated a prototype of the Dilon gamma camera and was not evaluated further. There also appears to be unpublished data that were presented at a professional meeting in 2005 comparing the performance of the Dilon 6800 camera to breast MRI.

One published study was identified that stated it used the LumaGem gamma camera to detect breast cancer in women with normal mammograms and clinical examinations (Coover et al., 2004). This study included 37 women and was critically appraised. A second, more recent study with 40 patients (Rhodes, 2005) may have used this or a similar technology, but the authors only stated that they used a prototype gamma camera. The Coover study was critically appraised. No studies were identified that used commercially available cameras to image patients in situations suggested by a manufacturer including patients dense breast tissue, multiple suspicious lesions or clusters of microcalcifications. *The studies reviewed were:* Brem RF et al. Occult breast cancer: Scintimammography with high-resolution breast-specific gamma camera in women at high risk for breast cancer. *Radiology* 2005; 237: 274-280. See Evidence Table. Coover LR, Caravaglia G, Kuhn P. Scintimammography with dedicated breast camera detects and localizes occult carcinoma. *J Nucl Med* 2004; 45: 553-558. See Evidence Table.

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The use of breast-specific gamma imaging in the diagnosis of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/19/2010: MTAC REVIEW
Breast Specific Gamma Imaging
Evidence Conclusion: There is limited evidence regarding the accuracy of BSGI compared to MRI. The best available evidence was the Brem et al. study (2007), which compared the sensitivity and specificity of BSGI, using a high-resolution breast-specific gamma camera with MRI in patient with indeterminate breast findings. In this study, 23 patients with indeterminate breast findings underwent both a BSGI scan and a MRI. The results were confirmed with pathological findings. The study found that compared to MRI, BSGI had a statistically significantly higher specificity (71% vs. 25%), and a lower sensitivity (89% vs. 100%). The authors indicated that this is not statistically significant; however, they used a qualitative rather than a quantitative approach to determine significance. Although an 11% difference in sensitivity may be of clinical relevance. This study compared BSGI to MRI using pathology as a gold standard; however, there were several limitations: the study had a small sample size, patient selection criteria were unclear, and it is not stated if reviewers were blinded to the results from the other imaging technique. There were no published studies that compared BSGI with MRI in high risk women or in younger women with dense breast tissue. Kaiser also reviewed this technology on March 23, 2009 and came to similar conclusions. Conclusion: There is insufficient evidence to date to determine whether BSGI improves diagnostic accuracy compared to MRI in patients with indeterminate breast findings.
Articles: The literature search revealed five relevant studies. Three were retrospective and two were prospective. All of the studies had methodological limitations. One of the prospective studies included a comparison group and was selected for review. Brem RF, Petrovitch I, Rapelyea JA et al. Gamma Imaging with 99mTc-Sestamibi and Magnetic Resonance Imaging in the Diagnosis of Breast Cancer-A Comparative Study. The Breast Journal 2007; 13: 456-469. See Evidence Table.

The use of breast-specific gamma imaging in the diagnosis of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/19/2011: MTAC REVIEW
Breast Specific Gamma Imaging
Evidence Conclusion: Since the 2010 review, the literature search revealed only one small observational study that addressed the diagnostic accuracy of BSGI. This study was not selected for review due to methodological limitations (small sample size, patient selection criteria and baseline characteristic were not addressed, and confidence intervals were not provided) (Ozulker 2010). Conclusion: There is insufficient evidence to determine whether BSGI improves diagnostic accuracy when used as an adjunct to mammogram.
Articles: Since the 2010 review, the literature search revealed only one small observational study that addressed the diagnostic accuracy of BSGI. This study was not selected for review due to methodological limitations (small sample size, patient selection criteria and baseline characteristic were not addressed, and confidence intervals were not provided) (Ozulker 2010).

The use of breast-specific gamma imaging in the diagnosis of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
03/21/2007	07/06/2010 [MDCRPC], 05/03/2011 [MDCRPC], 10/04/2011 [MDCRPC], 01/03/2012 [MDCRPC], 11/06/2012 [MDCRPC] ,09/03/2013 [MPC],11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	12/07/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD Non-Covered Services L34886 and L35008
12/07/2021	Removed reference to retired Non-Covered Services LCD (L35008).

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Clinical Review Criteria
Canaloplasty

- Circumferential Viscodilation and Tensioning of Schlemm's Canal for Primary Open-Angle Glaucoma

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Criteria

For Medicare Members

No review required for Medicare members

For Non-Medicare Members

Canaloplasty is covered when all of the following criteria have been met:

1. Diagnosis of glaucoma with eye pressures inadequately controlled on maximum tolerated topical medications and laser treatment
2. Documented risk for greater problems with standard glaucoma surgery (trabeculectomy or valve implant) as defined by one of the following:
   - Myopic diopters greater than 5
   - Hyperoptic diopters greater than 3
   - Moderate to severe dry eye
   - Blepharitis
   - Preservative allergy
   - Has allergy or side effects preventing the use of one or more of the standard glaucoma eye drops
   - Had problems with trabeculectomy or glaucoma valve implant surgery in the contralateral eye (such as bleb dysesthesia (chronic eye pain) or need for re-operation)

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Glaucoma is a common eye disease caused by elevated intraocular pressure (IOP) that leads to optic nerve damage and visual field loss. Glaucoma is frequently referred to as the "silent thief of sight" because it is not usually associated with ocular or systemic symptoms but can cause irreversible blindness if left undiagnosed and untreated. It is estimated that over 2 million people in the United States have glaucoma, 80,000 of whom are legally blind as the result of the disease (Lee 2005).

Glaucoma has been classically categorized into primary or secondary angle-closure glaucoma (closure of the anterior chamber angle), and primary or secondary open-angle glaucoma (where the anterior chamber angle of the eye remains open). The condition is considered primary if the eye has no pre-existing disease and secondary in an eye with a pre-existing disease. Primary open-angle glaucoma is the most common type in the US. It occurs insidiously and is usually asymptomatic in its early stages. In the later stages, when the optic nerve is damaged,

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the patient experiences progressive worsening of vision, and eventually peripheral followed by central visual loss (Lee 2005, Rotchford 2005).

The treatment goal for patients with glaucoma is preventing functional vision loss by lowering the IOP to a level where progressive glaucomatous optic neuropathy is stopped, or at least slowed. Conventional treatment usually begins with the use of topical IOP-lowering agents. These include beta-blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, cholinergic, and prostaglandin analogs. Laser trabeculoplasty has also been used to further lower the IOP to decrease or eliminate the need for antiglaucoma medications. Incisional filtering surgery is considered if the patient's IOP cannot be reduced with the maximal tolerated medical therapy, laser trabeculoplasty or a combination of both. Trabeculectomy is a filtration surgical procedure commonly used to lower the IOP. The procedure involves creating an opening in the anterior chamber angle to allow the aqueous humor flow from the anterior chamber into a space beneath the conjunctiva under the surface of the eye. A successful trabeculectomy procedure is marked by an elevated conjunctival zone, the bleb, where the aqueous gathers in pockets prior to absorption into the surrounding blood vessels and lymphatics. Trabeculectomy with or without antimetabolites can successfully control IOP, but not without risks. It may be associated with numerous intraoperative or postoperative complications including hypotony, bleb leaks, bleb infections /endophthalmitis, hyphaema, loss of visual acuity, increased risk of cataract formation, scar tissue which causes obstruction of the channel created and in turn blocking the drainage of the aqueous humor, and several other complications (Lee 2005, Rotchford 2005, Lewis 2007).

Nonpenetrating glaucoma procedures were first introduced in the late 1950s and early 1960s, and revived in the 1980s and 1990s, as alternatives to standard filtration surgeries for controlling IOP in open-angle glaucoma without penetration of the intraocular space. These procedures include deep sclerectomy with and without an implant, and viscocanalostomy. The latter is performed by several techniques that basically involve the production of superficial and deep scleral flaps, excision of the deep scleral flap to create a scleral reservoir, and unroofing of Schlemm's canal. An ophthalmic viscoelastic device is then injected into the deep scleral lake and toward the cut ends of Schlemm's canal to open it and create a passage from the scleral reservoir to the canal. The superficial scleral flap is then sutured water tight trapping the viscoelastic until healing takes place (Filippopoulos 2008, Green 2007, Noureddin 2006).

Recent advances in technology, ocular ultrasound, and viscoelastics have led to the development of canaloplasty as a promising nonpenetrating surgical technique for lowering the IOP in patients with open-angle glaucoma. The procedure aims at increasing the flow of aqueous humor from the anterior chamber through the trabecular meshwork and Descemet's window into and around the Schlemm's canal and out through the collector channels, thus reducing the IOP by restoring the trabeculocanalicular outflow pathway. The procedure utilizes the full 360 degrees of the canal and outflow system without creating a fistula or need for a bleb. Unlike viscocanalostomy, canaloplasty aims at opening the entire length of the canal rather than opening only a section of it. Canaloplasty uses viscoelastic and specialized flexible microcatheter with an illuminated tip (iScience surgical Ophthalmic Microcannula) to forcibly open the Schlemm's canal (Lewis 2006, 2007, Godfrey 2009).

Similar to viscocanalostomy, canaloplasty is completed under a scleral flap. A one-half thickness parabolic shaped scleral flap is dissected. A deep flap is then dissected down to a depth very close to the ciliary body/choroid and carefully carried forward anteriorly until the Schlemm's canal is unroofed. The canal is identified and intubated with a cannula which has a lighted tip to identify its location as it passes through the canal. The cannula has a lumen to allow for the passage of viscoelastic for dilatation of the canal. Once it has passed the full length of Schlemm's, a 10-0 Prolene suture is tied to the cannula which is then withdrawn leaving the suture in its place. Tying off the suture provides tension that holds the canal open. The scleral flap is then tightly closed as well as the conjunctiva. The procedure is usually performed under special ultrasound imaging to help identify the canal and its instrumentation (Lewis 2006, 2007).

Canaloplasty has a steep learning curve. Identifying and entering the Schlemm's canal, inserting the catheter, placing the tension suture, and providing the right tension in the suture depend on the surgeon's skill and experience. The outcome of the surgery also depends on the selection of the patients; those who had previous trabeculectomies with scarring in the canal are not good candidates. According to the authors of a review article, the ideal candidates would be patients who cannot have a bleb because they wear contact lenses, have a dry eye, or for cosmetic reasons. The procedure is contraindicated in patients with angle recession, neovascular glaucoma, chronic angle closure, narrow-angle glaucoma, narrow inlets with plateau iris, and in patients with previous surgery which would prevent 360o catheterization of Schlemm's canal (Lewis 2006, Godfrey 2009).

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In June 2008 The FDA cleared the iScience Interventional Canaloplasty Microcatheter for marketing for catheterization and vasodilatation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

Medical Technology Assessment Committee (MTAC)

Canaloplasty

10/06/2008: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of canaloplasty in the management of open angle glaucoma among adults. There are no published controlled trials that compared the outcomes of canaloplasty to other established medical therapies, laser trabeculoplasty, or filtration surgeries as trabeculectomy. The only published studies were 2 relatively small case series, conducted in the same centers with the same group of investigators, and possibly with a population overlap. None had a control or comparison group. Three of the principal authors had consulting agreement with iScience Interventional, the manufacturer of the microcatheter used. The interim analysis of one-year results of a multicenter case series (Lewis 2007) that included 94 patients from the 14 centers in US and Germany, showed that IOP dropped significantly after the procedure among all patients (from 24.7 + 4.8 mmHg at baseline to 15.3 +3.9 mmHg at 12 months), and among the sutured subgroup (from 23.9 + 4.3 mmHg at baseline to 15.3 + 3.8 mmHg at 12 months). The medication uses also dropped from a mean of 1.9 +1 per patient to 0.6 + 0.9 per patient at 12 months. The most common adverse events observed were hyphaema and increased IOP which occurred at a rate of 3% each. The other published series that included 54 patients with open-angle glaucoma and cataract reported similar outcomes. None of the two studies compared the procedure to any other established surgical or nonsurgical intervention. Conclusion: There is insufficient evidence to determine that canaloplasty has the same or better effect than medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty has the same or better effect than filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer for the patient than filtration surgical interventions as trabeculectomy.

Articles: The search yielded only two studies on canaloplasty: Lewis 2007, and Shingleton 2008. Both were prospective case series with no comparison or control groups. Lewis and colleagues reported the interim results of canaloplasty performed on 94 patients with open-angle glaucoma. Shingleton et al reported one-year results of canaloplasty combined with cataract surgery performed on 54 patients with open-angle glaucoma and cataract. The authors of the latter study were co-authors in the first study. Both studies involved the same 14 clinical sites and same group of ophthalmologists. It appears also that there could be an overlap of the patients participating in the two studies. Both reported on one-year results. The published case series with the larger population size was selected for critical appraisal. Lewis R A, von Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults. Interim clinical study analysis. J Cataract Refrat Surg 2007; 33:1217-1226. See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/05/2009: MTAC REVIEW

Canaloplasty

Evidence Conclusion*:* The available literature does not provide sufficient evidence to determine the safety and efficacy of canaloplasty in the management of open angle glaucoma among adults. There are no published controlled trials that compared the outcomes of canaloplasty to other established medical therapies, laser trabeculoplasty, or filtration surgeries as trabeculectomy. The only published studies were 2 relatively small case series, conducted in the same centers by the same study group, and possibly with a population overlap. Lewis and colleagues, reported on the one- and two-year interim results of canaloplasty with or without corneal phacoemulsification cataract surgery, and Shingleton et al (2008) reported on the results of a subgroup that underwent the two procedures. Neither of the two series had a control or comparison group. iScience Interventional, the manufacturer of the microcatheter used in the studies, supported the studies and had consulting agreement with three of the principal authors. In their first publication, Lewis and colleagues (2007) reported the one-year interim results of canaloplasty performed on 94 patients with open-angle glaucoma, and in their 2009 publication they reported on the results of the procedure among 127 patients. No explanation was provided why there were more patients in the 2-year follow-up. The interim analysis of one-year results showed that IOP dropped significantly after the procedure among all patients from 24.7 + 4.8 mmHg at baseline to 15.3 +3.9 mmHg at 12 months. The medication uses also dropped from a mean of 1.9 +1 per patient at baseline to 0.6 + 0.9 at 12 months. Eyes that underwent a combined canaloplasty and posterior chamber intraocular lens (IOL) implantation had lower IOP and medication use than those undergoing canaloplasty alone. The two-year

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postoperative data were similar to those observed at the end of the first-year follow-up with a minimal increase in the mean IOP and medication use. Overall 32% reduction in IOP and 74% reduction on medication use were achieved in 24 months. Surgical complications were reported in 15 patients (16%) in the first publication and in 10 patients in the second report, with hyphaema and increased IOP >30mmHg being the most common.
Conclusion: There is insufficient evidence to determine that canaloplasty is better than or equivalent to medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is better than or equivalent to filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer than filtration surgical interventions as trabeculectomy.
Articles: The search yielded only one more recent report (Lewis et al 2009) on the 2-year results of the same case series on canaloplasty that was published earlier in 2007 and reviewed by MTAC in 2008. No randomized or nonrandomized controlled trials comparing canaloplasty to another treatment or intervention were identified. The new report by Lewis and colleagues (2009) was critically appraised. Lewis R A, von Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults. Two-year interim clinical study results. J Cataract Refrat Surg 2009; 35:814-824 See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Medicare – Medical Necessity Review not required

CPT® Codes	Description
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/12/2008	01/05/2010 MDCRPC, 11/02/2010 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	07/26/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
07/26/2017	Added no review required for Medicare members

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KAISER PERMANENTE®

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Clinical Review Criteria
Capsule Endoscopy

- Given ® AGILE Patency System
- M2A™ Capsule Endoscopy
- PillCam™ SB
- Wireless Capsule Enteroscopy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	**Esophagus:** In April 2011 Noridian retired Wireless Capsule Enteroscopy (L23785). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. **Colon:** Colon Capsule Endoscopy (CCE) (L38826)
Local Coverage Article (LCA)	Billing and Coding: Colon Capsule Endoscopy (CCE) (A58438)

For Non-Medicare Members

Kaiser Permanente has elected to use the Capsule Endoscopy (KP-0134) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

> ***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente and share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 12 months of clinical notes from requesting provider &/or specialist (gastroenterology)
- Most recent lab works

Patency Capsule

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There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Wireless Endoscopy

Approximately 5% of patients presenting with obscure gastrointestinal (GI) bleeding do not have a source identified after evaluation with upper endoscopy, colonoscopy and/or barium studies. Enteroscopy, evaluation of the small bowel, is indicated in many of these patients. Push enteroscopy, sonde enteroscopy and intraoperative enteroscopy are commonly used options. Push enteroscopy is relatively easy to perform but is limited by its inability to examine beyond the mid to distal jejunum in most patients. Sonde-type enteroscopes are longer than push enteroscopes and in some cases can examine as far as the terminal ileum. Disadvantages include long procedure times and a steep learning curve to master the technique. Intraoperative enteroscopy was first reported in 1976 and is considered the “gold standard” for evaluating the small bowel for the source of unexplained GI bleeding. However, this is an invasive procedure that requires a laparotomy (Adrain and Kversky, 1996).

The M2A (mouth-to-anus), a pill-sized disposable endoscope, is proposed as an alternative non-invasive tool for identifying obscure GI bleeding. The M2A capsule contains a video camera, lights, transmitter and batteries. It is swallowed by the patient and, as it moves through the digestive tract, it transmits video signals which are stored in a recorder attached to the patient’s belt. The M2A moves through the digestive tract with the aid of peristalsis and is then excreted normally by the patient. About five hours of continuous reading is possible. The video can be downloaded from the recorder to a computer workstation with special software (Reporting and Processing of Images and Data, RAPID).

The M2A capsule, manufactured by Given Imaging (Yoqneam, Israel), received FDA approval in August 2001.

M2A capsule endoscopy for unexplained chronic gastrointestinal blood loss or anemia was previously reviewed by MTAC in December 2001. At that time there were no studies of health outcomes and no data on patients with unexplained chronic gastrointestinal blood loss.

Iron Deficiency Anemia:
Iron deficiency anemia (IDA) represents a major public health problem. Its estimated prevalence in the US is 2% of adult men and 9-12% of non-Hispanic white women. It is most commonly secondary to chronic occult bleeding from the gastrointestinal tract and is one of the common reasons for referral to gastroenterology clinics (Apostolopoulos 2006, Killip 2007).

Obscure gastrointestinal bleeding (OGIB) is defined as bleeding of unknown origin that persists or recurs after a negative initial endoscopy. OGIB accounts for at 5-10% of all gastrointestinal (GI) bleeds and may be overt or occult. Overt GI bleeding is clearly signified by rectal bleeding, bloody stools, or melena. Occult blood loss, on the other hand, is subtle and may only present as iron deficiency anemia or as a positive fecal occult blood test (Triester 2005, Concha 2007, Estevez 2006).

Diagnosing the cause of OGIB might be clinically challenging, especially when the origin of bleeding is a very small lesion in parts of the small bowel that is not apparent or accessible for direct viewing. Patients with OGIB may undergo multiple diagnostic procedures and invasive testing. Diagnostic work-up may include barium x-ray studies of the bowel, endoscopy, enteroscopy, computed tomography (CT), radionucleide scans, angiography, intraoperative endoscopy, and exploratory surgery.

Evaluation of the small bowel by conventional endoscopy has the advantage of allowing for intervention if the bleeding site is identified, but may be difficult due to the length, motility, tortuosity, looping, and free hanging course of the small bowel. Typically, an endoscope will reach only the proximal small bowel. Enteroscopy is an extension of an upper endoscopy where a longer endoscope that reaches down to the ileum is used. There are different types of enteroscopes including the push type and the sonde-type. Push enteroscopy allows the

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evaluation of the jejunal mucosa up to 150 cm beyond the ligament of Trietz; however, it is an invasive procedure that requires deep sedation or anesthesia, has a variable diagnostic yield (38-75%), and does not explore lesions in the ileum. Double balloon enteroscopy (DBE) is a modified push enteroscopy that is emerging as an alternative for operative enteroscopy. The balloons grip the intestinal wall allowing further insertion of the scope and the examination of larger areas of the small bowel reaching up to 300 cm in the oral direction. The entire small bowel could be potentially evaluated when a DBE is carried out with oral and anal approaches in conjunction (Lewis 2000, Mitchell 2004, Concha 2007).

Laparotomy with intraoperative enteroscopy is used after all other techniques fail to detect the source of bleeding, when there are adhesions that require lysis via a laparoscopic approach, or and when the risk of bleeding exceeds the risk of the procedure. It is considered the gold standard for a complete endoscopic evaluation of the small bowel. However, intraoperative endoscopy is invasive, risky, and may cause artifacts that could be falsely identified as the cause of bleeding. Moreover, it was reported that intraoperative endoscopy can examine only 50-80% of the small bowel and detect the source of bleeding in up to 40% of undiagnosed cases (Mitchell 2004).

Other indirect methods for visual examination of the small bowel such as x-ray series and enteroclysis, radioisotope bleeding scans, angiography, computed scans, and MRIs have been found to have low sentivities in detecting the source of bleeding, especially for vascular lesions which are the most frequent cause of OGIB (Estevez 2006, Leighton 2006).

Capsule endoscopy (M2A video capsule endoscope, Given Imaging Ltd, Yoqneam, Israel) was introduced in 2001 as a noninvasive direct endoscopic technique for visualization of the small bowel. It is a swallowable wireless capsule endoscope 26 mm in length and 11 mm in diameter. The device consists of an optical dome, 4 light emitting electrodes, a sensor, 2 batteries, and a micro transmitter. The capsule acquires and transmits digital images at the rate of 2/second to a sensory array attached to the patient's abdomen. It is able to capture video-images of the mucosal surface of the entire length of the small intestine directly for 7-8 hours. The capsule is propelled forward through the GI tract with the peristaltic movement and is excreted normally by the patient after 8-72 hours. The images can be downloaded from the recorder to a computer workstation with special software (Hara 2005, Eliakim 2007).

The capsule endoscopy is noninvasive and easy to perform. However, it lacks the ability to obtain a tissue sample for biopsy, deliver therapy, or treat pathology when it is found. In addition, it was reported that some lesions could be missed due to rapid or delayed small bowel transit. It might also be difficult to identify the precise location of the pathology when it is discovered. Unlike endoscopy, the lesion cannot be washed, and re-examined, and large amounts of intraluminal bile could be mistaken for blood. Interpretation of the small bowel images is highly subjective, and the potential inter-observer variation may compromise the reliability and accuracy of the technology. Moreover, some investigators have reported that the quality of the images taken by the capsule was not satisfactory, and that the duodenum was not effectively visualized. The 8 hour-battery life of the capsule is estimated to be enough time for 85% of the patients to image the entire small intestine. For the rest, the battery life expires before the capsule reaches the cecum. The major potential complication with capsule endoscopy is the risk of capsule retention due to stenosis, stricture, diverticulum, or fistula. The documented incidence of entrapment is 1%, however a retained capsule may potentially lead to intestinal obstruction, and its retrieval may necessitate surgical extraction (Concha 2007, Mazzarola 2007, Enns 2007).

The PillCam TM, previously marketed as M2A TM, manufactured by Given Imaging (Yoqneam, Israel), received FDA approval in August 2001 for detecting problems in the small bowel in adults and children ten years of age or older. The most common application for capsule endoscopy is the evaluation of obscure gastrointestinal bleeding. The second most studied indication is the evaluation of suspected Crohn's disease. It is also being used to detect polyps, cancers, other causes of chronic inflammation, bleeding, and anemia. Capsule endoscopy is contraindicated in patients with intestinal blockage, strictures or fistulas, pregnant women, patients with swallowing disorders, or those with a cardiac pacemaker or other implanted electromagnetic devices.

Patency Capsule

The capsule endoscopy is relatively noninvasive, easy to perform, well tolerated, and has a low incidence of complications. The most worrisome complication is capsule retention due to stenosis, stricture, diverticulum, or fistula. Overall, the documented incidence of capsule retention or entrapment is as low as 1% but may be higher in some population at risk. Studies reported retention rates of 5-13% in patients with known Crohn's disease, and a rate of 21% in suspected bowel obstruction. A retained or impacted capsule may potentially lead to small bowel ileus, intestinal obstruction, or fragmentation of the capsule with potential toxic hazard. Risk factors for capsule retention include major abdominal surgery, known or suspected Crohn's disease, previous intestinal obstruction, prolonged

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NSAID use, ischemic bowel disease, radiation injury, and suspected bowel tumors. Retrieval of a retained capsule requires medical, endoscopic or surgical intervention (Sears 2004, Signorelli 2006, Concha 2007, Enns 2007, Caunedo-Alvarez 2008).

Due to the risk of capsule retention, wireless capsule endoscopy is contraindicated in patients with suspected small bowel strictures. In most centers, a radiographic evaluation of the small bowel patency is mandatory before performing a wireless capsule endoscopy in patients with a risk of small bowel strictures. Standard imaging techniques include small bowel (SB) follow-through, barium enema, enteroclysis, or CT enteroclysis. Limitations of these techniques include a tendency to underestimate or overestimate SB strictures. They can identify long or medium stenosis with great reduction in their lumen size but may not detect a short intestinal stenosis or obstruction, leading to false negative results (Boivin 2005, Caunedo-Alvarez 2008, Karagiannis 2009).

Given Imaging, the manufacturer of the PillCam SB has developed a new system (The Given® Patency Capsule) to identify patients with strictures that may cause retention of the video capsule. The first generation was the M2A patency capsule, which due to the risk of obstruction, was modified to the AGILE Patency Capsule (PC). This consists of a dissolvable capsule and a scanner. The capsule is composed of a lactose body with 5% barium (to induce radiopacity) that surrounds a small radiofrequency identification tag (RFID). The body is coated with an impermeable cellophane membrane with two wax timer plugs located at each end of the capsule. The timer plugs seal the capsule's body, and each has a small window or opening that allows penetration by gastrointestinal (GI) fluids.

The Agile patency capsule (PC) has the same dimensions and shape as the PillCam. Once the patient ingests the capsule, it is propelled through the GI tract by normal peristalsis. The Agile PC is designed to remain intact for 30 hours (40 hours in the first generation). It is assumed that it will be excreted intact if there is no bowel obstruction. In this case a PillCam capsule can be administered. If there is any kind of stricture hindering its passage for more than 30 hours, the patency capsule starts to disintegrate (except for the identification tag), allowing the insoluble outer membrane to collapse and be excreted deformed or in fragments. The persistence of the PC inside the GI tract can be verified by means of radiology or with a radiofrequency emitting external detector device locating the RFID (Signorelli 2006, Caunedo-Alvarez 2008).

It is reported that the Given patency capsule may provide direct evidence of functional patency of the gut lumen, even in those patients showing radiological evidence of small bowel stricture. This information may allow a distinction between rigid fibrotic strictures and flexible ones (Spada 2005, Karagiannis 2009).

The Given® AGILE Patency System received marketing clearance from the U.S. Food and Drug Administration (FDA) in 2006, as an accessory to the PillCam to verify adequate patency of the gastrointestinal tract in patients with known or suspected strictures prior to administration of the PillCam video capsule.

Medical Technology Assessment Committee (MTAC)

Capsule Endoscopy

12/12/2001: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence on which to base a conclusion about the effect of M2A capsule endoscopy on health outcomes.
The search yielded 4 articles. One of these was a historical piece, one was a letter to the editor describing the use of the technology with 4 cases. The third was an empirical study conducted in dogs. The fourth was description of the technology including acceptability (e.g. ability to swallow, quality of images, mouth-to-evacuation time) in 10 normal human volunteers. There were no studies of health outcomes and no data on patients with unexplained chronic gastrointestinal blood loss. In addition to the studies found on Medline, there were several published abstracts in the Given Imaging reference list. None of the articles were suitable for critical appraisal.

The use of M2A™ (Given Imaging) capsule in the diagnosis of small bowel lesions/chronic bleed sites does not meet the *Kaiser Permanent Medical Technology Assessment Criteria* 2 for effectiveness.

12/10/2003: MTAC REVIEW
Capsule Endoscopy

Evidence Conclusion: The prospective comparative studies that were reviewed suggest that M2A capsule endoscopy has a significantly greater diagnostic yield than push enteroscopy among patients with unexplained gastrointestinal bleeding. The studies did not use the gold standard evaluation tool, an invasive surgical procedure, so diagnostic accuracy (e.g. sensitivity, specificity) cannot be calculated.

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Articles: The search yielded 23 articles. The ideal study would be an independent, blind comparison of M2A and a gold standard diagnostic test. There were 5 comparative studies in patients with gastrointestinal bleeding. No articles specifically studied use of the M2A for anemia, but patients with anemia suggestive of overt bleeding were included in some of the GI bleeding studies. The methodology was similar in the 5 studies. All compared M2A evaluation with push enteroscopy and none of the studies included evaluation with intraoperative enteroscopy, the invasive "gold standard" procedure. The primary outcome in each study was diagnostic yield (the ability to diagnose the source of bleeding) of the two procedures. All 5 studies included blinded evaluation of test results. Results of the studies were similar; all found a higher rate of diagnostic yield with the M2A. Findings were statistically significant in 4 of the 5 studies and did not reach statistical significance in the smallest study. Sample sizes ranged from 20 to 60 patients. The two largest studies (n=52, n=60) were critically appraised:
Mylonaki M, Fritscher-Ravens A, Swain P. Wireless capsule endoscopy: a comparison with push enteroscopy in patients with gastroscopy and colonoscopy negative gastrointestinal bleeding. *Gut* 2003; 1122-1125. See Evidence Table Saurin J-C, Delvaux M, Gaudin J-L. et al. Diagnostic value of endoscopic capsule in patients with obscure digestive bleeding: Blinded comparison with video push-enteroscopy. *Endoscopy* 2003; 35: 576-584. See Evidence Table

The use of M2A™ (Given Imaging) capsule in the diagnosis of small bowel lesions/chronic bleed sites does meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

12/03/2007: MTAC REVIEW
Capsule Endoscopy
Evidence Conclusion: Diagnostic accuracy: Triester, Leighton and colleagues' meta-analyses (2005, 2006) as well as the other published meta-analyses compared CE with one or more alternative diagnostic modalities for evaluation the small bowel in patients with OGIB. Triester's meta-analysis included studies either published in full or in the abstract form. The studies compared the performance of CE mainly to push enteroscopy and barium radiography, none of which is considered as a gold standard, nor is able to identify all kinds of lesions in the entire small bowel. The performance of CE and other diagnostic modalities were thus measured as diagnostic yield, which mainly depends on subjective interpretation, rather than sensitivity and specificity. CE was found to be associated with significantly higher incremental yield and number needed to test around 3. A higher yield might indicate that CE is superior to the alternative method but does not assess sensitivity of the test, nor is it able to discriminate the false positive findings. Hartmann and colleagues' 2005, study (not included in the meta-analysis) compared capsule endoscopy to the gold standard of intraoperative enteroscopy. In that study 47 consecutive patients with OGIB and a negative initial work-up underwent both capsule and intraoperative endoscopy. The source of bleeding was located by intraoperative endoscopy in 72.3% of cases and by capsule endoscopy in 74.5%. Compared to the gold standard CE had a sensitivity of 97%, specificity of 85%, positive predictive value of 95% and negative predictive value equal to 86%. CE was not associated with any major adverse events, while one patient died of postoperative peritonitis after laparotomy. Apostolopoulos and colleagues 2006, compared the performance of CE to enteroclysis among 51 patients with unexplained iron deficiency anemia after negative endoscopic evaluation of the upper and lower gastrointestinal tract. This was a highly selected group of patients which may limit generalization of the results. Upper GI series and push enteroscopy were not included among the diagnostic procedures performed. The authors compared the yield of CE with enteroclysis which is not considered as a gold standard, and the results were presented as diagnostic yields not sensitivity and specificity. Its results show that CE had a diagnostic yield of 56.9% vs. 11.8% for the enteroclysis ($p<.0001$). Impact of capsule endoscopy on patient management: The published studies, to date, on the influence of capsule endoscopy on patient management included highly selected groups of patients with wide variations in their baseline characteristics as age, indication of endoscopy, duration of bleeding, number and type of previous investigations undergone, as well as other variables. In addition, the investigators used different diagnostic criteria for the identification of the bleeding pathology, as reflected in the wide range of diagnostic yield. The latter was also influenced with the experience and number of researchers interpreting the CE images. Thus, the published studies with their potential biases and confounding factors, and with the lack of randomized controlled trials, do not provide sufficient evidence to determine that capsule endoscopy would lead to any incremental improvement in the management of patients. Impact of CE on patient outcome: There is insufficient evidence to determine the impact of CE on patient outcome. The published outcome studies were small case series with no control groups. The therapies and interventions received by the patients were not standardized and varied between studies. Patients were treated with medical, endoscopic or surgical interventions and complete resolution of bleeding was achieved in 40-85% of cases. This varied according to study, eligibility criteria, patient characteristics, bleeding condition, condition, and treatment received. Randomized controlled trials with long-term follow-up periods are needed to determine the effect of capsule endoscopy on patient management and outcomes. Assessment objective: To evaluate the diagnostic accuracy for the capsule endoscopy (CE) in identifying the lesion of, IDA or obscure gastrointestinal bleeding (OGIB)? To determine whether CE contributes substantially to improved

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diagnosis and/or replaces other diagnostic tests or procedures. To determine if diagnosing the source of IDA/OGIB with the CE would influence the management decisions? Would it result in providing more appropriate therapy? To determine whether using CE for locating the source of OGIB would improve the clinical and patient-oriented outcomes? Diagnostic accuracy: There were three meta-analyses (Triester 2005, Triester 2006, and Leighton 2006) that evaluated CE for OGIB and/or Crohn's disease. All three were conducted by the same investigators and the two meta-analyses on OGIB included the same studies. There was also another meta-analysis that compared CE to double-balloon enteroscopy, one study that compared CE with the gold standard intraoperative enteroscopy, and several other studies that compared the performance of CE with other diagnostic modalities. Almost all studies investigated the use of CE for patients with OGIB. Two very small studies investigated the use of CE for patients with iron deficiency anemia (IDA) after negative endoscopic evaluation of the upper and lower GI. Apostolopoulos et al 2006 performed CE on 51 out of 253 patients referred for the evaluation of iron deficiency anemia, and Bar-Meir et al 2004, assessed the diagnostic yield pf a second CE for 20 patients with severe IDA). Diagnostic/therapeutic impact:
Articles: The literature search identified several prospective studies on the influence of capsule endoscopy on management decisions and/or treatment outcomes. All were case series with no control or comparison groups. The largest more recent meta-analysis of studies that compared CE to other diagnostic modalities, the prospective study that compared it with intraoperative endoscopy, the study on its role in investigating unexplained iron deficiency anemia, a case series on its impact on patient management, as well as 4 outcome studies were critically appraised. The four outcome studies were summarized in one table. *The following studies were critically appraised:* Triester SL, Leighton JA, Leontiadis GL, et al. A meta-analysis of the yield of capsule endoscopy compared to other diagnostic modalities in patients with obscure gastrointestinal bleeding. Am J Gastroenterol; 2005; 100:2407-2418. See Evidence Table Leighton JA, Triester SL, Sharma VK. Capsule endoscopy: A meta-analysis for use with obscure gastrointestinal bleeding. And Crohn's disease. Gastrointest Endosc 2006;16:229-250 See Evidence Table Hartman D, Schmidt H, Bolz G, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure gastrointestinal bleeding. Gastrointest Endosc 2005;61:826-832 See Evidence Table Apostolopoulos P, Liatos C, Gralnek IM, et al. The role of wireless capsule endoscopy in investigating unexplained iron deficiency anemia after negative endoscopic evaluation of the upper and lower gastrointestinal tract. Endoscopy 2006; 38:1127-1132. See Evidence Table Sidhu R, Sanders DS, Kapur K et al., Capsule endoscopy changes patient management in routine clinical practice. Dig Dis Sci 2007; 52:1382-1386. See Evidence Table Viazis N, Papaxoinis K, Theodoropoulos I, et al. Impact of capsule endoscopy in obscure small-bowel bleeding; defining strict diagnostic criteria for a favorable outcome. Gastrointest Endosc 2005; 62:717-722 See Evidence Table Estevez, Gonzalez-Conde B, Vazquez-Iglesias JL, et al. Diagnostic yield and clinical outcomes after capsule endoscopy in 100 consecutive patients with obscure gastrointestinal bleeding. Europ J Gastroenterol Hepatol 2006;18:881-888 See Evidence Table Neu B, Ell C, May A, et al. Capsule endoscopy versus standard tests in influencing management of obscure digestive bleeding: results from a German multicenter trial. Am J Gastroenterol; 2005; 100:1736-1742. See Evidence Table Pennazio M, Santucci R, Rondonotti E, et al. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. Gastroenterol 2004; 26:643-653. See Evidence Table

The use of M2A™ (Given Imaging) capsule in the diagnosis of unexplained iron deficiency anemia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

4/18/2011: MTAC REVIEW
Capsule Endoscopy
Evidence Conclusion: There is limited published evidence on the usefulness and safety of Agile patency capsule in identifying patients who can safely undergo capsule endoscopy. There are no published randomized controlled trials, to date, that compared the accuracy of Agile capsule to any of the radiographic methods used to assess small bowel patency prior to capsule endoscopy. The case series by Herrerias and colleagues (2008) examined the ability of the Agile system in determining which patients with known strictures can safely undergo capsule endoscopy (CE). 106 eligible patients with evidence of intestinal stricture ingested the patency capsule and were followed up periodically with scanning devices until the capsule was excreted. The intestinal tract was considered sufficiently patent if the patency capsule was excreted intact without any changes in its original dimensions, or if the radiofrequency identification tag (RFID) was not detected by scanning the patients at 32-38 hours after ingestion. 59 patients (56%) excreted the patency capsules intact and underwent capsule endoscopy with the PillCam video capsule, with no cases of capsule retention. The majority of patients who excreted intact patency capsules still had to undergo fluoroscopy as the capsules were passed after the scheduled 38 hours (over 25% were excreted after 60 hours). A total of 17 patients had adverse events mainly abdominal pain; one patient had intestinal obstruction and underwent surgical resection of the proximal colon and terminal ileum. The authors indicate that no remnants of the capsule were found at surgery. The study may suggest that patients who

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pass the Agile Patency Capsule intact may be suitable candidates for capsule endoscopy but does not provide sufficient evidence that it is safer and more accurate than other radiographic methods used.
Articles: The literature revealed a limited number of articles on the Given Patency System. The published empirical studies were all case series and mainly on the first generation of the patency capsule (M2A Patency Capsule). Only one case series on the newer generation, the Agile Patency System, was identified, and critically appraised. Herrerias J, Leighton JA, Costamagno G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. *Gastrointest Endosc.* 2008;67:902-909. See Evidence Table

The use of patency capsule does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report
0355T	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

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Date Created	Date Reviewed	Date Last Revised
12/12/2001	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 01/08/2013 MDCRPC,02/05/2013 MDCRPC,12/03/2013 MPC, 10/07/2014MPC, 05/05/2015MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC,11/07/2017MPC ,10/02/2018MPC , 10/01/2019MPC , 10/06/2020MPC, 10/05/2021MPC, 10/04/2022MPC	10/05/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/05/2015	Slight modifications to the policy were made to include esophageal varices. Also, a notation and to allow approval for NSAIDS if ASA is used for anticoagulation.
08/31/2016	Added retired LCD language
07/11/2017	MPC approved to adopt revised indication
10/05/2021	Added Colon Capsule Endoscopy LCD/LCA for Medicare.

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Clinical Review Criteria

Capsule pH Monitoring System for Diagnosis of Gastroesophageal Reflux Disease (GERD)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	24-Hour Ambulatory Esophageal pH Monitoring (100.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

The disposable capsule pH monitor (Bravo pH Monitoring System) is considered an acceptable alternative to standard catheter-based ambulatory pH monitoring for adults and does not require medical necessity review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastroesophageal reflux disease (GERD) is a common condition, with an estimated lifetime prevalence of 25-35% in the US. Patients with GERD often report a compromised quality of life due to symptoms, dietary restrictions, and functional limitations. Complications of GERD include esophagitis, strictures, ulcerations and Barrett's esophagus. GERD can be diagnosed clinically when patients present with classic symptoms, heartburn and regurgitation. It is more difficult to diagnose in the absence of typical symptoms. Some less typical symptoms such as chest pain and weight loss may indicate GERD or a more serious condition (Scott & Gelhot, 1999).

Diagnostic tests are often used when the diagnosis is unclear or when there is a concern about complications. Possible diagnostic methods are response of symptoms to omeprazole (a proton pump inhibitor), radiology, endoscopy and ambulatory pH monitoring. Radiographic studies may not be useful because only about one-third of patients with GERD have radiologic signs of esophagitis. Endoscopy is more useful for diagnosing Barrett's esophagus and other complications of GERD than for diagnosing GERD itself.

Ambulatory pH monitoring is currently considered the "gold standard" for diagnosing GERD. It involves placing a nasally passed catheter into the esophagus. The catheter is connected to a monitoring device worn on the patient's belt and levels of pH are recorded over 24-hours. Many patients find this test uncomfortable. Patients

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may restrict their daily activities which could result in false negative findings or may not complete the test due to discomfort (Pandolfino & Kahrilas, 2005; Scott & Gelhot, 1999).

The Bravo pH monitoring system (Medtronic) is a non-invasive alternative to catheter-based ambulatory pH monitoring. This system involves attaching a radiotelemetry pH-sensing capsule (approximately the size of a gel cap) to the mucosal wall of the esophagus. The capsule is placed approximately 6 cm above the squamocolumnar junction using a customized delivery system that is removed after the capsule is in place. The capsule can be placed orally or trans-nasally, and the procedure is often done during endoscopy.

The capsule measures the pH in the esophagus and transmits the information via radio signal to an external receiver. The pager-sized receiver can be worn on the patient's belt or waistband. The receiver has a range of 3-5 feet. At the end of the 24-hour or 48-hour testing period, the information from the receiver is uploaded to a computer (Pandolfino, 2005; Medtronic website). Potential advantages of the Bravo system are increased comfort and patient compliance.

The Bravo system had been approved by the FDA and has not been previously reviewed by MTAC.

Medical Technology Assessment Committee (MTAC)

Capsule PH Monitoring System (Bravo System)

08/01/2005: MTAC Review

Evidence Conclusion: Only one study was identified that compared the findings of pH monitoring using the Bravo system and the "gold standard", catheter-based esophageal monitoring. This study (des Varannes et al., 2005) found that the Bravo system under-reported esophageal acid exposure compared to standard testing. The investigators used a correction factor obtained from their data to determine a cut-off value for abnormal acid exposure as measured by Bravo. After this correction, there was an 88% concordance in diagnostic yield between the two methods. As the authors noted in their conclusion, correction factors have not been standardized. Additional studies are needed to validate an appropriate cut-off value for diagnosing GERD with the Bravo system.

The other study that was reviewed (Pandolfino et al, 2003) primarily evaluated the feasibility of using the Bravo system. The investigators were highly successful at placing the Bravo system and recording pH levels. The Pandolfino study included an analysis that compared patient satisfaction with the Bravo and conventional systems. Findings were that the Bravo patients reported more esophageal discomfort and the conventional patients reported more throat discomfort. Overall satisfaction was higher in the Bravo group. Both studies were limited by small sample sizes.

Articles: The search yielded 12 articles, four of which were empirical studies. The ideal study would be an independent, blind comparison of the accuracy of GERD diagnosis using the Bravo PH monitoring system with the "gold standard", catheter-based esophageal PH monitoring. There was one study that compared these two diagnostic tests (des Varannes et al., 2005) and this was critically appraised. Another study that compared the findings of the Bravo pH monitoring system in healthy patients and patients with a clinical diagnosis of GERD (Pandolfino et al., 2003) was also critically appraised. There were also two case series (n=30 and n=60) that examined the feasibility of using the Bravo pH monitoring system and these were not evaluated further.

des Varannes SB, Mion F, Ducrotte P et al. Simultaneous recordings of esophageal pH monitoring and a wireless system (Bravo). Gut 2005; Published on-line before journal publication. See Evidence Table. Pandolfino JE, Richter JE, Ours T et al. Ambulatory esophageal pH monitoring using a wireless system. *Am J Gastroenterology* 2003; 98: 740-749. See Evidence Table.

The use of capsule PH monitoring system (Bravo System) in the evaluation of gastroesophageal reflux disease (GERD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Medical Necessity Review no longer required:

CPT® Codes	Description
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

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Date Created	Date Reviewed	Date Last Revised
08/01/2005	Initiated annual review because of Medicare criteria 05/3/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013MDCRPC, 03/04/2014 MPC, 09/02/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC , 05/02/2023MPC	04/23/2020

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
04/23/2020	Added clarification that this criteria policy is applicable to adults.

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Clinical Review Criteria
Thermal Capsulorrhaphy for Shoulder Instability

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**Thermal Capsulorrhaphy**," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Shoulder instability is a common orthopedic problem particularly in the young active population. It can occur from multiple minor traumatic events that result in stretching rather than detaching or tearing ligaments. Certain individuals may have a genetic predisposition that is complicated by repetitive overuse activities. Treatment is directed at reducing capsular volume. Most patients are suitable candidates for a trial of shoulder rehabilitation. Those who fail non-operative treatment may be candidates for surgical intervention.

A variety of surgical techniques are available to reliably prevent recurrent instability. There has been a recent trend towards arthroscopic stabilization and techniques for performing arthroscopic surgery have substantially developed in the past 20 years. Open surgical reconstruction used to be the traditional approach. Now it is reserved for patients with pathology inappropriate for arthroscopic techniques, and in cases where arthroscopic suturing is found to be inadequate intraoperatively.

Thermal capsulorrhaphy is a new treatment modality for shoulder instability, where the joint capsule is heated and reduced in length by laser or radiofrequency energy to regain shoulder stability. The use of heat can alter collagen within the glenohumeral capsule resulting in its contracture. It may be an alternative or an additional way to restore capsule tension and increase thickness of deficient tissues in shoulders with multidirectional and posterior instability.

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Experimental studies showed that thermal energy might cause immediate deleterious effects such as loss of mechanical properties, collagen denaturation, and cell necrosis. Over-treatment can lead to severe immediate and permanent damage.

Medical Technology Assessment Committee (MTAC)

Thermal Capsulorrhaphy

08/12/2002: MTAC REVIEW

Evidence Conclusion: The literature reviewed does not provide enough evidence to support the use of thermal capsulorrhaphy for the treatment of shoulder instability.

Articles: The search yielded 21 articles. The majority were reviews, tutorials, and opinion pieces. There was only one cohort study with historical control, and one case series with 30 patients. Savoie FH, and Field LD. Thermal versus suture treatment of symptomatic capsular laxity. *Clin Sports Med* 2000; 19:63-75. See Evidence Table. Fitzgerald BT, Watson T, and Lapoint JM. The use of thermal capsulorrhaphy in the treatment of multidirectional instability. *L Shoulder Elbow Surg* 2002; 11:108-113. See Evidence Table.

The use of Thermal Capsulorrhaphy in the treatment of shoulder instability does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/03/2006: MTAC REVIEW

Thermal Capsulorrhaphy

Evidence Conclusion: The case series published after the last MTAC review of thermal capsulorrhaphy for shoulder instability in 2004 do not provide any new or additional evidence to support the use of procedure for the treatment of shoulder instability. The ongoing multicenter RCT comparing capsulorrhaphy with open inferior capsular shift for patients with shoulder instability might provide evidence on the efficacy of the intervention.

Articles: The search yielded 28 articles. The majority were reviews, tutorials, and experimental studies. All studies published after the last update was small prospective, or retrospective case series. The search also identified an ongoing RCT comparing electrothermal arthroscopic capsulorrhaphy versus open inferior capsular shift for patients with shoulder instability (Mohtadi NG et al, 2006).

The use of Thermal Capsulorrhaphy in the treatment of shoulder instability does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
08/12/2002	04/04/2011 MDCRPC, 02/07/2012 MDCRPC,12/04/2012 MDCRPC ,10/01/2013 MPC, 08/05/2014MPC,06/02/2015MPC, 05/03/2016MPC, 03/08/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC,12/07/2021MPC,12/06/2022MPC	01/09/2018

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
01/09/2018	Adopted Kaiser Permanente criteria for Medicare Advantage members

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Clinical Review Criteria
Cardiac Rehabilitation

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Claims Processing Manual Chapter 32, Section 140
National Coverage Determinations (NCD)	Cardiac Rehabilitation Programs for Chronic Heart Failure (20.10.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	LCA A54070 Billing and Coding Outpatient Cardiac Rehabilitation

For Non-Medicare Members

Kaiser Permanente has elected to use the Cardiac Rehabilitation (KP-0358) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of cardiology notes

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Background

Cardiovascular disease (CVD) is the most common cause of office visits, hospitalizations, and deaths in the United States. In recent years, there has been great progress in pharmacological therapies as well as technology-based diagnostic and therapeutic interventions for CVD. As a consequence, a greater number of patients survive acute events, but with a heavier burden of chronic conditions and clinical needs. In addition to medication and interventional cardiology, these patients also need structured support to restore their quality of life and to maintain or improve functional capacity.

Cardiac rehabilitation (CR) was initially developed in response to the profound deconditioning caused by the prolonged bed rest that was common in the management of patients following acute cardiac events in the first half of the 20th century. Since then it has developed into multidisciplinary programs to optimize the health of patients with an expanding range of cardiovascular disease (Gordon 2010). CR is a multifactorial, comprehensive intervention defined as the coordinated sum of interventions required to ensure the best physical, psychological, and social conditions so that patients with chronic or post-acute CVD event may, by their own efforts, preserve or

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resume optimal functioning in society, and through improved health behaviors, slow or reverse progression of disease (Taylor 2004). It is also viewed as the clinical application of preventive care by means of a professional multi-disciplinary integrated approach for comprehensive risk reduction and global long-term care of cardiac patients (Piepoli 2010).

The American Heart Association (AHA), the American College of Cardiology (ACC), and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) consider cardiac rehabilitation / secondary prevention programs integral to the comprehensive care of patients with CVD. They recommend that all cardiac rehabilitation/secondary prevention programs should contain specific core components that aim at optimizing cardiovascular risk reduction, foster healthy behaviors and compliance with these behaviors, reduce disability, and promote an active lifestyle for patients with cardiovascular disease. The core components include baseline patient assessment, nutritional counseling, risk factor management (weight, blood pressure, lipids, diabetes mellitus and smoking), psychological interventions, physical activity counseling, and exercise training (Balady 2007). The goals of CR consist primarily of mobilizing the patient, optimizing drug therapy, implementing measures of secondary prevention, providing means for understanding the disease through education and advice, facilitating behavior modification, supporting the patient in overcoming the disease, treating psychological disturbances, and improving reintegration into professional life (Farin 2007). It is clearly understood and accepted that an isolated exercise program is not cardiac rehabilitation; however, physical activity and exercise training are considered the core components on which a comprehensive CR program is built (Piepoli 2010).

Most CR programs are held for groups in hospitals, gyms, or community centers. These may be inconvenient to patients (especially women and older patients) who may have problems with accessibility, dislike of groups, and/or work on domestic commitments. Home-based programs were thus introduced as an alternative to traditional CR in an attempt to increase participation rates. These programs have been defined as structured programs with clear objectives to the participants, including monitoring, follow-up, visits, letters, telephone calls from staff, or at least self-monitoring diaries (Dalal 2010).

Medical Technology Assessment Committee (MTAC)

Cardiac Rehabilitation

12/20/2010: MTAC REVIEW

Evidence Conclusion: The majority of the studies on cardiac rehabilitation for heart failure or stable MI were small trials, with short follow-up duration, and mainly examined the safety and efficacy of exercise-based programs. The CR programs undergone in the trials differed in their duration (range 1-6 months), frequency (1-5 sessions per week), and session length (20-60 minute /session), and most exercise programs and rehabilitation interventions were tailored on the individual patient's needs. Several meta-analyses were thus conducted to pool the results of these trials to provide sufficient power to adequately address the effect of comprehensive CR programs on morbidity, mortality, HRQoL, and modifiable risk factors. Cardiac rehabilitation programs for patients with CHD: Several earlier meta-analyses examined the effects of exercise based cardiac rehabilitation on patients with MI and found a survival benefit of the programs. The latest of these meta-analyses was performed by Taylor and colleagues (2004) and included 48 trials with 8,840 participants**.** Most studies recruited patients at low risk of another event after an MI. The exercise program, as well as the duration of follow-up varied widely between studies. The results of the pooled analysis showed that, compared with usual care, CR reduced total mortality by 20% and cardiac mortality by 26%. There were also significant reductions in some modifiable risk factors including total cholesterol, triglycerides, systolic blood pressure, and smoking. There were no statistically significant reductions in the rate of recurrent MI or revascularization. The main analysis combined the results of exercise only trials with studies on comprehensive cardiac rehabilitation. A subgroup analysis performed by the authors showed a significant mortality benefit with comprehensive CR programs. A decrease in total and cardiac mortality with CR may be due at least in part, to the serial surveillance provided by the rehabilitation staff, which may lead to the detection of any deterioration in the clinical status before it progresses to a more morbid condition or event.
Cardiac rehabilitation programs for patients with heart failure: Davies et al's Cochrane review in 2010, on the effect of exercise training in patients with systolic heart failure showed that exercise training reduces heart-failure related hospital admission and improves HRQoL in patients who were mainly men with a mean age ranging from 43-72 years, and with NYHA class II-III systolic HF. No effect on mortality was observed. All studies included in the analysis, except for one relatively small (N=200) trial, were exercise only interventions. The analysis included the HF-ACTION study which was a large trial (N=2,331) on the effect of exercise training on HF patients. CR programs aim at enhancing self-management and are not restricted to exercise but should also include education, risk factor management, pharmacological therapies, and psychological input. An earlier meta-analysis (van Tol 2006), evaluating the effect of exercise training on cardiac performance in 35 RCTs including 1,486 patients with stable mild to moderate CHF showed that exercise training leads to significant improvements in cardiac

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performance and quality of life. The meta-analysis did not study the effect on mortality or rate of hospitalization due to HF. Austin et al, 2008, reported on long term results of a trial that randomized 200 patients over 60 years of age with LV systolic dysfunction NYHA class II-III, to receive either standard care or undergo a comprehensive CR program for 24 weeks. Five-year follow up of 56% of the patients showed some long- term benefit on the functional performance and perceived exertion of the patients. In a more recent small study that included older HF patients, and HF patients with normal ejection fraction, Davidson and colleagues (2010) showed that a multidisciplinary heart failure CR program significantly reduced hospital admission rates due to a cardiovascular or any other event. Home-based versus center based cardiac rehabilitation for patients with coronary heart disease: A large number of trials compared the outcome of home versus center-based CR on patients with CVD. The majority of trials were small in size with the exception of a more recent trial (Birmingham Rehabilitation Uptake Maximization [BRUM]), which included 525 participants after experiencing an acute MI or coronary revascularization. The results of this trial found no difference in risk factor control or self-reported physical activity between patients randomized to home versus center-based CR. The study was not designed as an equivalence trial, and a lack of significant difference between the two strategies does necessarily indicate that they have similar effects. A recent Cochrane review (Dalal 2010) pooled the results of the 12 RCTs involving almost 1200 participants in total. The trials excluded high risk patients (those with arrhythmias or severe ischemia) and only 2 studies included HF patients. The patient characteristics as well as duration, frequency, and session lengths of CR programs varied widely between studies, and several of the home-based programs started with center-based CR then transitioned to CR at home. The results of the analyses showed no significant differences between the home versus center-based CR programs in risk factors control, HRQoL measures, and all-cause mortality. The authors concluded that home-based and center-based CR programs appear to be equally effective in improving clinical and health related QOL outcomes in patients with low risk after MI or revascularization. The results may suggest that the outcomes between home-based and center-based CR are similar, however lack of significant differences does not necessarily imply that the two strategies are equally effective.
Conclusion**:** There is fair evidence that exercise-based cardiac rehabilitation programs reduces mortality, morbidity, and improves health related quality of life (HRQoL), and modifiable risk factors in low risk patients with coronary heart disease. There is fair evidence that exercise-based cardiac rehabilitation programs reduce hospital admission and improves HRQoL among low- to moderate- risk patients with stable heart failure.
There is inconclusive evidence that home-based and center-based CR have similar benefits. The results of trials and meta-analyses comparing the two strategies suggest that they have similar outcomes. However, due to the study designs, a lack of significant statistical differences in the outcomes does not necessarily imply that the two strategies are equivalent.
Articles: The literature search revealed at least 15 meta-analyses on cardiac rehabilitation, and a large number of randomized controlled trials, and observational studies. The great majority of the meta-analyses and trials were performed on individual components of the cardiac rehabilitation (CR) program, mainly exercise-based programs, in stable patients post myocardial infarction or coronary revascularization, or in patients with heart failure. Overall, the randomized trials on the comprehensive CR were relatively small and with short duration of follow-up. One trial (Austin 2008), reported on 5 years outcome of patients with heart failure after undergoing a multidisciplinary 8-week CR program. The literature search also revealed 4 recent meta-analyses of RCTs that compared home-based cardiac rehabilitation versus center-based programs for patients with cardiovascular disease.
Studies (e.g. HF-ACTION) or meta-analyses (e.g. ExTraMATCH) that examined the safety and efficacy of exercise training or other single components of the program in patients with chronic heart failure or CAD were not included in the current review which evaluates the multidisciplinary cardiac rehabilitation program.
The following meta-analyses of trials on comprehensive CR for patients with heart failure or CHD, that compared and home-based vs. center-based CR as well as the RCT with 5-year follow-up were selected for critical appraisal.
Davies EJ, Moxham T, Rees K, et al. Exercise training for systolic heart failure: Cochrane systemic review and meta-analysis. *Eur J Heart Fail* 2010; 12:706-715. See Evidence Table. Davidson PM, Cockburn J, Newton PJ, et al. Can a heart specific cardiac rehabilitation program decrease hospitalization and improve outcomes in high-risk patients? *Eur J Cadiovasc Prev Rehabil 2010*; 17:393-402. See Evidence Table. Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: Systematic review and meta-analysis of randomized controlled trials. *Am J Med* 2004; 116:682-692. See Evidence Table. Austin J, Williams WR, Ross L, et al Five-year follow-up findings from randomized trials of cardiac rehabilitation for heart failure. *Eur J Cardiovasc Prev Rehabil 2008*; 15:162-167. See Evidence Table. Dalal HM, Zawada A, Jolly K, et al. Home based versus center based cardiac rehabilitation: Cochrane systemic review and meta-analysis. *BMJ* 2010;340:C 1133. See Evidence Table.

The use of cardiac rehabilitation facility and home based does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)
G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session
S9472	Cardiac rehabilitation program, nonphysician provider, per diem

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Date Created	Date Reviewed	Date Last Revised
05/15/1998	06/01/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC] ,11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	09/27/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/10/2015	Link for Medicare Pub 100-03 Cardiac Rehabilitation added
09/27/2016	Added NCD 20.31.3 and NCD 20.10.1

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Clinical Review Criteria
Cardiac Contractility Modulation Device

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cardiac Contractility Modulation Device"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Kaiser Interregional New Technologies Committee Assessment
Date: 04/27/2020

There is insufficient evidence regarding the efficacy and safety of Optimizer (cardiac contractility modulation [CCM]) as compared to optimal medical management for heart failure.

Based on the review of 4 randomized trials (n=801) that compared Optimizer CCM plus optimal medical therapy (OMT) versus OMT alone, there is moderate-quality evidence that treatment of heart failure with Optimizer CCM is associated with short-term improvements in quality of life and peak Vo_2; however,

findings for other symptom-related outcomes were mixed and there is a lack of long-term outcomes, including hospitalization and mortality data. Thus, the existing evidence regarding how Optimizer CCM effectively manages heart failure is of insufficient quantity and/or quality.

Heart failure (HF), also referred to as congestive HF, is a chronic, progressive condition that develops due to circumstances that overwork and damage the heart, rendering the heart muscle unable to pump enough blood to meet the body's needs for blood and oxygen. The primary causes of HF include coronary heart disease, high blood pressure, and diabetes. Approximately half of heart failure cases are associated with a reduced ejection fraction (HFrEF), typically defined as a left ventricular ejection fraction (LVEF) <35% or <40%. The impact of heart failure on patient quality of life as well as its economic costs are substantial.

Treatment of HF is focused on symptom relief and typically includes lifestyle modification and oral medications that treat underling conditions including hypertension, high cholesterol, diabetes, and obesity. Treatment options for patients with severe HFrEF with inadequate response to medications include cardiac resynchronization therapy (CRT), left ventricular assist devices (LVAD), and heart transplantation. However, many patients with moderate to severe HF symptoms—including the 25% to 35% of patients who have HFrEF categorized as NYHA functional class III—do not meet established indications for these options. The Optimizer Smart System (Impulse Dynamics, Inc., Orangeburg, NY, USA) is intended for patients in this treatment "gap."

The Optimizer Smart System is a pacemaker-sized, rechargeable, implanted device intended to deliver cardiac contractility modulation (CCM) therapy to increase the strength of the heart's ventricular contraction in patients with stage III to IV HF whose LVEF is 25% to 45% despite optimal medical therapy (OMT).

The following clinical question was the subject of the review:

What is the efficacy and safety of the Optimizer Smart System for treatment of heart failure?

A comprehensive search was conducted on March 18, 2020 to identify systematic reviews, technology assessments, and randomized trials addressing the clinical question.

Based on the existing literature:

- The body of evidence on the use of Optimizer CCM for treatment of heart failure consists of 4 randomized trials (n=801) that compared Optimizer CCM plus optimal medical therapy (OMT) versus OMT alone.
- Two early trials employed a sham-control group (FIX-HF-5 Pilot) and a crossover design (FIX-CHF-4), while the 2 more recent trials used a more traditional design. The sham-controlled and crossover trials noted significant placebo effects for several outcomes.
- Moderate-quality evidence suggests that Optimizer CCM plus OMT results in clinically and statistically significant improvements in short-term clinical outcomes including QOL and peak Vo_2 compared to OMT alone.
- It is unclear if Optimizer CCM has an impact on 6-minute hall-walk (6MHW) distance, NYHA class, ventilatory threshold, hospitalizations, or mortality. The quality of evidence for these outcomes was low due to mixed findings, a lack of between-group differences, insufficient power, and/or inadequate duration of follow-up.
- Moderate-quality evidence suggests that rates of serious adverse events were relatively low and similar between CCM and OMT groups. The implantation procedure and short-term use of the device appear to be relatively safe and comparable to similar interventions (e.g., pacemakers).
- The Optimizer CCM implantation procedure takes about 3 hours to complete, although there was considerable variation across patients and the quality of this evidence is low.

- The main limitations of the included trials are their relatively small sample sizes (801 patients total), lack of long-term follow-up, mixed findings for several key outcome measures (e.g., 6MHW, NYHA class), and lack of a sham control for the 2 most recent trials.
- These promising but preliminary findings suggest that Optimizer CCM is a safe and effective treatment for patients with NYHA class III heart failure with ejection fraction between 25% and 45%. Additional randomized trials are needed to confirm these initial findings and evaluate long-term outcomes.

Among several relevant clinical practice guidelines identified in the evidence search, the European Society of Cardiology (2016) notes that CCM may be considered in selected patients with HF, and NICE (2019) notes that although there are no major safety concerns, the device should only be used in research settings due to the lack of evidence on efficacy.

The committee discussed uncertainty regarding benefits of Optimizer CCM beyond symptomatic improvement. In particular, there is a lack of mortality data. Given the determination of "insufficient evidence," the plan is to continue participation in clinical trials and to await publication of mortality data prior to considering adopting this technology.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system
HCPC Codes	**Description**
C1824	Generator, cardiac contractility modulation (implantable)
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility

	modulation generator, replacement only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
04/07/2020	04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	10/26/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt new non-coverage criteria (Medicare's position)
05/26/2020	Added background from INTC review on 4/27/2020
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.

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Clinical Review Criteria

Coronary Artery Calcium Score with Computed Tomography (CT)

- Multidetector Computed Tomography (MDCT)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	05/13/2016 Noridian retired LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search. Per LCD L34137 - … Until such time as there is more evidence of the medical necessity for quantitative evaluation of coronary calcium, Medicare may not cover the procedure for coronary calcium scoring (75571).
Local Coverage Articles	None

For Non-Medicare Members

*Repeat CAC measurement not indicated within less than 5 years.

Adapted from KPWA ASCVD Primary Prevention Guideline (Oct 2020)

Coronary artery calcium scoring may be indicated for asymptomatic patients with **1 or more of the following**:

- Intermediate ASCVD risk* indicated by ALL of the following
  - Age 40-75 without DM and with LDL-C levels ≥ 70 mg/dL
  - At a 10-year ASCVD risk* of ≥ 7.5% and < 20 %
  - Risk status or decision about statin therapy is uncertain

For these patients, treatment with statin therapy may be withheld or delayed if CAC = 0, except in cigarette smokers and those with a strong family history of premature ASCVD. A CAC score of 1–99 favors statin therapy, especially in those aged ≥ 55 years. For any patient, if the CAC score is ≥ 100 or ≥ 75th percentile, statin therapy is indicated.

- May be considered in select adults age 40-75 with ALL of the following
  - Borderline elevated ASCVD risk (5-7.4% 10-year ASCVD risk*)

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- The presence of CAC may change decision-making with regard to statin treatment and intensity of ASCVD risk factor modification

Routine CAC measurement is not recommended for:
- Patients at low (< 5% 10-year risk) or high (≥ 20% 10-year risk) ASCVD risk
- Patients who are unlikely to initiate treatment even if CAC is identified

*ASCVD Risk Estimator Plus (American College of Cardiology)

If requesting review for this service, please send the following documentation:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Documented 10-year ASCVD risk score
  *ASCVD Risk Estimator Plus (American College of Cardiology)

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Background

Coronary heart disease (CHD) remains the leading cause of death among men and women in the United States. It is valuable to detect coronary atherosclerosis early in its course and try to alter its progression by modifying certain identifiable risk factors. The earliest detectable lesion of coronary atherosclerosis is a fatty streak, followed by crescent shaped lipid plaques, which may rupture and produce either progressive stenosis or sudden occlusion with myocardial infarction. It was previously thought that coronary artery calcification was the late result of end stage plaque degeneration. Now it is believed that calcium is present in all stages of plaque formation. Coronary artery calcification occurs in small amounts in the early lesions of atherosclerosis that appear in the second and third decades of life but is found more frequently in advanced lesions in older age (Janowitz 1993). Coronary artery calcium increases with increasing age in men, while women may experience accelerated calcification after menopause (Allison 2004).

The relation of arterial calcification to the probability of plague rupture is unknown. Some investigators postulate that calcification may actively contribute to the susceptibility of plaque rupture and subsequent events. While others believe that calcification may reflect stabilization and maturation of the plaque that would lead to fewer myocardial infarctions and CHD deaths (Lee 2002). Beckman 2001 reported that although radiographically detected coronary artery calcium can provide an estimate of total coronary plaque burden, calcium does not concentrate exclusively at sites with severe coronary artery stenosis due to arterial remodeling. Other researchers indicated that ultrafast scans cannot detect all calcium and that molecular calcium may go unnoticed. Thus calcium detected by ultrafast scans may represent only the tip of the iceberg (Rumberger 1996). Despite that, some investigators believe coronary artery calcium (CAC) detection may be able to globally define a patient's risk of CHD events.

Now that some believe that calcification can be used as a marker of the atherosclerotic process, and because calcific deposits are radio-opaque, numerous radiographic techniques have been used in the search for a noninvasive screening test for coronary artery disease. Fluoroscopy was used for decades to detect coronary artery calcium. However, its routine use for identifying patients with coronary artery disease is limited due to its low sensitivity to detect small amounts of coronary calcium that can be observed pathologically in complex atherosclerotic plaques. Conventional computed tomography (CT) have an advantage over fluoroscopy in its improved resolution, which is limited however when moving structures are imaged. This limitation has been overcome by the electron beam computed tomography (EBCT), and multidetector computed tomography (MDCT). Both technologies yield thin slice CT imaging using fast scan speeds that reduce motion artifact. 30-40 adjacent axial scans are usually obtained. The fast time scan allows the entire heart to be imaged over one or two breath holds. Images can be reconstructed to form three-dimensional or cross-sectional images. There are three methods for calcium quantification and scoring: The Agatston method, the volumetric method, and quantification of calcium mass. Agatston method is the most commonly used and is obtained by the summation of areas of the calcified lesions multiplied by a scaling cofactor; an Agatston score of zero indicates absence of coronary calcium,

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1-99 is considered low, 10-400 is intermediate, and 400 high (Sanz 2006). Calcium scores can be calculated for a coronary artery segment, a coronary artery, or summed for the whole coronary system.

Ultrafast CT scanners became commercially available in 1983, before the first study of their use was published in 1989. In the 1990s, another form of CT, the helical or spiral computed tomography has been developed. In helical tomography, continuous scanning is performed in combination with a continuous table feed. Thus, the x-ray beam traces a spiral path through the patient. The entire heart can be imaged with 3 mm non-overlapping slices, within one breath hold (30 sec). The initial goal of using cardiac computed tomography was to identify patients at risk of coronary artery disease based on the amount of calcium present. However, in the past 5-10 years these ultrafast scans have been used to: 1) Assist in CHD risk assessment in asymptomatic individuals, and, 2) To assess the likelihood of the presence of CHD in patients who present with atypical symptoms that could be consistent with myocardial ischemia.

The EBCT scanners currently used are produced by GE Imatron, South San Francisco California. They were approved by the FDA as Class II devices.

The use of EBCT for CAC scoring was reviewed by MTAC in 2002 and 2004 and did not meet its evaluation criteria. It is being re-reviewed due to the recent publications of studies with clinically important outcomes.

Medical Technology Assessment Committee (MTAC)

Ultrafast CT in the Screening and Diagnosis of CAD

02/11/2002: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the value of Ultrafast CT as a screening test for coronary artery disease among asymptomatic patients. In the studies reviewed, ultrafast CT and angiography were done among patients because of suspected coronary artery disease. The prevalence of CAD in these studies was high and it may not be appropriate to extrapolate these results to scans done in the population at large, or those done for screening purposes. The studies reviewed show that ultrafast CT scanning had a high sensitivity and low specificity in detecting coronary artery disease among the participants. The sensitivity increased with age and was highest for symptomatic patients older than 50 years. The specificity on the other hand, increased with the number of calcified vessels and was highest among patients with 4-vessel calcification. The majority of studies did not address clinical end-points, as their primary outcome. Detrano, et al (1996) however, followed-up the patients for a mean of 30 months, to determine the relative prognostic value of coronary calcification for predicting CHD events among symptomatic patients. They found that cardiac events and deaths tended to be more frequent in the higher quartiles of calcium score. In conclusion, the results of these studies indicate that in a population where CAD is more prevalent, the absence of coronary calcification is more helpful in ruling out CAD than is the detection of calcium in confirming the presence of CAD. Ultrafast CT seems promising, but as yet, there is no evidence that it may substitute angiography, but can be helpful in excluding or increasing the likelihood of significant CAD in certain situations.

Articles: The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See Evidence Table. Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See Evidence Table. Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. A*JR* 1996; 167:439-444. See Evidence Table.

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

12/08/2004: MTAC REVIEW

Ultrafast CT in the Screening and Diagnosis of CAD

Evidence Conclusion: A screening test for preclinical coronary artery disease among asymptomatic individuals, and A diagnostic test for coronary artery disease among symptomatic patients. Use of EBCT for coronary artery disease screening among asymptomatic individuals: There is insufficient published evidence to determine the

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value of EBCT (Ultrafast CT) as a screening test for coronary artery disease among asymptomatic individuals. Ideally, a screening test should be highly sensitive in detecting previously undiagnosed disease and should lead to changes in management that improves outcomes. The meta-analysis and observational studies reviewed evaluated EBCT coronary artery calcium as a risk predictor of future coronary events among asymptomatic individuals. These studies suggest that coronary artery calcium detected by EBCT may be an independent predictor for coronary events and may add to the information provided by the Framingham risk score. However, the studies had some threats to validity that may limit generalization of the results. The majority is office-based and included self-referred individuals or others at high risk referred by their primary care physicians for further evaluation. Risk factors were self-reported and not measured in more than one study. Different techniques and scans were used, and there was no established cut-off level for calcium scores. The endpoints included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. The endpoint in one of the studies was all-cause mortality that might be due to other causes than coronary atherosclerotic diseases. None of these observational studies examined the influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. There is no evidence that more effective therapy or management could be provided by evaluating CAC score beyond that provided based on FRS. A recent RCT showed that the detection of coronary artery calcium among asymptomatic individuals was not associated with behavior modification or reduction of their cardiac risk scores. This RCT also had its limitations. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients: The studies reviewed show that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies reviewed in the meta-analysis, and the more recent study. The sensitivity was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results.
Articles: The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See Evidence Table. Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See Evidence Table. Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. A*JR* 1996; 167:439-444. See Evidence Table.

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/02/2007: MTAC REVIEW
Ultrafast CT in the Screening and Diagnosis of CAD
Evidence Conclusion: This report focuses on the use of electron bean computed tomography for detecting calcium deposits in coronary arteries as 1. A screening test for preclinical coronary artery disease among asymptomatic individuals, and 2. A diagnostic test for coronary artery disease among symptomatic patients. Use of EBCT for coronary artery disease screening among asymptomatic individuals: Ideally a screening test for predicting outcomes should not only prove to independently contribute to risk stratification, but also to provide further prognostic information beyond and above the traditional risk factors i.e. in this case, the Framingham Risk Stratification. Constructing the Receiver Operator Characteristic (ROC) curves and measuring the Area Under the ROC curve (AUC) would determine if a new marker or test has an additive benefit. An ideal screening test would also lead to changes in the management that will improve health outcomes e.g. fewer events, extended life or better quality of life. Fletcher's meta-analysis (2004), reviewed for the previous update, offered some support that there is a linear relationship between CAC and CHD events, but the analysis did not address whether CAC adds any incremental value to Framingham Risk Score (FRS) for CHD risk prediction. Greenland and colleagues (2007) pooled the results of 6 observational studies published after Fletcher's meta-analysis. There was some heterogeneity between the studies in the assessment of risk factors, cut-off levels used for calcium scores, as well as in the endpoints. The latter included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. None of the studies included in the meta-analysis examined the
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influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. The pooled results of the studies in the meta-analysis showed that patients with any measurable calcium were at a significantly higher risk compared to those with a low-risk CAC (using a score of 0) over a 3-5 years period of observation. This analysis also showed that there was an incremental relationship between CAC and CHD risk. The authors however did not discuss if adding CAC scoring to the traditional factors would significantly increase the AUC. Arad and colleagues published two articles on the St Francis Health Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first was a prospective cohort study that investigated the accuracy of CAC scores in predicting atherosclerotic cardiovascular disease (ASCVD) events independent of standard risk factors. The second article reports on the results of an RCT embedded in the cohort study. This RCT investigated whether lipid-lowering therapy and antioxidants retard the progression of coronary calcification and prevent ASCVD events. The St Francis Health Study enrolled 4,903 mainly White, healthy men and women 50-70 years old. All participants underwent EBCT but only a subset (n=1,357) with CAC score >80th percentile for age and gender, also underwent risk factor assessment. Participants were followed up for an average of 4.3 years for a composite outcome of coronary death, nonfatal MI, surgical or percutaneous coronary revascularization, nonhemorrhagic stroke and peripheral vascular surgery. A multivariate regression analysis showed that CAC scoring predicted CAD events independent of standard risk factors, and that it was strongly predicted by age, male gender, and family history of premature coronary disease. The Receiver Operator Curve (ROC) showed that CAC score predicted CAD events more accurately than Framingham risk stratification (AUC= 0.79 vs. 0.68). It has to be noted however that this comparison was made only for participants with the highest percentiles of CAC, and that this study included all ASCVD outcomes while FRS predicts only the hard CHD outcomes. The majority of the observed events in this study were cardiovascular procedures rather than the traditional cardiac events. One other limitation of the study was low participation rate as only 2% of the eligible subjects we enrolled in the study. The RCT embedded in that study (Arad, Spadaro 2005) randomized 1,005 participants, with CAC score >80th percentile for age and gender, to receive a combination of atorvastatin, vitamin C, and vitamin E or a placebo. All participants in the two groups also received aspirin 80 mg daily. After 4.3 years of follow-up, active treatment group showed nonsignificant reduction in the primary or secondary outcomes. The results also showed no significant change in the progression of CAC. The lack of significant difference in ASCVD events might be due to the small sample size, short follow-up duration, and /or the administration of aspirin to the control as well as the active therapy group. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients: There is no new published evidence on the use of coronary calcium scoring as a diagnostic test for CAD. The studies reviewed earlier for the last update showed that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies and was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results. *In conclusion:* There is some evidence that CAC may add a prognostic incremental value to Framingham risk score among selected asymptomatic individuals. Indirect evidence suggests that asymptomatic individuals at intermediate risk might potentially benefit from adding CAC to the risk assessment. The majority of the participants in the studies reviewed were Caucasians which may limit generalization of the results. The studies do not provide an optimal coronary calcium threshold. There is no single cutoff value that defines a high score. The coronary calcification differs according to age, sex, and race. There is no evidence to date that CAC scoring would result in an intervention that would improve CHD related health outcomes among individuals at an increased risk for CHD. The test results may lead to unnecessary invasive procedures, or overtreatment in some patients.

Articles: The search yielded around 50 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Use of EBCT for coronary artery disease screening:
The search identified a recent meta-analysis of observational studies (Greenland 2007) and several prospective cohort studies that evaluated EBCT coronary artery calcium (CAC) score as a risk marker predicting the likelihood of future coronary events among asymptomatic patients. It also revealed two articles on the St. Francis Heart Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first reported on the prospective cohort study, and the second on the RCT embedded in the cohort. The meta-analysis and the two articles on the St. Francis Heart Study were selected for critical appraisal. Use of EBCT for coronary artery disease diagnosis:
The search did not reveal any newly published large valid study on the use of CAC scoring in the detection of coronary artery stenosis among symptomatic patients. *The following articles were critically appraised:*
Greenland P, Raggi P, Harrington R, et al. ACC/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment an in evaluation of patients with chest pain. J Am Coll Cardiol. 2007; 49:378-402. See Evidence Table. Arad Y, Goodman KJ, Roth M, et al. Coronary calcification, coronary disease risk factors, C-reactive protein, and atherosclerotic cardiovascular disease events. The St. Francis Heart Study. J Am Coll Cardiol. 2005; 46:158-165. See Evidence

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Table. Arad Y, Spadaro LA, Roth M, et al. Treatment of asymptomatic adults with elevated coronary calcium scores with atorvastatin, vitamin C, and vitamin E. The St. Francis Heart Study randomized clinical trial. J Am Coll Cardiol.2005;46:166-172. See Evidence Table.

The use of EBCT in the treatment of coronary artery calcium scoring does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

CORONARY ARTERY CALCIUM (CAC) SCORING WITH COMPUTED TOMOGRAPHY, FOR CARDIOVASCULAR DISEASE RISK ASSESSMENT

Date: 10/12/2020

Evidence Conclusion:

- There is evidence from published long-term large longitudinal population studies indicating that:
  - CAC is strongly associated and in a graded fashion with 10-year risk of incident ASCVD in asymptomatic White, Black, Hispanic and Chinese American men and women 45-84 years of age with no known history of CHD.
  - CAC scoring provides additional predictive information on ASCVD events and mortality, beyond the traditional risk factors, in men and women at different age groups, races, ethnic background, at different levels of risk, and in the presence or absence of comorbid conditions such as diabetes mellitus.
- There is insufficient published evidence, to date, from valid RCTs with long-term follow-up to determine that treatment guided by CAC scoring levels in addition to the traditional risk factors have an impact on patient management and /or health outcomes in asymptomatic adults at intermediate CV risk.

Articles: The literature search identified multiple large long-term population-based observational studies conducted in the US and Europe published over the last 20 years, that examined the association between CAC scoring and incidental CVD events and mortality in asymptomatic individual with no known coronary artery disease and its potential utility for CVD risk stratification in asymptomatic population. the largest population cohorts and/or those with longest follow-up duration were included in the review. The search did not identify any recent RCT with important clinical outcomes to determine the impact of CAC on guiding statin therapy an improving outcome in individuals at intermediate ASCVD risk.

The use of Coronary Artery Calcium (CAC) Scoring with Computed Tomography, for Cardiovascular Disease Risk Assessment does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Considered Not Medically Necessary (prior to 8/1/2021):

CPT® Codes	Description
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/11/2002	Established annual review for Medicare criteria 05/03/2011[MDCRPC], 09/06/2011[MDCRPC], 07/03/2012[MDCRPC], 05/07/2013[MDCRPC], 06/04/2013[MDCRPC], 03/04/2014 [MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	09/10/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

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Revision History	Description
09/01/2015	Revised LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137)
09/06/2016	Adopted retired LCD policy for Medicare members
04/24/2018	Added Medicare non-coverage language from LCD
03/02/2021	Added October 2020 MTAC Review. MPC approved criteria for Coronary Artery Calcium Scoring for non-Medicare members. The criteria are based on the KPWA ASCVD Primary Prevention Guideline. Removed Electron Beam Computed Tomography (EBCT), Helical or Spiral Computed Tomography, and Ultrafast Computed Tomography from criteria. Requires 60-day notice, effective date 08/01/2021.
09/10/2021	Added additional documentation requirements

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Clinical Review Criteria

Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure

- CardioMEMS

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure***, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Interregional New Technologies Committee

There is insufficient evidence to determine whether CardioMEMS is a medically appropriate option for patients with NYHA functional class III heart failure. The existing evidence is of insufficient quantity and quality. Patients undergoing IRB clinical trials could be potential candidates if the IRB trial has a well-designed protocol, appropriate informed consent, and structured follow-up.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Heart failure (HF) is a major public health problem in the United States and worldwide. It is estimated that more than six million Americans are currently living with heart failure, and that approximately 550,000 new cases are diagnosed in the US every year. Hospitalization for patients with chronic HF is also on the rise despite the major advances in medical and device therapies. Statistics show that HF is the primary diagnosis in over one million hospitalizations annually, and that patients hospitalized for HF are at high risk for all-cause rehospitalization with a 1-month readmission rate of 25%. The prognosis of these patients is suboptimal especially for those with serial readmissions (Hoppe 2009, Adamson 2011, Go 2013, Yancy 2013, Sandhu 2018).

More than 90% of hospitalizations for worsening HF are due to signs and symptoms of congestion leading to the decompensated state. Investigators found that increases in the intracardiac and pulmonary artery (PA) pressures are the cause of clinical congestion and that these begin several days or weeks before the onset of overt clinical signs and symptoms that are commonly used as indicators of congestion and volume overload leading to hospitalization. Thus, outpatient monitoring of markers for impending hemodynamic decompensation may allow early interventions to reduce both morbidity and hospitalization. Researchers also found that successful treatment of acutely decompensated HF patients is associated with a decrease

in diastolic pressures to values equivalent or below those present at baseline, and that continuous monitoring pressure during treatment may allow the clinicians to tailor the treatment more accurately. Based on these observations, it was hypothesized that ambulatory implantable hemodynamic monitoring (IHM) may provide information that would help avoid discharging patients from the hospital before decreasing the pressure sufficiently and returning the patient to a chronic compensated state. Continuous hemodynamic monitoring after the hospital discharge is also believed to proactively detect signs of congestion and reduce the risk of rehospitalization (Hoppe 2009, Abraham 2011, Adamson 2011, Mooney 2015, Sandhu 2018, Ayyadurai 2019).

Research has thus focused on ambulatory hemodynamic monitoring of chronic HF as a surrogate measure to guide the patients' medical therapy before the onset of acute hemodynamic decompensation. Several implantable systems have been developed to measure various cardiac pressures and tailor medical therapy accordingly "pressure guided therapy". Among these devices is the CardioMEMS HF System, which is the focus of the current review.

The CardioMEMS™ HF System (Abbott [previously St Jude Medical], Inc, USA) is a leadless battery-free, permanently implantable pressure measurement system designed to directly measure systolic, diastolic, and mean pulmonary artery pressure (PAP) to help guide heart failure management in an outpatient setting. The design of the system is based on the microelectromechanical principles of resonance whereby an external antenna wand emitting radiofrequency energy can cause varying degrees of oscillations in the sensor depending on the ambient pressure The CardioMEMS HF System consists of three main components: 1. A miniaturized wireless electromechanical leadless sensor (15mm x 3mm x 2mm) that comprises a coil and capacitor encased in silicone case, with a nitinol wire loop at each end of the sensor to keep the device in place in a pulmonary artery. The capacity and coil of the sensor creates an electrical circuit that resonates at a given frequency that varies depending on the pulmonary artery pressure 2. A transverse delivery system designed to deploy the implantable sensor in the distal PA; and 3. The Champion Electronics System, which acquires and processes signals from the implantable sensor and wirelessly transfers PA pressure measurements to a secure database to be reviewed and evaluated by the treating physician (Loh 2013, Adamson 2011, Mooney 2015, Ayyaduri 2019, FDA website).

The CardioMEMS sensor is delivered during a standard right heart catheterization procedure and implanted in a descending branch of the pulmonary artery via a delivery catheter. The implanted patients are started on aspirin and clopidogrel for one month followed by aspirin monotherapy. At home, HF patients use a portable electronic unit and a special pillow containing an antenna to take daily sensor readings. The reading takes place when the antenna is held against the body or when the patients lies on the pillow. The pressure readings are then wirelessly transmitted to a secure website and accessed by the clinicians to guide treatment decisions. Automated alerts will be sent to health care providers if pressure readings fall outside of prespecified ranges (Poor Ghaz 2019).

The U.S. Food and drug Administration (FDA) premarket approval (PMA) of CardioMEMS HF System was first rejected in 2011 due to concerns on the validity of the pivotal study results. After discussing additional follow-up data and further analyses of the results provided by the investigators and sponsors, the FDA cautiously approved the system in May 2014 to *"Remotely measure and monitor PA pressure and heart rate in New York Heart Association (NYHA) functional Class III heart failure patients who have been hospitalized for heart failure in the previous year*". According to the FDA, the system may be used by the physician in the hospital or medical office to better manage the patients and potentially reduce HF- related hospitalizations. Continued FDA approval of CardioMEMS HF System is contingent upon the submission of periodic reports at intervals of one year (unless otherwise specified) from the date of approval of the original PMA, as well as conducting two post-approval studies (FDA Website).

The CardioMEMS HF system may not be appropriate for patients with an active infection, history of recurrent deep vein thrombosis or pulmonary embolism, are unable tolerate a right heart catherization, have congenital heart disease or mechanical right heart valve, with known coagulation disorders, hypersensitivity to aspirin or clopidogrel, with an estimated GFR <25 ml/min and not responsive to diuretics or are on chronic renal dialysis, also for patients who had undergone implantation of CRT-D within the past 3 months, or have BMI >35 kg/m^2 (Ayyaduri 2019).

Medical Technology Assessment Committee (MTAC)

Evidence Conclusion

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- The CHAMPION trial remains the only published RCT that evaluated CardioMEMS HF device for monitoring NYHA functional class III heart failure patients.
- There is no additional evidence from published RCTs with valid methodology and long- term follow-up that would change the conclusion of the MTAC 2016 evidence review:
    - The results of the CHAMPION study show that previously hospitalized NYHA functional class III heart failure patients who received pressure guided management in addition to the standard care, had statistically significant lower hospital admission rates compared to those managed according to standard of care alone. It is unclear if the hospitalizations prevented in the device-guided management group were among the lower risk patients, and whether it had any impact on mortality.
    - It is hard to make a firm conclusion on the safety and effectiveness of CardioMEMS HF System from one single-blinded randomized trial, with an intermediate endpoint, potential performance bias, strict inclusion/exclusion criteria, conducted under a controlled environment, with a relatively short follow- up period, and funded by the manufacturer of the device that was also responsible for data collection and analysis. In addition, the principal investigators who analyzed, interpreted, and /or wrote the report had financial ties to the manufacturer.
- More RCTs with valid methodology and long-term clinical outcomes are needed to provide stronger evidence on the safety and efficacy of CardioMEMS HF System in monitoring patients with HF.

Articles: The updated literature search on CardioMEMS HF System for patients with Heart failure did not identify any RCTs published after the pivotal CHAMPION trial. The search revealed a propensity matched retrospective study, several review articles on pulmonary artery pressure guided management of patients with heart failure, sub-analyses of data from CHAMPION trial, and case series of patients implanted with CardioMEMS. A CardioMEMS post approval study was presented by Shavelle D, MD, in the 2019 annual meeting of the American College of Cardiology but, have not been published, to date, in a peer reviewed journal. The propensity matched study (Abraham et al, 2019) as well as the results of the CardioMEMS post- approval study (Shavelle 2019) ** were reviewed and summarized. See Evidence Table.

The use of Implantable Pulmonary Artery Pressure Monitoring Device (CardioMEMS HF System) For Patients with Heart Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
07/05/2016	07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC] , 02/01/2022[MPC], 02/07/2023[MPC]	07/05/2016

[MPC] Medical Policy Committee

Revision History	Description
02/10/2021	Added MTAC review from July 2020 for CardioMems

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Carotid Intima Media Thickness (IMT or CIMT) for Coronary Artery Disease Screening and Monitoring

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Carotid Intima Media Thickness (IMT or CIMT) for Coronary Artery Disease Screening and Monitoring"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Atherosclerosis is a progressive disease that usually starts early in life. It begins with thickening of the vessel wall due to proliferation of smooth muscle cells, and progresses with the accumulation of lipids carbohydrates, calcium deposits, fibrous tissue, and blood products within the lesions resulting in hard calcified plaques (Libby 2000). Acute manifestations of atherosclerosis such as acute myocardial infarction, stroke, or sudden cardiac death are due to thrombosis following rupture of an unstable plaque. It is thus valuable to detect coronary atherosclerosis early in its course and try to alter its progression by modifying certain identifiable risk factors. Several noninvasive imaging techniques to identify and quantify atherosclerosis have evolved in the last decades. These include echocardiography, stress echocardiography with perfusion, MRI, electron beam computed tomography, carotid artery imaging, and others.

B-mode ultrasound is a well-established method to evaluate atherosclerosis of peripheral arteries, and ultrasonographic assessment of 0easily accessible arteries has been advocated as surrogate markers for less accessible vessels. To consider a test as a surrogate marker, it should have the ability to predict the risk of a disease, and to improve with the improvement of the disease process (Feinstein 2002).

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Atherosclerosis predominantly affects the intima of the vessel wall; however, ultrasound imaging cannot discriminate between the intima and media, and is thus applied to the intima-media complex. Carotid artery intima-media thickness (IMT or CIMT) involves a high-resolution ultrasound imaging of the distance between the lumen-intima interface and the media-adventitia interface, reflecting the arterial wall characteristics. It can be measured at several areas along the vessel wall; at the posterior aspect of the common carotid artery, the anterior wall of the internal carotid artery or at the common carotid artery bifurcation. Researchers differ on the choice of wall or segment of the carotid artery to image. It is believed however that imaging from different segments will most likely increase the likelihood of providing more relevant information, based on the fact that atherosclerosis tends to develop in an asymmetric manner. IMT thickness measurements can be calculated as the average of arterial wall thickness, the maximal measured value, or the average of maximal values of different segments. The inter-reader variability is fairly high, and there is no clear cut-off point above which atherosclerosis can be defined. The cut-off points to determine the presence of an atherosclerotic plaque were arbitrarily chosen. It was suggested that an average thickness of the combined intima and media ranging between 0.5 and 1.2 mm is considered to be normal, and that ≥1.2 mm is used to define the presence of a plaque. It was also reported that the abnormal range of IMT is age dependent, and an IMT >1.00 mm is considered highly abnormal in younger patients and is sometimes used as the cutoff in clinical trials (Feinstein 2002).

The estimated progression of atherosclerosis per year is 0.02 to 0.05 mm (Feinstein 2002). IMT may be a potential useful marker for coronary atherosclerosis, as well as an indicator for its progression or regression, on the condition that the carotid atherosclerosis reflects coronary atherosclerosis. Still the occurrence of an acute event does not only depend on the condition of the coronaries, and carotid IMT does not visualize coronary arteries, and does not provide detailed insight into plaque composition or stability.

Medical Technology Assessment Committee (MTAC)

Carotid IMT in the Evaluation of Risk for CVD or to Monitor the Treatment Effect on CAD

04/04/2005: MTAC REVIEW

Evidence Conclusion: *Use of IMT as a screening tool, or risk predictor of CVD:* The literature search did not reveal any RCT that investigated carotid IMT as a screening tool for CHD. Ideally subjects would be randomized to receive or not receive a screening test, then followed up for a sufficient period of time, then compare the outcomes in the two groups. Carotid IMT was only evaluated in cohort studies as a risk predictor for future coronary heart disease. The ARIC study and Cardiovascular Health Study (CHS) were two large population-based cohort studies that assessed the association of IMT with coronary artery disease. ARIC study included 12,841 men and women aged 45-64 years and followed them up for 4-7 years. CHS followed 4,476 adults aged 65 years or older for 6 years. The primary outcome was the first coronary heart disease event in ARIC study, and. incidence of myocardial infarction and stroke in CHS. The Rotterdam study was a cohort study of 8,000 patients aged 55 years or older, followed up for 4.2 years. A case-control study with 374 subjects was nested in that study to determine the contribution of carotid IMT in the prediction of future coronary and cerebrovascular diseases when added to the traditional risk factors. All three studies investigated the association of the carotid IMT to the incidence of coronary heart disease (and stroke in two studies) but the added value of the carotid IMT to the predictive value of the established risk factors was only quantified in the Rotterdam's study. Carotid IMT was measured only once at baseline. Different sites of the carotid artery were imaged, and different methods of measurements were used, as well as different standards or cutoff values for the threshold thickness. The results of these studies suggest that the carotid IMT is associated with the incidence of coronary heart disease events, however the Rotterdam's study suggest that the information provided by IMT measurement does not seem to have clinically important additional predictive value over that calculated using the established risk factors. In conclusion, there is evidence for an association between carotid artery IMT and risk of coronary heart disease events, but there is no evidence that measuring carotid IMT, or treating patients based on this measurement would reduce their risk of CVD. There is also insufficient evidence to support the additive value of carotid IMT markers over the global risk assessment strategies using Framingham risk stratification. Use of carotid ITM to monitor effect of treatment on CAD: Several studies evaluated the effect of statins on the progression of atherosclerosis using imaging of carotid ITM thickness as an outcome measure. In these studies, carotid IMT was used a surrogate marker for coronary atherosclerosis. The LIPID trial randomized 522 subjects to receive pravastatin 40 mg/day or placebo in addition to a low-fat diet. Total cholesterol, triglycerides, HDL, and LDL cholesterol were measured at randomization repeatedly during follow-up. Ultrasound scans of the common carotid artery were performed before randomization, and after 2- and 4-years using B-mode ultrasonography. The study showed a regression of the common carotid artery IMT following pravastatin therapy. Carotid IMT was only an intermediate marker, and the relation between the IMT and cardiovascular events was not studied. A change in carotid intima-media thickness does not necessarily indicate a change in cardiovascular risk.

Articles: The search revealed 214 articles. The majority were review articles, opinion pieces, or dealt with specific subgroups of patients. As a screening tool/ risk predictor for coronary artery disease: The search did not reveal

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any randomized controlled trial that evaluated the use of carotid IMT as a screening test for coronary artery disease. There were several prospective studies that investigated carotid IMT as a risk predictor for CHD including two large population based-studies conducted in the USA (ARIC study and CHS). The search also revealed few other studies conducted in Europe (e.g. Rotterdam study in the Netherlands, and KIHD study in Finland). ARIC study and CHS were selected for critical appraisal, as well as Rotterdam study that evaluated the benefit of adding carotid IMT measurement to traditional risk factors used to predict risk of CHD. Chambless LE, Heiss G, Folsom AR, et al. Association of coronary heart disease incidence with carotid artery wall thickness and major risk factors: The Atherosclerosis Risk in Communities (ARIC) Study, 1987-1993. *Am J Epidemiol.* 1997; 146:483-494. See Evidence Table. O'Leary DH, Polak JF, Kronmal RA, et al, for the Cardiovascular Health Study Collaborative Research Group. Carotid-artery intima and media thickness as a risk factor for myocardial infarction and stroke in older adults. *N Engl J Med.* 1999; 340:14-22. See Evidence Table. Iglesias del Sol A, Moons KGM, Hollander M, et al. Is Carotid Intima-media thickness useful in cardiovascular diseases risk assessment. The Rotterdam Study. *Stroke* 2001; 32:1532-1538. See Evidence Table As a monitoring tool measure efficacy of a therapeutic intervention: The search revealed several earlier studies conducted in the 1990s to examine the effect of statins and lipid modifying therapy on the progression of atherosclerosis, using changes in the carotid IMT, measured by B-mode Ultrasonography, as their surrogate outcome. Among these studies were ACAPS, BCAPS, KAPS, LIPID, REGRESS, PLAC II as well as others. These studies did not have clinical outcomes, only the intermediate endpoint of carotid IMT. The LIPID trial with a large population size and long follow-up period of 4 years was selected for critical appraisal. MacMahon S, Sharpe N, Gamble G, et al. Effects of lowering average or below-average cholesterol levels on the progression of carotid atherosclerosis. Results of the LIPID atherosclerosis substudy. Circulation. 1998; 97:1784-1790. See Evidence Table. As a diagnostic tool for coronary artery disease: The search revealed at least six studies that investigated the potential use of carotid intima media thickness in the diagnosis of coronary artery disease. In these studies, results of carotid ultrasonography were compared to those of coronary angiography, and/ or exercise tests, or SPECT among symptomatic patients with a suspected CAD. None of these studies was critically appraised as it not the purpose of this review to evaluate the technology as a diagnostic test.

The use of carotid IMT in the evaluation of risk for CVD or to monitor the treatment effect on CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
04/04/2005	04/04/2005, 04/12/2005 MDCRPC, Initiated annual review because of Medicare criteria on 05/03/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.

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05/04/2021	Updated applicable codes – removed deleted code 0126T

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cell-Free Fetal DNA Analysis

- Panorama
- MaterniT21™
- Harmony™
- Verifi™
- QNatal Advanced

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Criteria

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage)

Prevention and Invitae Corporation is the preferred lab for genetic testing when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae.*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions

For the genetic test(s) listed below, please use the lab specified:

- ***Cell Free Fetal DNA testing* –Any of these three labs can be used:**
  - *Ariosa Diagnostics, Inc. (81507)*
  - *Invitae (81420)*
  - *LabCorp (81420)*

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Molecular Diagnostic Tests (L36256)
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente will cover cell-free fetal DNA testing for trisomies without clinical review for pregnant women regardless of age when performed at Ariosa Diagnostics (CPT code 81507) or at Invitae (CPT code 81420) or at Labcorp (CPT code 81420).

Prior Authorization will still be required for Non-Invasive Prenatal Testing (NIPT) at any other lab in advance of submitting a claim for payment. For patients who are tested for trisomies using cell-free fetal DNA, the sequential

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screen and nuchal translucency (NT) ultrasound (76813/76814) should no longer be routinely ordered without clinical indication.

The only codes that Kaiser Permanente will pay for Cell-Free Fetal DNA Analysis for Trisomies are 81420 and 81507.

Considered not medically necessary:

Test Name	Criteria Used	Codes
Cell-Free Fetal DNA - Microdeletion Syndromes	A-0848: This service is not covered per MCG guidelines	CPT – 81331 *not medically necessary when performed using cell-free fetal DNA*, 81422
Cell-Free Fetal DNA - Monogenic Disorders	A-0849: This service is not covered per MCG guidelines	CPT – 81479
Cell-Free Fetal DNA - Sex Chromosome Disorders	A-0850: This service is not covered per MCG guidelines.	CPT – 81479

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

***MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

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Background

Fetal chromosomal abnormalities occur in approximately 1 in 160 live births. Most fetal chromosomal abnormalities are aneuploidies, defined as an abnormal number of chromosomes. The trisomy syndromes are aneuploidies involving 3 copies of 1 chromosome. The most important risk factor for trisomy syndromes is maternal age. The approximate risk of a trisomy 21 (T21; Down syndrome) –affected birth is 1 in 1100 at age 25 to 29. The risk of a fetus with T21 (at 16 weeks of gestation) is about 1 in 250 at age 35 and 1 in 75 at age 40.1

T21 is the most common chromosomal aneuploidy and provides the impetus for current maternal serum screening programs. Other trisomy syndromes include T18 (Edwards syndrome) and T13 (Patau syndrome), which are the next most common forms of fetal aneuploidy, although the percentage of cases surviving to birth is low and survival beyond birth is limited. The prevalence of these other aneuploidies is much lower than the prevalence of T21 and identifying them is not currently the main intent of prenatal screening programs. Also, the clinical implications of identifying T18 and 1T3 are unclear because survival beyond birth is limited for both conditions.

Standard aneuploidy screening involves combinations of maternal serum markers and fetal ultrasound done at various stages of pregnancy. The detection rate for various combinations of noninvasive testing ranges from 60% to 96% when the false-positive rate is set at 5%. When tests indicate a high risk of a trisomy syndrome, direct karyotyping of fetal tissue obtained by amniocentesis or chorionic villous sampling (CVS) is required to confirm that T21 or another trisomy is present. Both amniocentesis and CVS are invasive procedures and have an associated risk of miscarriage. A new screening strategy that reduces unnecessary amniocentesis and CVS procedures and increases detection of T21, T18, and T13 could improve outcomes. Confirmation of positive noninvasive screening tests with amniocentesis or CVS is recommended; with more accurate tests, fewer women would receive positive screening results.

Commercial, noninvasive, sequencing-based testing of maternal serum for fetal trisomy syndromes is now available. The test technology involves detection of cell-free fetal DNA fragments present in the plasma of pregnant women. As early as 8 to 10 weeks of gestation, these fetal DNA fragments comprise 6% to 10% or more of the total cell-free fetal DNA in a maternal plasma sample. The tests are unable to provide a result if the fetal

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fraction is too low (ie, <4%). Fetal fraction can be affected by maternal and fetal characteristics. For example, fetal fraction was found to be lower at higher maternal weights and higher with increasing fetal crown-rump length.

Medical Technology Assessment Committee (MTAC)

MaterniT21

08/20/2012: MTAC REVIEW

Evidence Conclusion: Kaiser identified two observational studies that evaluated MaterniT21. The first study was a case-control study that evaluated 212 samples with by trisomy 21 matched with 1,483 euploid samples, 62 samples with trisomy 18 matched with 183 euploid samples, and 12 samples with trisomy 13 matched with 36 euploid samples. All of the samples were taken from women at high-risk for fetal aneuploidy. Before adjustment the test had a sensitivity of 98.6% and a false positive rate of 0.2% for detecting trisomy 21. After adjusting for guanine cytosine content and removing repetitive regions, the test had a sensitivity of 99.1% and a false positive rate of 0.1% for diagnosing trisomy 21. After adjustment for guanine cytosine content the test had a sensitivity of 100% and a false positive rate of 0.3% for diagnosing trisomy 18, and a sensitivity of 91.7% and a false positive rate of 0.9% for diagnosing trisomy 13 (Palomaki 2011, Palomaki 2012). The second study was a cohort study that included 480 samples from women at high-risk for fetal aneuploidy. Results from this study suggest that before adjusting for guanine cytosine content and removing repetitive regions this test has a sensitivity of 100% and a false positive rate of 0.2% (Ehrich 2011). Based on this evidence Kaiser concluded that despite a promising diagnostic performance, MaterniT21 suffers from an extremely sparse, vendor-involved body of evidence specific to a high-risk population, and lacks studies examining the prospective impact of MaterniT21 on patients' decisions of whether to purse chorionic villus sampling or amniocentesis (Kaiser 2012). *Conclusion*: Kaiser concluded that there is insufficient evidence to determine whether the MaterniT21 prenatal test to detect Down syndrome is medically appropriate for any patient.

Articles: In March 2012, Kaiser review MaterniT21 for the detection of trisomy 21. No additional studies were identified since the Kaiser review. The following technology assessment was selected for review: Kaiser Permanente. Sequenom's MaterniT21 prenatal test to detect Down syndrome. March 2012. http://cl.kp.org/pkc/national/cpg/intc/materials/MaterniT21toDetectTrisomy21(G121107).pdf.

The use of MaterniT21 does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
81420	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

Considered Not Medically Necessary when performed using cell-free fetal DNA:

CPT® Codes	Description
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
81403	Molecular Pathology Procedure Level 4
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81479	Unlisted molecular pathology procedure

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Date Created	Date Reviewed	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012[MDCRPC], 02/05/2013[MDCRPC], 1, 03/01/2022[MPC] 2/03/2013[MPC], 01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC],03/07/2023[MPC]	10/07/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34101
07/05/2016	Adopted GHC-0724
04/08/2020	Added temporary change for code 81507 due to COVID-19 pandemic
06/02/2020	Extended temporary change until September 15, 2020 for code 81507 due to COVID-19 pandemic
08/04/2020	Extended temporary change until November 1, 2020 for code 81507 due to COVID-19 pandemic
12/07/2020	Extended temporary change until February 15, 2021 for code 81507 due to COVID-19 pandemic
03/08/2021	Extended temporary change until May 15, 2021 for code 81507 due to COVID-19 pandemic
05/04/2021	Extended temporary change until June 15, 2021 for code 81507 due to COVID-19 pandemic
06/01/2021	Extended temporary change until August 15, 2021 for code 81507 due to COVID-19 pandemic
08/03/2021	MPC approved to permanently eliminate age restrictions on cell-free fetal DNA (NIPT) testing for trisomies for commercial members (81507 and 81420). Prior authorization is still required for this testing at labs other than Ariosa. Requires 60-day notice, effective date January 1, 2022. Extended temporary change until December 31, 2021 for code 81507 due to COVID-19 pandemic.
03/01/2022	Updated applicable codes.
08/16/2022	MCG* A-0847 was removed from the 26th edition; removed from criteria
10/7/2022	Added labcorp as preferred vendor for Cell Free Fetal DNA testing. Noted Prevention as preferred lab for genetic testing.

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Clinical Review Criteria
Ceramic on Ceramic Hip Replacement Systems

- Ceramic TRANSCEND® Articulation Hip System

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Criteria

For Medicare Members

This service is covered, and no medical necessity review required.

For Non-Medicare Members

This service is not recommended for coverage, as the evidence indicates that squeaking with movement is a common side effect, resulting in frequent requests for replacement and insufficient evidence of efficacy.

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Background

Total hip replacement (THR) is a widely performed procedure to relieve pain and restore joint function in patients with osteoarthritis or injury. In THR, the femoral head is replaced with a synthetic ball fixed through a stem to the femur. The ball fits into a synthetic acetabular cup fixed in the pelvis. Several artificial cup-femoral head material combinations are currently in use. Soft-on-hard combinations consist of a cup made of ultra-high molecular weight polyethylene and head made of stainless steel, cobalt-chromium (Co-Cr) alloy or alumina. There are also hard-on-hard combinations where both the cup and the head are made of Co-Cr (metal-on-metal, MOM) or alumina (ceramic-on-ceramic, COC).

The initial metal-on-metal designs of the 1960s had high premature failure rates compared with metal-on-polyethylene devices. However, the metal-on-polyethylene devices have been associated with polyethylene wear debris, leading to osteolysis and aseptic loosening. Second-generation metal-on-metal implants, believed to have lower wear rates, were introduced in the 1990s. Still, the newer MOM implants may generate metallic debris, and there is concern about the long-term effects of these metallic particles (Figueiredo-Pina et al., 2008; Keurentjes et al., 2008). Advantages of ceramic-on-ceramic implants are durability and biocompatibility. First generation COC implants, however, had relatively high fracture rates. The ceramic material has undergone modifications, and a third-generation ceramic, released in the mid-1990s, is believed to have better wear properties. This has reduced, though not eliminated, the risk of fracture. Potential remaining disadvantages of ceramic-on-ceramic systems include cup migration and osteolysis (Lusty et al., 2007; Takata et al. 2007; Zhou et al., 2006). One documented problem with ceramic-on-ceramic bearings is a squeaking sound during walking or other movement. The cause of squeaking remains unknown; possible sources include suboptimal anteversion and inclination of the cup, focally increased surface roughness, and lack of lubrication fluid between the articulating surfaces (Keurentjes et al., 2008). Squeaking problems have led to some revision surgeries to replace the hip systems (FDA website).

Medical Technology Assessment Committee (MTAC)

Ceramic TRANSCEND® Articulation Hip System

10/08/2003: MTAC REVIEW

Evidence Conclusion: There was only one published empirical study on the Ceramic TRANSCEND® Articulation Hip System, a case series with 333 patients (Garino). This study provides insufficient evidence to

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make conclusions about the effect of the TRANSCEND® system on health outcomes. As a case series, it is subject to selection bias and there was no comparison or control group. The authors found an improvement in the mean Harris hip score and short form-12, but details of the data analysis were not provided. There were 4 ceramic-related complications requiring intraoperative revision and 4 patients received revision surgery; there were no ceramic fractures. There is also insufficient evidence to make conclusions about the effectiveness of two similar ceramic hip systems made by Howmedica Osteonics, which D'Antonio compared to a cobalt-chrome-on-polyethylene hip system in an RCT. D'Antonio did not present statistical comparisons among groups, but scores on the outcome variables appear to be similar (e.g. patients in all three treatment groups had Harris hip scores in the "excellent" range at follow-up). The study may have been underpowered to detect clinically meaningful differences and there were other threats to validity. No ceramic fractures were reported during a mean of 35 months' follow-up; there was a 2-3% rate of intraoperative insert chips.
Articles: The search yielded 170 articles. Many of the articles were reviews, opinion pieces, non-clinical studies or evaluated other, similar technologies. Preliminary findings from the key clinical study (case series) resulting in FDA approval was published in 2000 and this study was critically appraised. No published randomized or non-randomized controlled trials on the TRANSCEND® system were identified. There was one RCT on a similar ceramic-on-ceramic system manufactured by Howmedica Osteonics. The case series and RCT were critically appraised: Garino JP. Modern ceramic-on-ceramic total hip systems in the United States: Early results. *Clinical Orthopedics and Related Research* 2000; 379: 41-47. See Evidence Table.

The use of ceramic on ceramic hips in total hip replacement surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/06/2008 MTAC REVIEW
Ceramic TRANSCEND® Articulation Hip System
Evidence Conclusion*:* There are RCTs published since 2003 comparing ceramic-on-ceramic hip implants to metal-on-metal or metal-on-polyethylene systems. Two had a safety/durability measure as their primary outcomes. Zhou et al., 2006 did not find a significant difference in cup migration with a ceramic-on-ceramic vs. a metal-on-polyethylene implant system. In the Grubl et al. (2006) study, serum levels of aluminum and cobalt, the primary outcomes, did not appear to differ with a ceramic-on-ceramic versus a metal-on-metal implant, although p-values were not reported. The third study (D'Antonio et al., 2005) did not list its primary outcome measure. The D'Antonio study, conducted by the team with substantial financial links to Stryker, found a significantly lower rate of revision in the group receiving ceramic-on-ceramic implants compared to metal-on-polyethylene systems after a mean follow-up of 5 years. However, the absolute difference in revision rate was small (8% vs. 6%). All of the studies reported pain and functioning as secondary outcomes, so these were likely underpowered. None found significantly better pain or patient functioning with the ceramic systems, as measured by the Harris Hip Score and/or SF-36. One of the case series reviewed focused on fracture (Koo et al., 2008) and found 5 ceramic head fractures out of 367 hip implants (1.4%) after a mean of 23 months. In the Murphy et al. (2006) series, there were 3 implant-related complications in 174 hips (1.7%) after a mean of 4 years. Both of these series found statistically significant improvement in patient functioning after the THA compared to baseline, but there was no comparison group that received a different type of implant. Two studies (case series and case-control) were identified that specifically investigated the issue of noise or squeaking associated with ceramic hip implants. The study funded by Stryker found a lower rate of squeaking than the study without industry funding (28/999, 2.8% versus 9/42, 21%). The study finding the higher rate required objective verification of the squeaking noise. In conclusion, there is insufficient evidence on the safety and efficacy of ceramic hip implant systems compared to other types of systems. Studies tended to be small, assess different safety variables, and be underpowered to measure differences in pain and function. The prevalence of squeaking differed across studies (3-28%) and needs additional investigation. Although this is largely a nuisance side effect, it is a reason for revision surgeries. The evidence base is limited by relatively small sample sizes. The largest studies have been conducted by investigators associated with Stryker, which may lead to bias.
Articles: Three randomized controlled trials evaluating ceramic-on-ceramic hip implants were identified and critically appraised. All had at least some industry funding, but the research group led by James D'Antonio, which published the largest RCT, has substantial financial links with the implant manufacturer. Several authors are paid consultants to Stryker. The two other RCTs were smaller and focused on potential adverse effects associated with ceramic implants. Several case series were also identified. Two series with larger sample sizes, no reporting of industry funding and using FDA-approved ceramic implants were critically appraised (Koo et al., 2008; Murphy et al. 2006). In addition, the findings of the two series that specifically addressed squeaking are included (Keurentjes et al., 2008; Restrepo et al., 2006). *References for the studies critically appraised are as follows*:
RCTs D'Antonio J, Capello W, Manley M et al. Alumina ceramic bearings for total hip arthroplasty. Clin Orthop Rel Res 2005; 436: 164-171. See Evidence Table. Grubl A, Weissinger M, Brodner W et al. Serum aluminum and cobalt levels after ceramic-on-ceramic and metal-on-metal total hip replacement. J Bone Joint Surg (Br); 2006;

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88-B: 1003-1005. See Evidence Table. Zhou Z, Li MG, Borlin N et al. No increased migration in cups with ceramic-on-ceramic bearing. Clin Orthop Rel Res 2006; 448: 39-45. See Evidence Table.

The use of ceramic on ceramic hips in total hip replacement surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare - Medical necessity review not required
Commercial - Considered not medically necessary

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/08/2003	10/08/2003[MDCRPC], 10/06/2008[MDCRPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	07/07/2015

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Chronic Cerebrospinal Venous Insufficiency Treatment

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **Chronic Cerebrospinal Venous Insufficiency Treatment**, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Multiple sclerosis is an autoimmune inflammatory disease of the central nervous system that affects approximately 250,000 to 500,000 people in the United States. Although the cause of multiple sclerosis is unknown, evidence suggests it may be caused by the interplay of genetic and environmental factors. However, it has recently been hypothesized that a phenomenon known as chronic cerebrospinal venous insufficiency (CCSVI) may also play a role in the etiology, pathogenesis, and/or disease progression of multiple sclerosis. This theory suggests that abnormal drainage of venous blood due to stenosis or malformation of the internal jugular and/or azygous veins may be a cause of multiple sclerosis (Ghezzi 2011, Khan 2010, Vedantham 2010).

The evidence pertaining to the association between CCSVI and multiple sclerosis is inconsistent. Depending on the study, the frequency of CCSVI in patients with multiple sclerosis ranged from 0 to 100%. The frequency of CCSVI in controls ranged from 0 to 23%. Different methods of assessing CCSVI may explain some of the variability among these studies. Doppler sonography, venous MRI, and venous angiography have all been used to assess CCSVI; however, it is not clear which is the gold standard (Ghezzi 2011). Additionally, it is not clear if CCSVI is a cause of multiple sclerosis, an effect of multiple sclerosis, or an unrelated finding (Singh 2009, Vedantham 2010). Based on the CCSVI hypothesis balloon angioplasty has been proposed as a treatment for multiple sclerosis patients with CCSVI.

Medical Technology Assessment Committee (MTAC)

Chronic Cerebrospinal Venous Insufficiency Treatment

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06/10/2011: MTAC REVIEW

Evidence Conclusion: A recent open-label, prospective case-series evaluated the safety of CCSVI endovascular treatment and its influence on clinical outcomes in 65 consecutive patients with multiple sclerosis. No operative or postoperative complications were recorded. After the endovascular treatment, disease severity significantly improved for patients with relapse remitting multiple sclerosis, but not for patients with primary progressive or secondary progressive multiple sclerosis. In patients with relapse remitting multiple sclerosis, significantly more patients were relapse free during the 18 months posttreatment compared to the year proceeding endovascular treatment; however, there was no significant difference in annualized relapse rate. Quality of life improved significantly for subjects with relapse remitting and primary progressive multiple sclerosis, but not for subjects with secondary progressive multiple sclerosis. Results from this study should be interpreted with caution as this is a small, open-label study with no comparison group (Zamboni 2009). Another prospective case-series evaluated the safety of endovascular treatment for CCSVI in 331 patients with multiple sclerosis. Overall, three patients experienced major complications. Two patients (1.2% of implanted stents) experienced stent thrombosis and one patient (0.3%) required surgical opening of the femoral vein to remove the angioplastic balloon. Minor complications included: local bleeding from the groin (4 patients, 1.2%), minor gastrointestinal bleeding (1 patient, 0.3%), transient cardiac arrhythmia (2 patients, 0.6%), difficulty removing the angioplastic balloon or delivery system (4 patients, 1.2%), problems with proper placement of the stent (4 patients, 2.3% of implanted stents), unsuccessful catheterization of the stenosed internal jugular vein (4 patients, 1.3%). Long-term complications were not addressed (Ludyga 2010). *Conclusion:* Currently, there is insufficient evidence to determine the safety and efficacy of balloon angioplasty for the treatment of CCSVI in patients with multiple sclerosis. In a recent position statement, the Society of Interventional Radiology also concluded that the current published literature was inconclusive on whether CCSVI is a clinically important factor in the development and/or progression of multiple sclerosis and on whether balloon angioplasty is clinically effective in patients with multiple sclerosis (Vedantham 2010).

Articles: To determine the safety and efficacy of balloon angioplasty for the treatment of multiple sclerosis patients with CCSVI. No randomized controlled trials were identified that assessed the safety or efficacy of balloon angioplasty for the treatment of multiple sclerosis patients with CCSVI. The best evidence came from an observational study. This study was selected for review. The following study was critically appraised:
Zamboni P, Galeotti R, Menegatti E, et al. A prospective open-label study of endovascular treatment of chronic cerebrospinal venous insufficiency. *J Vasc Surg 2009;* 50:1348-1358. See Evidence Table.

The use of chronic cerebrospinal venous insufficiency treatment for multiple sclerosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary for Multiple Sclerosis:

CPT® or HCPC Codes	Description
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (List separately in addition to code for primary procedure)
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein
37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein (List separately in addition to code for primary procedure)
With diagnosis code	
G35	Multiple sclerosis

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/05/2011	07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 03/05/2013[MDCRPC], 01/07/2014[MDCRPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	09/08/2015

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.

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Clinical Review Criteria

Cervical Fusion (Anterior or Posterior)

- **Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)**

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Cervical Fusion (Anterior or Posterior)" for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Effective until December 1, 2022

Procedure	Criteria
Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Effective December 1, 2022

**All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.*

NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery (unless there is evidence of cord compression, infection, malignancy or progressive neurologic deficit). For persons with recent nicotine use, documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to fusion in patients without progressive neurologic deficit or cord compression

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I. ANTERIOR CERVICAL FUSION FOR DEGENERATIVE DISEASE

Single or multilevel anterior cervical discectomy and fusion (ACDF) is considered medically necessary for treatment of symptomatic degenerative disease when **EITHER of the following** criteria are met:

A. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy** (see below), resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management *** (see below)
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
   - Herniated nucleus pulposus
   - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
   - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
   - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following**:

1. Clinical diagnosis of myelopathy*(see below)
2. Refractory to at 3 months of standard conservative physician supervised medical management *** (see below)
3. Complex imaging studies (i.e., CT, MRI, Xray, Myelogram) demonstrate structural cord compression associated with cord signal change/myelomalacia on MRI imaging
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

II. CERVICAL FUSION FOR INSTABILITY

Single or multilevel cervical fusion is considered medically necessary for **ANY of the following** indications when there is an associated spinal instability:

- Acute spinal fracture and/or dislocation
- Neural compression after spinal fracture
- Traumatic ligamentous disruption
- Epidural compression, fracture or vertebral destruction from spinal tumor or cyst
- Spinal decompression or debridement for infection (e.g., discitis, osteomyelitis, epidural abscess, TB)
- Spinal decompression for myelopathy associated with subluxation in rheumatoid arthritis
- Cervical spinal deformity associated with neurological symptoms of myelopathy* or radiculopathy** (e.g., sagittal plane angulation of more than 11 degrees between adjacent segments, subluxation of >3.5 mm)
- As an adjunct to cyst excision of synovial facet cysts in the cervical spine
- Atlantoaxial instability (e.g., atlas and axis fracture, nonunion)
- Treatment of cervical spine fracture/dislocation associated with acute cervical radiculopathy** or myelopathy*
- Multilevel spondylotic myelopathy with kyphosis, when symptoms of myelopathy are present and
- Imaging studies correlate with symptoms and demonstrates cord compression
- Cervical instability from any **ONE of the following**:

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- Klippel-Feil syndrome
- Down's syndrome
- Skeletal dysplasia or connective tissue disorder

III. CERVICAL FUSION FOR IATROGENIC INSTABILITY

Cervical fusion is considered medically necessary for anticipated intraoperative iatrogenic spinal instability of the level or levels involved resulting from **ANY of the following** surgical procedures:

- Removal of 50% or more of the facets bilaterally
- Removal of 75% or more of a single facet
- Following cervical corpectomy*, as part of a stabilization procedure

***Note:** Corpectomy is a procedure in which the at least 50% or more of the body of the vertebrae is removed.

IV. POSTERIOR CERVICAL FUSION: SPINAL STENOSIS

Posterior cervical fusion is considered medically necessary for the treatment of spinal stenosis with laminectomy when **EITHER of the following** criteria are met**:**

C. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy**(see below) resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management ***
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
   - Herniated nucleus pulposus
   - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
   - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
   - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

D. Myelopathy, must meet **ALL of the following**:

1. Clinical diagnosis of myelopathy*
2. Radiographic evidence of **ANY of the following**:
   - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
   - Sagittal plane angulation of more than 11 degrees between adjacent segments
   - Structural cord compression associated with cord signal change/myelomalacia on MRI
3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

V. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY:

Cervical fusion is considered medically necessary for treatment of symptomatic adjacent or same segment stenosis following prior cervical surgery, when **EITHER of the following** criteria have been met:

A. Radiculopathy, must meet **ALL of the following**:

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1. Clinical diagnosis of unremitting cervical radiculopathy** resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management ***
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
   - Herniated nucleus pulposus
   - Spondylosis/ foraminal stenosis due such as an osteophyte causing nerve root compression
   - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
   - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following:**

1. Clinical diagnosis of myelopathy*
2. Radiographic evidence of **ANY of the following**:
   - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
   - Sagittal plane angulation of more than 11 degrees between adjacent segments
   - Structural cord compression associated with cord signal change/myelomalacia on MRI
3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

VI. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY: PSEUDOARTHROSIS

Cervical fusion is considered medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) of the cervical spine at the same level(s) when it has been at least 12 months from the prior surgery and **ALL of the following criteria** are met:

- Mechanical neck pain that correlates to the level of the pseudoarthrosis
- Imaging studies (e.g., radiographs, CT) confirm evidence of a pseudoarthrosis (e.g., lack of bridging bone, dynamic motion on flexion-extension radiographs)
- Failure of three (3) consecutive months of physician-supervised conservative*** management which includes exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy **AND**
- Activity lifestyle modification

VII. CERVICAL FUSION NOT MEDICALLY NECESSARY

Cervical fusion is considered not medically necessary for the following indications:

- anterior or posterior cervical fusion for chronic axial neck pain
- posterior cervical fusion performed with laminectomy in the absence of kyphosis (e.g., degenerative spine) or subluxation/translation of more than 3.5 mm

Isolated cervical facet fusion, with or without instrumentation, including facet joint implants and/or bone graft substitutes used exclusively as a stand-alone stabilization device is considered experimental, investigational or unproven.

***Cervical Myelopathy:** signs suggestive of *spinal cord* involvement:

- Upper limb weakness in more than a single nerve root distribution

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- Lower limb weakness
- Loss of dexterity (e.g., clumsiness of hands)
- Bowel or bladder incontinence
- Frequent falls
- Hyperreflexia
- Hoffmann sign (overreaction to flick of the fingernail)
- Increased extremity muscle tone or spasticity
- Spastic Gait/ataxic Gait
- Positive Babinski

** **Radicular pain/suspected radiculopathy** defined as:

- Pain in a *nerve root* distribution (e.g., C6, C7)
- Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) *OR*
- EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

***Physician-supervised conservative medical management** defined as: Patients must have three months of non-operative treatment as demonstrated by a trial of **one or more of the following** medications:

- Non-steroidal anti-inflammatory drugs (oral or topical)
- Acetaminophen
- Epidural steroid injection of corticosteroids as appropriate

AND

- A trial of **All** of the following physical measures:

Effective until March 1, 2023

- Supervised Physical therapy, attendance at >75% of sessions
  - At least half of PT must be in person (not virtual)

Effective March 1, 2023

- Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits

- Flexibility and muscle strengthening exercises
- Reasonable restriction of activities
- If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present

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Procedure	Criteria
Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Neck pain occurs in many people and typically involves more than one component of the spine, such as the vertebrae, intervertebral discs, spinal nerves, other anatomic structures such as ligaments, muscles, and joints. Conditions that frequently result in neck pain include soft tissue injury, trauma, infection, herniated disc, degenerative spine conditions, neoplastic conditions, and deformities such as kyphosis. While the cause of neck pain is often multifactorial (e.g., originating from the vertebrae, discs, ligaments, tendons and muscles) the location of pain varies. Axial neck pain occurs along the spine, is of musculoskeletal or soft tissue origin, and is a non-radiating type of pain. The most common cause of axial neck pain is degenerative change to the cervical spine, which occurs as a natural consequence of aging. Radicular pain involves a nerve root, is due to nerve root compression, follows the nerve root distribution, and radiates to one or both upper extremities, and/or into the shoulder area. Radicular pain can include varying degrees of sensory, motor, and/or reflex changes related to nerve root(s) without evidence of myelopathy (North American Spine Society, [NASS], 2013). Myelopathy is a term that describes any neurological deficit related to the spinal cord and is often used to describe loss of function in the upper or lower extremities (NASS, 2013). Depending on the cause of neck pain associated symptoms may include numbness, tingling, weakness, and other types of neurologic dysfunction in the presence of spinal cord compression. Conservative measures for treatment of neck pain include analgesics, muscle relaxants, local injections, physical therapy, cervical bracing and home exercise. Conservative treatment is often effective for alleviating symptoms and typically lasts six to eight weeks. However, conservative therapy is not recommended in the presence of progressive neurological deficits, in the presence of unstable spinal fractures or dislocations, or for progressive spinal deformity. In the absence of progressive neurologic compromise, or when conservative management has been attempted and fails to relieve pain and disability, surgery may be required for conditions with underlying pathology confirmed by physical examination and radiological imaging. When spinal cord compression is present surgical methods to relieve the pressure on the nerves is often necessary and is referred to as decompression surgery. Decompression typically includes surgical procedures such as discectomy (removal of the disc), laminectomy (removal of the lamina), corpectomy (removal of the vertebral body), or osteotomy (removal of a piece of bone). When performed, these procedures may result in spinal instability. As such, decompression is often performed as part of cervical fusion in order to regain stability of the spine. For example, anterior cervical fusion is usually performed with decompression. Posterior cervical fusion is typically performed with stabilization (using rods, screws) although may be performed with decompression in some instances (NASS, 2014). Instability of the cervical spine can also result from trauma and/or disease, or a combination of all (White, Panjabi, 1980), which may or may not require a decompression. Instability of the cervical spine has been defined by White, Panjabi (1980) and is well-accepted in the medical literature as sagittal plane translation of >3.5 mm, and/or rotation between motion segments of 11˚, in addition to other notable factors such as destruction of elements or inability to function, a positive stretch test, spinal cord or nerve root damage, and abnormal disc narrowing (White, Panjabi, 1980). In the absence of instability, evidence in the published peer-reviewed scientific literature does not provide strong support that when used for this indication cervical fusion is clinically effective for reducing pain and disability. 2011; Persson, et al., 1997). Psychological assessment and treatment as part of a multidisciplinary approach to conservative pain management is recommended. Risk factors, such as drug or

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alcohol abuse and depression may act as a barrier to recovery following spinal fusion (Washington State Department of Labor and Industries, 2002; Hanley, David, 1999; Tang, et al., 2001). Authors have recommended psychological screening, and treatment if applicable, of patients with neck and/or back pain prior to surgery for identification of risk factors that may be associated with chronic disability. Cervical spinal fusion is in many situations an elective surgery, therefore it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. Modifiable risk factors and the influence on outcomes of spine surgery has been studied, modification of such risk factors can assist with improved patient selection for spine surgery and better postoperative management (Shahrestani, et al., 2021). Along with alcohol and opioid use, tobacco/nicotine increases the risk of perioperative complications, cardiopulmonary complications, pseudoarthrosis and infection (Shahrestani, et al., 2021) furthermore it is well-established that smoking is a preventable cause of morbidity and mortality. Tobacco use in particular is considered a risk factor for poor healing and has been associated with nonunion. Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudoarthrosis (Brown, et al., 1986). The American Academy of Orthopedic Surgeons (AAOS) supports avoidance and cessation of all tobacco products and cigarette smoking due to the harmful impact on musculoskeletal health, as well as overall health (AAOS, 2016).

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Cervical Fusion: Anterior

CPT® or HCPCS Codes	Description
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments

Cervical Fusion: Posterior

CPT® or HCPCS Codes	Description
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
22600	Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional vertebral segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments

Considered Experimental, Investigational or Unproven when used to report isolated cervical facet fusion, including facet joint implants and/or bone graft substitutes used exclusively as stand-alone stabilization devices for treatment of facet joint pain:

CPT® or HCPCS Codes	Description
22899	Unlisted procedure, spine

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0219T	**Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical**
0222T	**Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure**

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Date Created	Date Reviewed	Date Last Revised
07/05/2022	07/05/2022[MPC],	10/04/2022

[MPC] Medical Policy Committee

Revision History	Description
10/04/2022	MPC approved to include quantifying number of 3 visits for conservative treatment. 60-day notice required.

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Clinical Review Criteria
Chelation Therapy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Edetate (EDTA) Chelation (KP-0297) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Chelation is a process to remove certain heavy metals from the blood. In this treatment, a chemical solution is injected into the bloodstream or taken by mouth. Molecules then bind to heavy metals and/or minerals. The heavy metals are then cleared out of the body through urination. Chelation therapy has been studied and approved by the Food and Drug administration to treat certain conditions. This includes removing dangerously high levels of iron, as well as lead or mercury. Thinking that the process of chelation could also remove the buildup of some other substances in the body, some doctors have tried to use it to try to treat other conditions. Examples of these other conditions include Alzheimer disease, autism, diabetes, and plaque inside of arteries (atherosclerosis). Scientific research has not proven that using chelation therapy treatment for these or other conditions is effective. For this reason, chelation therapy for many conditions is considered investigational (unproven).

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
M0300	IV chelation therapy (chemical endarterectomy)
J3520	Edetate disodium, per 150 mg
J0600	Injection, edetate calcium disodium, up to 1,000 mg

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
02/04/2020	02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC]	05/05/2020

[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	Updated MCG guideline name

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Chemical Dependency – Inpatient Detox

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Inpatient Hospital Stays for Treatment of Alcoholism (130.1) Outpatient Hospital Services for Treatment of Alcoholism (130.2) Chemical Aversion Therapy for Treatment of Alcoholism (130.3) Electrical Aversion Therapy for Treatment of Alcoholism (130.4) Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5) Treatment of Drug Abuse (Chemical Dependency) (130.6) Withdrawal Treatments for Narcotic Addictions (130.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare members

Kaiser Permanente has elected to use the following MCG* guidelines for medical necessity determinations:

- Substance-Related Disorder, Inpatient Behavioral Health Level of Care, Adult (B-903-IP)
- Substance-Related Disorder, Inpatient Behavioral Health Level of Care, Child/Adolescent (B-907-IP)
  For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Medical Necessity Criteria for Coverage of Admission:

An Inpatient Hospital Stay for Substance Detoxification is medically necessary when **ALL** of the following have been met:

1) MCG* Admission Guidelines are met.
2) There is a reasonable expectation that the member's illness, condition, or level of functioning will improve as a result of the treatment plan or that stabilization is possible.
3) Services must be provided in a state-licensed facility for the proposed level of care.

Medical Necessity Criteria for Coverage of Continued Stay:

Continued Inpatient Hospital Stay for Substance Detoxification is medically necessary when **ALL** of the following have been met:

1) Continued inpatient substance abuse treatment is medically necessary based on MCG Ongoing Care Guidelines and Discharge Criteria.
2) All the criteria for coverage of an admission continue to be met as well as both of the following:
   a) The patient cannot be treated safely at an alternative level of care, and
   b) There is a reasonable expectation that the member's illness, condition, or level of functioning will improve as a result of the treatment plan or that stabilization is possible.

Exclusions

Inpatient detoxification services will not be authorized or reimbursed if any contract exclusion criteria are met.

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If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria the MCG for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Inpatient detoxification services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms of substance withdrawal, in order that treatment can be continued effectively in a less restrictive and disruptive level of care.

Inpatient detoxification treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG for inpatient substance abuse, dependence and withdrawal care. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental/guardian figure involved.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
08/23/2010	05/01/2012[MPC], 03/05/2013[MDCRPC], 03/04/2014[MPC], 01/06/2015[MPC], 11/03/2015[MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC]	07/11/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
01/05/2016	MPC approved to adopt 19th ed. MCG guidelines
07/11/2017	MPC approved to adopt 21st ed. MCG guidelines

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Substance Use Disorder Treatment –
Office-Based Opioid Agonist Treatment for Opioid Use Disorder

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Criteria

For Medicare members

Source	Policy
CMS Coverage Manuals	Medicare Prescription Drug Benefit Manual – Chapter 6 – Part D Drugs and Formulary Requirements: Section 10.8 Drugs Used to Treat Opioid Dependence
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare members

I. **ALL of the following** met in order to qualify for admission to a provider for office-based treatment (e.g. buprenorphine/naloxone (Suboxone), buprenorphine (Subutex, Sublocade, Probuphine), and naltrexone (Vivitrol)):
   1. The primary use for the office-based opioid management is for treatment of the patient's Opioid Use Disorder (e.g. not as primary treatment of the patient's pain disorder).
   2. The patient is assessed to be an appropriate candidate for office-based medication maintenance therapy.

Continued Stay Criteria:
In addition to meeting criteria for admission into office-based opioid use disorder medication treatment, **ALL of the following** must be met in order to meet criteria for continued stay in office-based opioid use disorder medication treatment:
1. Patient is adhering to their treatment plan, as determined by the physician.
2. Treatment is primarily for Opioid Use Disorder

Discharge Criteria:
The patient meets discharge criteria when meeting **One or more of the following**:
1. Patient is failing office-based opioid use disorder medication treatment provider treatment requirements, as defined by the individual provider.
2. Patient voluntarily discontinues office-based opioid use disorder medication treatment.

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Background

In 2007, Kaiser Permanente Pharmacy and Therapeutics Committee approved the use of Suboxone for the maintenance treatment of opiate dependence (previously only approved for short-term opiate detoxification). In

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2008 Kaiser Permanente made the decision that Behavioral Health Services would manage the referral pathway for Suboxone treatment which is largely provided in an external delivery system.

As with other addiction pharmacotherapy interventions, it is recommended that Suboxone medication be prescribed as an adjunct to chemical dependency treatment for optimal treatment outcomes. Physicians prescribing Suboxone will determine if chemical dependency treatment (by a licensed WA State Chemical Dependency Treatment Program or independent provider with chemical dependency expertise) is required based upon their clinical/medical assessment and the patients progress while on Suboxone.

Evidence and Source Documents

References:

The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions, Third Edition (2013). Copies of the criteria can be obtained at www.asam.org.
Revised Code of Washington (RCW) 41.05.528

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Dates	Date Last Revised
07/18/2008	09/08/2008[MDCRPC], 08/10/2009[MDCRPC], 07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC] ,01/08/2013[MDCRPC], 11/05/2013[MPC] ,12/03/2013[MPC],10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	01/07/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/04/2017	Updated criteria
01/08/2019	Modified criteria to define “treating prescriber” and eliminated the indication that prohibited members from receiving treatment if administratively discharged or voluntarily discontinued engagement in methadone treatment program.
01/07/2020	MPC approved the minor changes made to criteria to eliminate levels of severity

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Clinical Review Criteria
Substance Use Disorder – Residential Admission & Concurrent Stay

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Inpatient Hospital Stays for Treatment of Alcoholism (130.1) or Outpatient Hospital Services for Treatment of Alcoholism (130.2) Chemical Aversion Therapy for Treatment of Alcoholism (130.3) Electrical Aversion Therapy for Treatment of Alcoholism (130.4) Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5) Treatment of Drug Abuse (Chemical Dependency) (130.6) Withdrawal Treatments for Narcotic Addictions (130.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
American Society of Addiction Medicine (ASAM)	Kaiser Permanente uses ASAM criteria as a supplement to the above NCDs or LCDs for medical necessity review of residential, inpatient, and detoxification treatment for Medicare members.

For Non-Medicare Members

Kaiser Permanente uses criteria from the American Society of Addiction Medicine (ASAM) to review for residential, inpatient, and detoxification services for adults and adolescents. ASAM criteria were created to improve access to and quality of care in the treatment of substance use disorders. These criteria match individual patients with the appropriate services to help patients succeed in their recovery. This policy describes which types of substance use disorder treatment may be considered medically necessary when using ASAM criteria.

The following services may be considered medically necessary when criteria are met using ASAM® Criteria:

- Residential/Inpatient Services

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***The ASAM criteria are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our Behavioral Health department, you may request a copy of the criteria that is being used to make the coverage determination. Call the Behavioral Health Unit for more information regarding the case under review.

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Background

The purpose of the behavioral health medical necessity criteria is to provide a guide to coverage. Behavioral health policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their clinical judgment in providing the most appropriate care. To qualify for the chemical dependency benefit, members must have a DSM-IV diagnosis of substance dependence that is the primary reason for placement at the residential level of care.

Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Adult Residential Treatment

Substance use disorders are chronic medical problems associated with changes in the nervous system that require months of abstinence for recovery. Clinically, these diseases require long-term engagement in care to have the best outcomes for patients. Outcomes research over the past 27 years consistently finds that longer treatment duration leads to improved outcomes. This has led the Department of Veterans Affairs to set performance measures for substance use disorders treatment to continuing treatment for 90 days or more.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH) considers outpatient treatment to be the most promising course for those that are chemically dependent and, thus, the preferred care strategy. However, residential care does have a role in the continuum of treatment for patients with addictive diseases. When severe addictive disease and other co-morbidities are present, we believe it is important to provide residential care as a covered benefit for those patients who may need more intensive treatment. It should allow them to better engage in and benefit eventually from continued outpatient treatment, which is central to their recovery. As with other chronic health conditions, relapse is expected. Therefore, effective care plans include relapse prevention strategies as well as actions to take in the event of a relapse. Relapse does not constitute a need for residential treatment; rather, it supports the need for engagement or re-engagement in outpatient care and other support activities.

Current data reflects that 50% – 75% of patients with substance use disorders seeking treatment have co-occurring mental health conditions. Patients with co-occurring conditions are more likely to benefit from residential care. Effective treatment should optimally address both disorders via an integrated care plan. The care plan will help guide treatment in residential care and will inform transition and discharge planning related to follow-up needs.

Medical evaluation is often an important component of care. In addition to general medical conditions, attention needs to be given to assessing the patient's need for detoxification. Medical assessment ideally includes evaluation of the patient's eligibility for medications to assist with the medical management of cravings and/or opiate replacement treatment (if applicable).

Adolescent Residential Treatment

Residential treatment services are provided or authorized with the overall goals of assessing and stabilizing the member's severe symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Since substance use disorders are chronic disorders, treatment is optimally provided over longer periods of time. Residential treatment may serve as the level of care needed to help youths to stabilize and engage in treatment with the ultimate goal of transitioning to longer term treatment at a lower level of care.

Residential chemical dependency treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and these clinical review criteria. When treating children or adolescents under the age of 18 in a residential treatment program, the parents or guardians must consent for the treatment and be included in both the evaluation and treatment planning processes, except for youths who have been living outside of the family home and the parents are unavailable, unable, or unwilling to provide consent to treatment. Admitting a self-consenting youth is a determination made by the program to which the youth applies, based on information obtained by the program, and the program must document efforts to locate and engage the parents in the treatment process.

Medical evaluation is often an important component of care. In addition to general medical conditions, attention needs to be given to assessing the youths need for detoxification, and ideally includes evaluation of the patients

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eligibility for medications to assist with the medical management of cravings, and/or opiate replacement treatment (if applicable).

ASAM placement criteria for both adult and adolescents
Washington State requires the use of ASAM criteria by State-certified chemical dependency treatment providers, when determining placement of patients with substance use disorders (criteria includes placement recommendations related to residential treatment). Clinical recommendations must be documented in writing and must contain objective clinical information. Clinical criteria do not factor in family, employer or legal mandates or requests for treatment. Clinical criteria are intended to evaluate the impact of the substance use disorder on the affected individual (via a bio-psychosocial assessment) and to guide decision making related to care strategies.

Evidence and Source Documents

References for Adult Residential Treatment:

1) Mojtabai R, Graff Zivin J. "Effectiveness and Cost-Effectiveness of Four Treatment Modalities for Substance Disorders: A Propensity Score Analysis" Health Services Research. 38(1):233-259, 2003.
This study was a data analysis from the Services Research Outcomes Study, surveying 3,047 clients in 99 drug treatment facilities across the United States. No long-term differences in abstinence or reduced drinking between outpatient treatment and residential treatment. Outpatient treatment was the most cost-effective treatment modality.

2) Weisner C, Mertens J, Parthasarathy S, Moore C, Hunkeler EM, Hu T, Selby JV. "The Outcome and Cost of Alcohol and Drug Treatment in an HMO: Day Hospital Versus Traditional Outpatient Regimens" Health Services Research. 35(4):791-812; 2000.
This study was a randomized controlled trial of 668 adults entering drug treatment in an HMO (Kaiser) randomized to day hospital treatment or to outpatient treatment. Patients randomized to either outpatient or day hospital treatment fared equally well. Patients with mid-level psychiatric severity did fare better with the higher level of care.

3) Witbrodt J, Bond J, Kaskutas LA, Weisner C, Jaeger G, Pating D, Moore C. "Day Hospital and Residential Addiction Treatment: Randomized and Nonrandomized Managed Care Clients" Journal of Consulting and Clinical Psychology. 75(6):947-959; 2007.
This study was a randomized controlled trial of 293 adults entering substance abuse treatment in an HMO (Kaiser) randomized to day hospital treatment or to residential treatment. Despite differences in baseline severity between groups, patients randomized or non-randomized fared equally well in either treatment intensity. 12-month outcomes were most closely related to continued 12-step participation.

4) Kaskutas LA, Witbrodt J, French MT. "Outcomes and costs of day hospital treatment and nonmedical day treatment for chemical dependency." Journal of Studies on Alcohol. 65(3):371-382; 2004.
This study was a randomized controlled trial of adults entering substance abuse treatment in an HMO (Kaiser) randomized to hospital-based day treatment or to one of two community-based day treatment programs. Patients randomly assigned to either hospital-based day treatment or community-based treatment fared equally well, while costs were lower in community-based programs.

5) Guydish J, Sorensen JL, Chan M, Werdegar D, Bostrom A, Acampora A. "A Randomized Trial Comparing Day and Residential Drug Abuse Treatment: 18-Month Outcomes" Journal of Consulting and Clinical Psychology. 67(3):428-434; 1999.
This study extends similar findings from a report on 6-month outcomes from a randomized trial assigning 188 clients entering a therapeutic community to either day treatment or residential treatment. Both groups had similar improvements over time with those in residential treatment having greater improvement for psychiatric symptoms and social problems.

6) Moos RH, Moos BS. "Long-term influence of duration and intensity of treatment on previously untreated individuals with alcohol use disorders." Addiction. 98:325-337; 2003.
This study was a naturalistic study following 473 alcoholic adults over 8 years following SUD identification. Rapidly entering treatment and duration of treatment (i.e., longer duration being better) were related to better short and long-term (i.e., 3 and 8 year) alcohol-related outcomes. In general, intensity of treatment was not related to better outcomes.

7) Chen S, Barnett PG, Sempel JM, Timko C. "Outcomes and costs of matching the intensity of dual-diagnosis treatment to patients' symptom severity." Journal of Substance Abuse Treatment. 31:95-105; 2006.

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This study evaluated a patient-treatment matching strategy for dual-diagnosis patients in the VA (N=230). Patients with high severity dual disorders had better alcohol, drug and psychiatric outcomes and higher health care costs. Moderate severity patients generally had similar outcomes whether they were matched to low-intensity treatment or not.

References for Adolescent Residential Treatment:

1. Sussman S, Skara S, Ames SL. "Substance Abuse Among Adolescents". *Substance Use & Misuse.* 43:1802-1828; 2008.
2. This paper summarizes the findings in adolescent substance abuse treatment with occasional comparisons to adult substance abuse and treatment. There is little evidence to guide selection of treatment modality or setting in adolescents. There are some differences between substance use disorders in adolescents and adults, notably, adolescents typically have less motivation for abstinence than adults.
3. Hser YI, Grella C, Hubbard RL, Hsieh SC, Fletcher BW, Brown BS, Anglin MD. "An Evaluation of Drug Treatments for Adolescents in 4 US Cities." *Archives of General Psychiatry.* 58:689-695; 2001.
   This was a naturalistic study of 1167 adolescents who were treated in one of three different treatment settings and followed for one year. This study did not compare treatment settings with one another, but in general, found treatment in all settings to lead to improvements in most substance use and overall functioning domains and that length of time in treatment is associated with better outcomes.
4. Grella C, Hser YI, Joshi V, Rounds-Bryant J. "Drug Treatment Outcomes for Adolescents with Comorbid Mental and Substance Use Disorders." *Journal of Nervous and Mental Disease.* 189(6): 384-392; 2001.
   A naturalistic study of 992 adolescents treated in three different treatment settings compared those with and without comorbid psychiatric disorders. Psychiatric comorbidity was associated with greater substance use problems entering treatment, which was associated with less favorable treatment outcomes. Compared to those without comorbidity, comorbid youth were more likely to use cannabis and hallucinogens and were more likely to engage in illegal acts a year after treatment.
5. American Academy of Child Psychiatry Practice Parameters.
6. American Society of Addiction Medicine Patient Placement Criteria, 2nd Edition Revised.
7. American Society of Addiction Medicine Patient Placement Criteria, 3rd Edition.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

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Date Created	Date Reviewed	Date Last Revised
12/18/2009	03/15/2010[MDCRPC], 01/04/2011[MDCRPC], 05/03/2011[MDCRPC], 07/05/2011[MDCRPC], 08/02/2011[MDCRPC], 03/06/2012[MDCRPC],01/08/2013[MDCRPC] ,11/05/2013[MPC], 03/04/2014 [MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/26/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/11/2017	MPC approved to adopt hybrid (MCG/KP) criteria

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12/31/2020	Adopted ASAM Criteria for non-Medicare per mandated Washington state requirement, effective January 1, 2021.
05/26/2021	Adopted ASAM criteria for Medicare members. Requires 60-day notice, effective October 1, 2021.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Substance Use Disorder – Sub-Acute Detox

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Inpatient Hospital Stays for Treatment of Alcoholism (130.1) Outpatient Hospital Services for Treatment of Alcoholism (130.2) Chemical Aversion Therapy for Treatment of Alcoholism (130.3) Electrical Aversion Therapy for Treatment of Alcoholism (130.4) – Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5) Treatment of Drug Abuse (Chemical Dependency) (130.6) Withdrawal Treatments for Narcotic Addictions (130.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
American Society of Addiction Medicine (ASAM)	Kaiser Permanente uses ASAM criteria as a supplement to the above NCDs or LCDs for medical necessity review of residential, inpatient, and detoxification treatment for Medicare members.

For Non-Medicare members

Kaiser Permanente uses criteria from the American Society of Addiction Medicine (ASAM) to review for residential, inpatient, and detoxification services for adults and adolescents. ASAM criteria were created to improve access to and quality of care in the treatment of substance use disorders. These criteria match individual patients with the appropriate services to help patients succeed in their recovery. This policy describes which types of substance use disorder treatment may be considered medically necessary when using ASAM criteria.

The following services may be considered medically necessary when criteria are met using ASAM® Criteria:

- Sub-acute Detoxification

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If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

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The purpose of the behavioral health medical necessity criteria is to provide a guide to coverage. Mental health policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their clinical judgment in providing the most appropriate care. To qualify for the chemical dependency benefit, members must have a DSM-5 diagnosis of substance use disorder that is the primary reason for placement at the residential level of care.

Kaiser Permanente Mental Health and Wellness operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Adult Residential Treatment

Substance use disorders are chronic medical problems associated with changes in the nervous system that require months of abstinence for recovery. Clinically, these diseases require long-term engagement in care to have the best outcomes for patients. Outcomes research over the past 27 years consistently finds that longer treatment duration leads to improved outcomes. This has led the Department of Veterans Affairs to set performance measures for substance use disorders treatment to continuing treatment for 90 days or more.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH) considers outpatient treatment to be the most promising course for those that are chemically dependent and, thus, the preferred care strategy. However, residential care does have a role in the continuum of treatment for patients with addictive diseases. When severe addictive disease and other co-morbidities are present, we believe it is important to provide residential care as a covered benefit for those patients who may need more intensive treatment. It should allow them to better engage in and benefit eventually from continued outpatient treatment, which is central to their recovery. As with other chronic health conditions, relapse is expected. Therefore, effective care plans include relapse prevention strategies as well as actions to take in the event of a relapse. Relapse does not constitute a need for residential treatment; rather, it supports the need for engagement or re-engagement in outpatient care and other support activities.

Current data reflects that 50% – 75% of patients with substance use disorders seeking treatment have co-occurring mental health conditions. Patients with co-occurring conditions are more likely to benefit from residential care. Effective treatment should optimally address both disorders via an integrated care plan. The care plan will help guide treatment in residential care and will inform transition and discharge planning related to follow-up needs.

Medical evaluation is often an important component of care. In addition to general medical conditions, attention needs to be given to assessing the patient's need for detoxification. Medical assessment ideally includes evaluation of the patient's eligibility for medications to assist with the medical management of cravings and/or opiate replacement treatment (if applicable).

Adolescent Residential Treatment

Residential treatment services are provided or authorized with the overall goals of assessing and stabilizing the member's severe symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Since substance use disorders are chronic disorders, treatment is optimally provided over longer periods of time. Residential treatment may serve as the level of care needed to help youths to stabilize and engage in treatment with the ultimate goal of transitioning to longer term treatment at a lower level of care.

Residential chemical dependency treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and these clinical review criteria. When treating children or adolescents under the age of 18 in a residential treatment program, the parents or guardians must consent for the treatment and be included in both the evaluation and treatment planning processes, except for youths who have been living outside of the family home and the parents are unavailable, unable, or unwilling to provide consent to treatment. Admitting a self-consenting youth is a determination made by the program to which the youth applies, based on information obtained by the program, and the program must document efforts to locate and engage the parents in the treatment process.

Medical evaluation is often an important component of care. In addition to general medical conditions, attention needs to be given to assessing the youths need for detoxification, and ideally includes evaluation of the patient's eligibility for medications to assist with the medical management of cravings, and/or opiate replacement treatment (if applicable).

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ASAM placement criteria for both adult and adolescents
Washington State requires the use of ASAM criteria by State-certified chemical dependency treatment providers, when determining placement of patients with substance use disorders (criteria includes placement recommendations related to residential treatment). Clinical recommendations must be documented in writing and must contain objective clinical information. Clinical criteria do not factor in family, employer or legal mandates or requests for treatment. Clinical criteria are intended to evaluate the impact of the substance use disorder on the affected individual (via a bio-psychosocial assessment) and to guide decision making related to care strategies.

Evidence and Source Documents

References for Adult Residential Treatment:

1) Mojtabai R, Graff Zivin J. "Effectiveness and Cost-Effectiveness of Four Treatment Modalities for Substance Disorders: A Propensity Score Analysis" Health Services Research. 38(1):233-259, 2003.
This study was a data analysis from the Services Research Outcomes Study, surveying 3,047 clients in 99 drug treatment facilities across the United States. No long-term differences in abstinence or reduced drinking between outpatient treatment and residential treatment. Outpatient treatment was the most cost-effective treatment modality.

2) Weisner C, Mertens J, Parthasarathy S, Moore C, Hunkeler EM, Hu T, Selby JV. "The Outcome and Cost of Alcohol and Drug Treatment in an HMO: Day Hospital Versus Traditional Outpatient Regimens" Health Services Research. 35(4):791-812; 2000.
This study was a randomized controlled trial of 668 adults entering drug treatment in an HMO (Kaiser) randomized to day hospital treatment or to outpatient treatment. Patients randomized to either outpatient or day hospital treatment fared equally well. Patients with mid-level psychiatric severity did fare better with the higher level of care.

3) Witbrodt J, Bond J, Kaskutas LA, Weisner C, Jaeger G, Pating D, Moore C. "Day Hospital and Residential Addiction Treatment: Randomized and Nonrandomized Managed Care Clients" Journal of Consulting and Clinical Psychology. 75(6):947-959; 2007.
This study was a randomized controlled trial of 293 adults entering substance abuse treatment in an HMO (Kaiser) randomized to day hospital treatment or to residential treatment. Despite differences in baseline severity between groups, patients randomized or non-randomized fared equally well in either treatment intensity. 12-month outcomes were most closely related to continued 12-step participation.

4) Kaskutas LA, Witbrodt J, French MT. "Outcomes and costs of day hospital treatment and nonmedical day treatment for chemical dependency." Journal of Studies on Alcohol. 65(3):371-382; 2004.
This study was a randomized controlled trial of adults entering substance abuse treatment in an HMO (Kaiser) randomized to hospital-based day treatment or to one of two community-based day treatment programs. Patients randomly assigned to either hospital-based day treatment or community-based treatment fared equally well, while costs were lower in community-based programs.

5) Guydish J, Sorensen JL, Chan M, Werdegar D, Bostrom A, Acampora A. "A Randomized Trial Comparing Day and Residential Drug Abuse Treatment: 18-Month Outcomes" Journal of Consulting and Clinical Psychology. 67(3):428-434; 1999.
This study extends similar findings from a report on 6-month outcomes from a randomized trial assigning 188 clients entering a therapeutic community to either day treatment or residential treatment. Both groups had similar improvements over time with those in residential treatment having greater improvement for psychiatric symptoms and social problems.

6) Moos RH, Moos BS. "Long-term influence of duration and intensity of treatment on previously untreated individuals with alcohol use disorders." Addiction. 98:325-337; 2003.
This study was a naturalistic study following 473 alcoholic adults over 8 years following SUD identification. Rapidly entering treatment and duration of treatment (i.e., longer duration being better) were related to better short and long-term (i.e., 3 and 8 year) alcohol-related outcomes. In general, intensity of treatment was not related to better outcomes.

7) Chen S, Barnett PG, Sempel JM, Timko C. "Outcomes and costs of matching the intensity of dual-diagnosis treatment to patients' symptom severity." Journal of Substance Abuse Treatment. 31:95-105; 2006.
This study evaluated a patient-treatment matching strategy for dual-diagnosis patients in the VA (N=230). Patients with high severity dual disorders had better alcohol, drug and psychiatric outcomes and higher health care costs.

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Moderate severity patients generally had similar outcomes whether they were matched to low-intensity treatment or not.

References for Adolescent Residential Treatment:

1. Sussman S, Skara S, Ames SL. "Substance Abuse Among Adolescents". *Substance Use & Misuse.* 43:1802-1828; 2008.
2. This paper summarizes the findings in adolescent substance abuse treatment with occasional comparisons to adult substance abuse and treatment. There is little evidence to guide selection of treatment modality or setting in adolescents. There are some differences between substance use disorders in adolescents and adults, notably, adolescents typically have less motivation for abstinence than adults.
3. Hser YI, Grella C, Hubbard RL, Hsieh SC, Fletcher BW, Brown BS, Anglin MD. "An Evaluation of Drug Treatments for Adolescents in 4 US Cities." *Archives of General Psychiatry.* 58:689-695; 2001.
   This was a naturalistic study of 1167 adolescents who were treated in one of three different treatment settings and followed for one year. This study did not compare treatment settings with one another, but in general, found treatment in all settings to lead to improvements in most substance use and overall functioning domains and that length of time in treatment is associated with better outcomes.
4. Grella C, Hser YI, Joshi V, Rounds-Bryant J. "Drug Treatment Outcomes for Adolescents with Comorbid Mental and Substance Use Disorders." *Journal of Nervous and Mental Disease.* 189(6): 384-392; 2001.
   A naturalistic study of 992 adolescents treated in three different treatment settings compared those with and without comorbid psychiatric disorders. Psychiatric comorbidity was associated with greater substance use problems entering treatment, which was associated with less favorable treatment outcomes. Compared to those without comorbidity, comorbid youth were more likely to use cannabis and hallucinogens and were more likely to engage in illegal acts a year after treatment.
5. American Academy of Child Psychiatry Practice Parameters.
6. American Society of Addiction Medicine Patient Placement Criteria, 2nd Edition Revised.
7. American Society of Addiction Medicine Patient Placement Criteria, 3rd Edition.

Date Created	Date Reviewed	Date Last Revised
05/05/2020	05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/26/2021

[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	MPC approved to adopt new clinical criteria
12/31/2020	Adopted ASAM Criteria for non-Medicare per mandated Washington state requirement, effective January 1, 2021.
05/26/2021	Adopted ASAM criteria for Medicare members. Requires 60-day notice, effective October 1, 2021.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Substance Use Disorder – General

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Inpatient Hospital Stays for Treatment of Alcoholism (130.1) Outpatient Hospital Services for Treatment of Alcoholism (130.2) Chemical Aversion Therapy for Treatment of Alcoholism (130.3) Excluded Service: Electrical Aversion Therapy for Treatment of Alcoholism (130.4) Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5) Treatment of Drug Abuse (Chemical Dependency) (130.6)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
American Society of Addiction Medicine (ASAM)	Kaiser Permanente uses ASAM criteria as a supplement to the above NCDs or LCDs for medical necessity review of residential, inpatient, and detoxification treatment for Medicare members.

For Non-Medicare Members

Kaiser Permanente uses criteria from the American Society of Addiction Medicine (ASAM) to review for residential, inpatient, and detoxification services for adults and adolescents. ASAM criteria were created to improve access to and quality of care in the treatment of substance use disorders. These criteria match individual patients with the appropriate services to help patients succeed in their recovery. This policy describes which types of substance use disorder treatment may be considered medically necessary when using ASAM criteria.

The following services may be considered medically necessary when criteria are met using ASAM® Criteria:

- Outpatient Services
- Intensive Outpatient/Partial Hospitalization Services
- Residential/Inpatient Services

***The ASAM criteria are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our Behavioral Health department, you may request a copy of the criteria that is being used to make the coverage determination. Call the Behavioral Health Unit for more information regarding the case under review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

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Background

Kaiser Permanente Mental Health and Wellness Services has adopted American Society of Addiction Medicine (ASAM) criteria to define medical necessity for substance use disorder treatment and to define substance use disorder level of care.

Evidence and Source Documents

References:

The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions, Third Edition (2013)
Copies of the criteria can be obtained at www.asam.org.
Revised Code of Washington (RCW) 41.05.528

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
01/09/2006	07/02/2013[MDCRPC],10/01/2013[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	09/17/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
01/05/2016	Online version of criteria has been updated with editorial changes
07/11/2017	Minor changes to criteria to note ASAM criteria, 3rd edition
12/31/2020	Adopted ASAM Criteria for non-Medicare per mandated Washington state requirement, effective January 1,
05/26/2021	Adopted ASAM criteria for Medicare members. Requires 60-day notice, effective October 1, 2021.
09/17/2021	Updated Background and References with current information.

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Clinical Review Criteria
Substance Use Disorder Treatment – Partial Hospital Program

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Inpatient Hospital Stays for Treatment of Alcoholism (130.1) Outpatient Hospital Services for Treatment of Alcoholism (130.2) Chemical Aversion Therapy for Treatment of Alcoholism (130.3) Electrical Aversion Therapy for Treatment of Alcoholism (130.4) Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5) Treatment of Drug Abuse (Chemical Dependency) (130.6) Withdrawal Treatments for Narcotic Addictions (130.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
American Society of Addiction Medicine (ASAM)	Kaiser Permanente uses ASAM criteria as a supplement to the above NCDs or LCDs for medical necessity review of residential, inpatient, and detoxification treatment for Medicare members.

For Non-Medicare Members

Kaiser Permanente uses criteria from the American Society of Addiction Medicine (ASAM) to review for residential, inpatient, and detoxification services for adults and adolescents. ASAM criteria were created to improve access to and quality of care in the treatment of substance use disorders. These criteria match individual patients with the appropriate services to help patients succeed in their recovery.

The following services may be considered medically necessary when criteria are met using ASAM® Criteria:

- Intensive Outpatient/Partial Hospitalization Services

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Kaiser Permanente Mental Health and Wellness Services has adopted American Society of Addiction Medicine (ASAM) criteria to define medical necessity for substance use disorder treatment and to define substance use disorder level of care.

Evidence and Source Documents

References:

The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions, Third Edition (2013)
Copies of the criteria can be obtained at www.asam.org.
Revised Code of Washington (RCW) 41.05.528

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
03/01/2016	03/01/2016[MPC], 01/03/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/07/2021

[MPC] Medical Policy Committee

Revision History	Description
11/07/2017	MPC approved to adopt hybrid criteria for CD- Partial Hospitalization
12/31/2020	Adopted ASAM Criteria for non-Medicare per mandated Washington state requirement, effective January 1, 2021.
05/26/2021	Adopted ASAM criteria for Medicare members. Requires 60-day notice, effective October 1, 2021.
09/07/2021	Updated Background and References sections with current information.

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Clinical Review Criteria
Spinal Manipulations – Chiropractic and Osteopathic

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 15 Section 30.5 - Chiropractor's Services and Section 240 Chiropractic Services - General
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Chiropractic Services (L34009) 12/31/2019 Noridian retired LCD Chiropractic Services (L34009). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34009 for determining medical necessity.
Local Coverage Article	Billing and Coding: Chiropractor Services (A57914)

For Non-Medicare Members

When considering clinical information submitted for medical necessity review, the following data elements and corresponding details are evaluated to ensure correlation to the presenting diagnosis and proposed care plan*:

- Chief Complaint(s)
- Past Medical History
- Mechanism of Onset
- Duration of Symptoms (acute or chronic)
- Evaluation and Re-evaluation findings
- Results of Diagnostic Testing
- Diagnostic Impression
- Complicating Factors (conditions or circumstances that may affect the patient's response to care)
- Prior and/or Concurrent History of Treatment
- Prognosis and Provider Comments

Manipulative Therapy*

In establishing a fundamental need for manipulation, the treating provider must maintain a clinical record that includes an appropriate new and/ or established patient history and physical examination, and a goal-oriented care plan with measurable treatment goals. This collectively will be considered the key components of an evaluation and management service.

Examples of clinically significant improvement include, but are not limited to:

- Corresponding reduction and/or mitigation in subjective symptoms;

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- Measured improvement in objective findings (i.e., orthopedic tests, neurologic signs, joint specific and region specific ranges of motion, musculoskeletal asymmetry at rest, palpation of tender and sensitive zones, tissue texture changes, muscle strength metrics); and
- A qualitative and/or quantifiable improvement in the patient's ability to perform specific functional tasks and/or activities of daily living as measured by the Patient-Specific Functional Scale (PSFS) or similar validated patient reported clinical outcome measure. For example, a clinically relevant improvement in the PSFS can be indicated by a change of at least 2 points in the average score of all activities or at least a 3-point change in a single activity over the reported baseline within a 4-week period.

  For Manipulative therapy services, Medicare requires the primary diagnosis to be a spinal subluxation diagnosis code, followed by a secondary neuro-musculoskeletal diagnosis code. Medicare mandates that the physical exam must demonstrate a causal relationship between the spine and the patient's presenting complaint, which demonstrates medical necessity for spinal manipulation.

  Medical necessity for manipulative therapy services should be supported by three elements of documentation:
  ▪ Presence of a spinal subluxation;
  ▪ Evidence of the subluxation by X-ray or physical examination; and
  ▪ Documentation of the initial and subsequent visits.

  Medicare requires the acronym P.A.R.T. (Pain, Asymmetry, Range of Motion, and Tissue/Tone) must be used to describe the examination components indicating that a patient is suffering from a spinal condition amenable to manipulation. At least 2 of the 4 P.A.R.T. criteria must be met, with a least one of them being the "A" or "R" component.

*Excerpted from Tivity WholeHealth Network Clinical Criteria to Determine Medical Necessity: Physical Medicine Services (reviewed and updated January, 2021)

Take home equipment and supplies must follow Kaiser Permanente coverage rules and guidelines.
See Devices, Equipment and Supplies
See Compression Garments
See Magna Bloc

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Spinal manipulation is defined by chiropractors as "a specific form of direct articular manipulation utilizing a short lever and characterized by a dynamic, forceful, high velocity thrust of controlled amplitude" (Janse, 1975, as cited by Coulehan. 1985, p. 355). Chiropractors distinguish between chiropractic adjustments and spinal manipulation. Spinal manipulation is a generic term that refers to techniques used by osteopathic physicians, physiatrists (rehabilitation specialists), physiotherapists, or orthopedic surgeons. Spinal adjustment therapy usually involves more frequent visit than medical treatment for the same condition. (Coulehan, 1985).
Manual manipulation of the spine is composed of four elements: patient positioning, location of applied load, peak velocity of the load that is achieved, and peak load developed. The total displacement of the body segments is believed to be properly controlled by a combination of patient positioning and peak load. Techniques used by chiropractors to augment the manipulation may include mobilization, manual traction, soft-tissue massage, and pressure-point techniques (Haldeman, 1983).
Spinal manipulation and adjunct therapies (physical therapy) have been demonstrated to be effective when delivered alone, but no therapy has been consistently demonstrated to be more effective than the other modalities. A 2011 Cochrane Back Group review of 26 randomized controlled trials with 6070 participants (9 studies with low bias) found high quality evidence that spinal manipulative therapy for low back pain indicates provides clinically relevant, statistically significant short-term effect on pain relief as compared to other interventions, including exercise therapy, standard medical care or physical therapy. (Rubinstein, 26Feb2011)

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The reviewers note that spinal manipulation appears to be no better or no worse than other existing therapies for pain relief. This review affirms the 2008 Cochrane Database Review of Spinal Manipulative Therapy for low-back pain results indicating no evidence that spinal manipulative therapy is superior to other standard treatments (physical therapy, exercises, back school, general physician care) for pain relief or improved functional outcomes. (Assendelft, et al., Cochrane Library Review, 8Oct2011)
There is mixed evidence on the clinical effectiveness of adjunct modalities, including physical therapy and rehabilitative services and durable medical equipment and supplies, when delivered concurrently with spinal manipulation.
An April 2010 Cochrane Back Group Review of combined chiropractic interventions demonstrated slightly improved pain and disability for patients with acute and subacute back pain in the short term. No difference was demonstrated for combined chiropractic interventions for chronic lower back pain and for studies that had a mixed population of lower back pain. Any demonstrated differences were small and were only seen in studies with a high risk of bias. For acute and subacute LBP, chiropractic interventions improved short- and medium-term pain (SMD -0.25 (95% CI -0.46 to -0.04) and MD -0.89 (95%CI -1.60 to -0.18)) compared to other treatments, but there was no significant difference in long-term pain (MD -0.46 (95% CI -1.18 to 0.26)). Short-term improvement in disability was greater in the chiropractic group compared to other therapies (SMD -0.36 (95% CI -0.70 to -0.02)). However, the effect was small and all studies contributing to these results had high risk of bias. There was no difference in medium- and long-term disability. (Walker, 14APR2010)
In a randomized controlled trial of chiropractic care (flexion distraction) or physical therapy (exercise program), Cambron found that subjects in both groups had decreased pain and disability regardless of which therapy was utilized (p<.002). During the year after care, chiropractic subjects had significantly lower pain scores (p=.002) and received fewer visits but experienced no difference in timing of care following intervention when compared to than those in physical therapy treatment. Physical therapy subjects attended significantly more health care visits than subjects who received chiropractic care only. (Cambron, Cochrane Register of Controlled Trials, Chiropractic care vs medical care for low back pain: Assessment of long-term follow-up data, 2005).

Evidence and Source Documents

Hayes Report, Chiropractic Treatment of Low Back Pain, May 26, 1999
Spinal Manipulative Therapy for Chronic Low Back Pain, The Cochrane Library. Rubinstein, SM, van Middelkoop, M, Assendelft, WJJ, de Boer, MR, vanTulder, MW. 8 Oct 2011 online publication.
Walker B, French S, Grant W, Green S, Cochrane Library Review of Combined Chiropractic Interventions for Low Back Pain, 14APR2010 online publication.
Cambron JA, Cochrane Register of Controlled Trials, Chiropractic care vs medical care for low back pain: Assessment of long-term follow-up data, 2005.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved
98940	Chiropractic manipulative treatment (CMT); spinal, 1-2 regions
98941	Chiropractic manipulative treatment (CMT); spinal, 3-4 regions
98942	Chiropractic manipulative treatment (CMT); spinal, 5 regions
98943	Chiropractic manipulative treatment (CMT); extraspinal, 1 or more regions

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Date Created	Date Reviewed	Date Last Revised
02/10/2000	10/05/2010[MDCRPC], 08/02/2011[MDCRPC], 06/05/2012 [MDCRPC], 10/02/2012 [MDCRPC] , 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC] ,09/04/2018[MPC] , 09/03/2019[MPC] , 09/01/2020[MPC] , 09/07/2021[MPC], 09/06/2022[MPC],06/06/2023[MPC]	09/07/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2015	The chiropractic policy was modified. The Healthways Clinical Criteria for Chiropractic Services was adopted as GHC policy.
09/08/2015	Revised LCD L34009
09/07/2021	Updated Tivity criteria reference for manipulative therapy.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Chromoendoscopy
Narrow Band Imaging for Colonoscopy

- Barrett's Esophagus
- Colorectal Cancer
- Inflammatory Bowel Disease (IBD)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"Chromoendoscopy, Narrow Band Imaging for Colonoscopy"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Chromoendoscopy: • Barrett's Esophagus • Colorectal Cancer Screening	There is insufficient evidence in the published medical literature to show that these procedures provide better long-term outcomes than current standard services/procedures during endoscopy.
Chromoendoscopy: • Inflammatory Bowel Disease	Medically necessary when undergoing cancer surveillance for Inflammatory Bowel Disease (Crohn's and Ulcerative Colitis). **Please refer to Kaiser Permanente payment policy *Chromoendoscopy and Narrow Band Imaging* for reimbursement clarification (Not separately reimbursed).**

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

Chromoendoscopy (also known as chromoscopy or chromocolonoscopy) is an image-enhanced endoscopic technique that has the potential of providing detailed contrast enhancement of the surface of gastrointestinal mucosa. It can be used during any endoscopic examination to improve detection and characterization of subtle mucosal abnormalities, circumscribed dysplastic lesions and malignant changes in the gastrointestinal tract. Chromoendoscopy however, requires optimal bowel preparation in order to provide adequate visualization (Bisschops 2019, Buchner 2017, Clarke 2019, Shukla 2017).

Types of chromoendoscopy:

1. Dye-based chromoendoscopy. This involves actual spraying of absorptive stains or contrast stains directly onto the GI mucosa, through a spray catheter inserted into the endoscope. Dye spraying, or chromoscopy techniques, were first described in the 1970s to provide visualization of the mucosal surface with more clarity and sharpness. It has been used to aid in the detection and evaluation dysplastic changes in the esophagus, stomach, small intestine, and large intestine. Several stains have been described and can broadly be categorized into three groups:
    - Contrast stains (e.g., indigo carmine) that permeate through mucosal crevices and highlights surface topography and mucosal irregularities. Indigo carmine is the most commonly used stain with colonoscopy to enhance the detection of colorectal neoplasms.
    - Absorptive stains (e.g. methylene blue and Lugol's solution) that diffuse or are preferentially absorbed across specific epithelial cell membranes. The normal epithelial cells absorb the methylene blue dye and stain blue while dysplastic and cancerous lesions remain unstained. Methylene blue has been used to detect colonic neoplasia and to aid in the detection of intraepithelial neoplasia in individuals with chronic ulcerative colitis. It has also been used for the detection of Barrett's esophagus and associated dysplasia and/or early cancer, and for the diagnosis of early gastric cancer.
    - Reactive stains (e.g., Congo red and phenol red) undergo chemical reactions with specific cellular constituents, resulting in a color change. These are primarily used to identify gastric abnormalities and are not used with colonoscopy.

    The stains used in chromoendoscopy are transient in contrast to endoscopic tattooing that involves the use of a long-lasting pigment for future localization of lesions (Bisschops 2019, Brown 2016**,** Buchner 2017, Clarke 2019, Shukla 2017).
2. Virtual chromoendoscopy, also called electronic chromoendoscopy (EC), involves imaging enhancements with endoscopy systems using a computer algorithm to simulate different colors of light resulting from dye or stain spraying. The EC techniques depend on finding lesion first with WLE and then using EC function to characterize it (Desai 2019)

    Electronic chromoendoscopy includes:
    - Narrow-band Imaging (NBI) (Olympus Medical Systems Tokyo, Japan),
    - Flexible spectral imaging color enhancement (FICE) (Fujinon, Fujifilm Medical Co, Saitama, Japan),
    - i-SCAN (PENTAX Endoscopy, Tokyo, Japan).

    Selective light transmittance is accomplished by optical filtering of white light in NBI, and by software driven post-image processing in FICE and i-SCAN (Buchner 2017)

    Narrow-band Imaging technology is the most studied in clinical trials. It is a blue light technology that enhances visualization of superficial mucosal structures, especially superficial microcapillaries. The technology is based on the penetration properties of light that is directly proportional to wavelength. Short wavelengths penetrate only superficially into the mucosa, whereas longer wavelengths are capable of penetrating more deeply in the mucosa. In contrast to conventional white-light endoscopy (WLE) that uses the full visible wavelength range (400-700 nm) to produce a red-green-blue image, NBI illuminates the tissue surface using special filters that narrow the red-green-blue bands and simultaneously increase the relative intensity of the blue band. The resulting narrow-band blue-green light improves visualization of mucosal patterns due to the limited optical scattering and shallow penetration depth; therefore, the color contrast is enhanced between the neoplastic lesions and adjacent normal mucosa. The blue light is also absorbed by hemoglobin for optimal detection of mucosal, glandular, and vascular patterns as well as the presence of abnormal blood vessels that are associated with the development of dysplasia. It is hypothesized that as adenomas have increased vascularity and look brown with NBI against a blue-green normal background mucosa, this increased

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contrast might improve visualization in wide-field observation (Thosani 2016, Buchner 2017, Atkinson 2019).

Chromoendoscopy has been evaluated for its use with or without standard white light colonoscopy for screening, diagnosis, and/or surveillance of gastrointestinal dysplasia or cancer including the following:

- As an adjunct to colonoscopy for colorectal cancer (CRC) screening to increase the sensitivity of the procedure by facilitating the identification of mucosal abnormalities. The traditional colonoscopy using white light is considered the gold standard method for screening the general population for colon cancer, detection of precursor lesions, and for the diagnosis of colorectal neoplasia in symptomatic patients. However, it is not a perfect imaging test and has been found to miss polyps in 1 of 5 cases with an estimated polyp miss rate of up to 22% especially with very small adenomas. This may lead to an increase in the interval CRC rates. Potential explanations for these missing lesions include the small size or flatness of lesions, difficulty in finding lesions such as those hidden behind folds or flexures, shorter withdrawal time, and poor bowel preparation Over the years, several modifications have been made in the imaging modalities to enhance the traditional colonoscopy and improve its sensitivity in polyp detection. The introduction of High-definition (HD) imaging in the last decade have improved the detection of more adenomas and sessile lesions that may have been missed with the standard colonoscopy. Chromoendoscopy is another technique introduced to potentially improve polyp detection and characterization particularly the flat or nonpolypoid colonic adenomas. The technology can be used for the whole colon (pan-colonic chromoendoscopy) or directed to a specific lesion or lesions (targeted chromoendoscopy). Chromoendoscopy however may to be time consuming and labor intensive (Buchner 2017, Desai 2019, Kim 2020).
- Endoscopic surveillance of patients with inflammatory bowel disease (ulcerative colitis and Crohn's disease) with the goal of early detection of dysplasia and identification of mucosal abnormalities for targeted biopsy as an alternative to multiple random biopsies (Shukla 2017, Clarke 2019).
- Endoscopic surveillance of Barrett's esophagus to potentially improve the image quality and the diagnostic accuracy of white light endoscopy. It can also potentially allow visualization of advanced esophageal neoplasms and identifying any subtle changes in the esophageal mucosa that may correspond to early stages of the disease or abnormalities that may not be seen in upper gastrointestinal endoscopy (Morita 2017, Cerrone 2019).

Medical Technology Assessment Committee (MTAC)

Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Barrett's Esophagus

Date: 01/11/2021

Evidence Conclusion:

- The published literature suggests that using acetic acid chromoendoscopy or NBI electronic endoscopy for BO surveillance may have a higher diagnostic yield compared to WLE and standard Seattle protocol when performed by experienced endoscopists (considering all limitations discussed earlier).
- There is insufficient published evidence on the long-term benefit of the using chromoendoscopy and targeted biopsy as a replacement to or in adjunct to the current standard of WLE and Seattle protocol on reducing the rate of biopsy, improving patient QoL or reducing the BO-related morbidity and mortality.

Articles: The literature search for recent of studies and meta-analyses of studies evaluating the accuracy and /or efficacy of chromoendoscopy versus WLE in detecting and characterizing dysplastic lesions and reducing the rate of unnecessary biopsies identified three meta-analyses published in the last 5 years, as well as the protocol and feasibility study for the ABBA trial on the use of acetic acid targeted biopsies in Barrett's surveillance. The search did not reveal ant recently published RCTs or prospective longitudinal studies that compared the efficacy of chromoendoscopy versus WLE in the detection and characterization of dysplastic lesions during surveillance of BO. The more recent and /or relevant meta-analysis comparing chromoendoscopy versus WLE and the standard surveillance protocol were selected for critical appraisal. See Evidence Table

The use of Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Barrett's Esophagus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Chromoendoscopy Imaging (Dye-Based Chromoendoscopy & Virtual Electronic Chromoendoscopy) for Colon Cancer Screening, Diagnosis and Disease Surveillance

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Date: 01/11/2021
Evidence Conclusion:

- The overall results of the published trials and meta-analyses suggest that dye-based chromoendoscopy marginally improves the detection of the adenoma as well as small polyps and flat lesions per subject when compared to standard colonoscopy. There were no significant differences between the two imaging modalities in the detection rate of advanced adenomas, advanced neoplasia, or cancer. The duration of withdrawal time is known to be directly associated with the adenoma detection rate (ADR), and thus the higher detection rates of adenomas, flat, and diminutive lesions with chromoendoscopy may be attributed to the increased withdrawal time with the dye-spray techniques.
- Electronic chromoendoscopy using NBI may modestly improve the adenoma detection rate compared with standard white-light colonoscopy, but the observed difference was only significant with optimal bowel preparation and use of NBI second generation. There were no significant differences in polyp or adenoma detection was observed between high definition white-light colonoscopy and high definition NBI.
- There is a lack of long-term studies to determine whether the use of chromoendoscopy would reduce rates of colorectal interval cancers.
- There is a lack of published studies comparing the effect of chromoendoscopy versus standard or high definition white light endoscopy in reducing the incidence of CRC or the associated morbidity and mortality.
- There is no published evidence, to date, to determine the effects of technology on net health outcome.

Articles: The literature search identified over 40 RCTs and more than 20 meta-analyses (dating back to the year 2012) that examined the impact of different dyes or electronic chromoendoscopy modalities on increasing the detection rate of colonic lesions when compared to one another or to white light colonoscopy.
Due to the large number of published studies and meta-analyses, the most recent meta-analyses of RCTs, that were more inclusive of trials, and had valid methodology were selected for the current review as well as recently published RCTs that compared neoplasia detection rates with chromoendoscopy (dye -based or NBI) versus standard white light (WL) of high-definition white light (HDWL) colonoscopy used for screening or diagnosis of colorectal cancer. The use of chromoendoscopy for the surveillance of Barrett's esophagus and the surveillance of irritable bowel disease will be reviewed separately in different reports. See Evidence Table**.**

The use of Chromoendoscopy Imaging (Dye-Based Chromoendoscopy & Virtual Electronic Chromoendoscopy) for Colon Cancer Screening, Diagnosis and Disease Surveillance does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Patients with Inflammatory Bowel Disease (IBD)
Date: 01/11/2021
Evidence Conclusion:

- There is strong evidence that dye chromoendoscopy (DCE) is superior to standard white light endoscopy (SD-WLE) in detecting dysplastic lesions in patients with IBD.
- There is moderate to high strength evidence indicating that DCE does not provide any additive benefit over HD-WLE in the overall ability to detect dysplasia in patients with IBD. Randomized controlled trials, meta-analyses of RCT, and a recent US-based case control sturdy (Clarke et al 2020) showed no significant difference in dysplasia detection rate between DCE and HD-WLE. The studies that showed higher dysplasia detection rate with of DCE were mainly observational studies (with the exception of Alexandersson et al's 2020 RCT).
- Narrow band imaging (NBI) is not superior to SD or HD-WLE. Other technologies such as i-scan and Fujifilm Intelligent Chromoendoscopy have not been sufficiently studied in dysplasia surveillance.
- There is insufficient evidence to determine the safety of dye-chromoendoscopy.
- There are no published long-term longitudinal studies to date, to determine the impact of chromoendoscopy on treatment decisions for patients with IBD, patient health outcomes, e.g. reducing colectomy, reducing interval cancer and CRC-related morbidity and mortality, improving the quality of life and other patient-oriented outcomes.

Articles: The literature search identified four RCTs published in the last two years, one case control study , and nine meta-analyses of RCTs and /or prospective studies that examined the impact of dye or electronic chromoendoscopy modalities on increasing the dysplasia detection rates when compared to one another or to the standard or high definition white light colonoscopy. Three of the meta-analyses were network meta-analyses, two MAs compared dye chromoendoscopy versus white light endoscopy, and five compared different modalities of WLE and chromoendoscopy. See Evidence Table

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The use of Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Patients with Inflammatory Bowel Disease (IBD) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes-*commonly submitted with CPT code 43499 or 45399*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
7/10/2020	08/03/2021 MPC, 08/02/2022MPC	05/04/2021

MPC Medical Policy Committee

Revision History	Description
08/04/2020	MPC approved to adopt non-coverage policy. Requires 60-day notice, effective date 01/01/2021.
05/04/2021	Added MTAC reviews for BE, CRC, and IBD. MPC approved to adopt MTAC's recommendation of non-coverage for chromoendoscopy for Barrett's Esophagus (BE) and Colon Cancer Screening (CRC). MPC approved to adopt MTAC's recommendation of coverage for chromoendoscopy for Inflammatory Bowel Disease (IBD). Criteria align with Kaiser Permanente payment policy (not separately reimbursed). Requires 60-day notice, effective date August 15, 2021.

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Clinical Review Criteria
ClariFix® Cryotherapy for Chronic Rhinitis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “ClariFix Cryotherapy for Chronic Rhinitis” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Chronic rhinitis is long-term inflammatory condition of the nasal mucosa. Its etiology is not precisely understood, but it is thought to result from deregulation of the autonomic innervation of the nasal mucosa leading to increased vascular permeability, mucous secretion and edema. Rhinitis is generally classified as allergic and non-allergic rhinitis. Allergic rhinitis may be seasonal, perennial or both and is mainly characterized by sneezing, runny nose, stuffiness, and itchy watery eyes. The symptoms of non-allergic rhinitis include nasal obstruction, irritability, and hypersecretion (Kompelli 2018, Chang 2019, Krespi 2020).

The first-line treatment of chronic rhinitis involves avoiding known triggers and the use of over the counter or prescription medications including saline irrigation, topical steroids, topical or systemic adrenergic agents, antihistamine therapy, anticholinergic agents, and antileukotrienes. Medication use improves symptoms for the majority of patients, but needs constant daily use, and may not completely control symptoms in some patients (Kompelli 2018, Chang 2019, Krespi 2020).

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Different procedural or operative interventions have been developed over the years for the treatment of patients with medically refractory rhinitis. Vidian neurectomy, first described in the early 1960s, aims at disrupting preganglionic parasympathetic innervation (autonomic supply) of the nasal mucosa. The surgery was found to be effective in reducing the symptoms of chronic rhinitis, but had its complications including severe bleeding from the sphenopalatine artery, numbness of the cheek and palate, and persistent dry eye symptoms due to the collateral disruption of the parasympathetic innervation of the lacrimal gland. In addition, the procedure must be performed in an operating room under general anesthesia. Resection of the postganglionic nerve fibers via the posterior nasal nerves (PNN) was proposed as an alternative for vidian neurectomy to avoid the dry eye complication. However, its use is limited by its technical complexity, lack of complete resolution of symptoms in some patients, and similar the vidian neurectomy, it must be performed in an operating room under general anesthesia (Huang 2017, Kompelli 2018, Chang 2019, Yan 2020).

Cryosurgical therapy for the treatment of chronic rhinitis was first proposed in the early 1970s and involves the placement of a cryoprobe in the nasal cavity against the posterior end of the inferior turbinate. Several cryoablation devices were developed over the years including Basco-Cryos, Krymed, Frigitronic, Cryospray, Cooper's cryo Unit, and SAmils Cryo. Cryotherapy for rhinitis, however. was not widely adopted due to its potential complications, lack of endoscopic visualization, non-ergonomic probe design, need for external cryogen reservoirs, and other associated challenges (Hwang 2017, Kompelli 2018, Yan 2020).

More recently a novel cryotherapy device (ClariFix™) was developed for cryosurgical ablation of the PNN region in an office setting and under local or mild sedation. The procedure involves the introduction of a cryosurgical ablation device under endoscopic visualization to deliver cryogen to the posterior middle meatus and freeze the posterior nerve (Yan,2020).

The ClariFix™ cryoablation device (Arrinex Inc, redwood City, CA, recently acquired by Stryker Corporation, Kalamazoo MI) is a hand-held, single-use, disposable cryosurgical device (cryoprobe) that uses nitrous oxide as the cryogen to freeze the mucosal tissue in a targeted fashion in the nasal cavity. The target tissue lies in the posterior aspect of the middle meatus adjacent to the sphenopalatine foramen and corresponding to the trajectory of the PNN as it emerges from the pterygopalatine fossa. The cryogen cartridge is inserted into the handle of the device immediately prior to the procedure. The Cryoprobe is then placed into contact with the target tissue via direct endoscopic visualization under local anesthesia with the patient seated upright or partially reclined. Once the Cryoprobe is in the desired position, the cryogen is released into the probe tip by the surgeon via a control dial. As cryogen flows into the Cryoprobe, the liquid partially evaporates and the inside of the Cryoprobe cools to -60 to -80°C; a freezing zone forms in the adjacent tissue destroying the unwanted tissue. The treatment is estimated to achieve
-20°C cryoablation at a depth of 3 millimeters. Nitrous oxide is fully contained within the Cryoprobe and does not come in direct contact with the tissue. Once the Cryoprobe has thawed it can be safely removed from the treatment area. The cryoprobe is activated for a single treatment of 30-60 seconds for each side. Additional treatment cycles can be initiated at the physician's discretion. The device is designed for singe patient use and is disposable. (Huang 2017, Chang 2019, FDA website).

The most common side effects associated with ClariFix cryotherapy are temporary increased congestion and transient pain or discomfort. Other reported adverse events include moderate or severe nasal dryness, nose bleeds, headache, ear blockage, dry eyes, watery eyes, oral numbness and sinusitis.

Hayes Conclusion

There is insufficient published evidence to evaluate the use of ClariFix for treatment of chronic rhinitis.

Reference

Cryotherapy Using ClariFix (Arrinex Inc.) for Treatment of Chronic Rhinitis. (2019, October 24). Retrieved July 10, 2020, from https://evidence.hayesinc.com/report/hss.clarifix4569

Medical Technology Assessment Committee (MTAC)

CRYOTHERAPY FOR THE TREATMENT OF CHRONIC RHINITIS USING THE CLARIFIX DEVICE

7/13/2020: MTAC REVIEW

The literature search did not identify any published randomized controlled trials, to date, that compared cryoablation therapy for chronic rhinitis using the ClariFix device versus any medical therapy, surgery, or a sham procedure. The published literature on ClariFix consisted of a small pilot study (Evidence table 1), and a

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prospective observational multicenter single-arm open-label study (Evidence table 2). The two studies were sponsored by the manufacturer and were subject to selection and observational bias.

Evidence Conclusion:
There is insufficient published evidence to date, to support Cryosurgery using ClariFix device for the treatment of chronic rhinitis.

The use of ClariFix® Cryotherapy for Chronic Rhinitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary - experimental, investigational or unproven:

CPT® or HCPCS Codes	Description
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach **frequently submitted with this code, although code 30999 "Unlisted procedure, nose" is most appropriate per manufacturer guidance*
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral

ICD-10 Codes	Description
J30.0	Vasomotor rhinitis
J30.1-J30.9	Allergic rhinitis
J31.0	Chronic rhinitis
J31.1	Chronic nasopharyngitis
J34.89	Other specified disorders of nose and nasal sinuses
R09.81	Nasal congestion
R09.82	Postnasal drip

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Date Created	Date Reviewed	Date Last Revised
09/01/2020	09/01/2020 [MPC] ,09/07/2021 [MPC], 09/06/2022[MPC]	09/01/2020

[MPC] Medical Policy Committee

Revision History	Description
09/01/2020	MPC approved to endorse a non-coverage policy for ClariFix/cryotherapy for chronic rhinitis

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Clinical Review Criteria
Cochlear Implant

- Cochlear Implant Device
- Hybrid Cochlear Implant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Cochlear Implantation (50.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Service	Criteria Used
Cochlear Implant	Kaiser Permanente has elected to use the Cochlear Implant Effective 12.01.2022 (KP-0177 12012022) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Most recent audiogram/hearing test • Most recent clinical notes from requesting provider &/or specialist (otolaryngology, ENT)
Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant, including but not limited to the Nucleus® Hybrid™ L24 Cochlear Implant System	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

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The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

A cochlear implant is an electronic device that can enable patients with severe to profound hearing loss to perceive sound. Cochlear implants have two main parts:

1) An internal device that is implanted under the skin behind the ear; and
2) A speech processor that is worn or carried (externally) by the individual.

Sounds are detected by a microphone and transformed into an electrical signal. The speech processor codes the signals into a particular pattern of electrical pulses. The pulses are sent to the implant, which in turn transmits them via the auditory nerve to the brain, which recognizes them as sound. Use of a cochlear implant requires both a surgical procedure to implant the device, and substantial post-implantation therapy to learn or re-learn the sense of hearing. In the United States, approximately 22,000 adults have cochlear implants and about 15,000 children have received them (NIDCD, 2006).

Provision of unilateral cochlear implants is currently standard practice. Although results are often positive, particularly in the ability to understand speech in a quiet situation, normal hearing is not restored. There is increasing interest in bilateral cochlear implants to further improve the ability to patients to detect sound. Potential advantages of bilateral implantation include improvements in:

- Hearing in noise, due to the ability to benefit from a “head shadow effect
- Speech perception, due to the availability of sound information from both ears;
- Sound localization, the ability to correctly identify the directional location of sounds surrounding the listener (Litovsky et al., 2006; Tyler et al., 2003).

A potential problem with bilateral cochlear implants is that bilateral coordination of pulsed signals is not yet possible. Instead, the two implants function independently. This is not likely to be as effective as normal binaural hearing which takes advantages of the integration of binaural acoustical cues. In addition, patients with severe hearing loss may have different patterns of loss on each side, and also may have developed abnormal binaural brain maps (Tyler et al., 2003). Response to bilateral cochlear implants, especially localization ability, may also depend on previous experience with hearing. Adults who have had exposure to binaural stimulation early in life appear to perform better with bilateral cochlear implants than adults who were born without hearing or lost hearing at a very young age (Litovsky et al., 2006).

Experts have pointed out that a challenge in studying the effectiveness of bilateral cochlear implants is that learning may influence an individual’s ability to detect aural cues, either unilateral or bilateral. Studies that evaluate users of bilateral implants without comparing them to experienced users of unilateral users may be limited because they do not include patients who have been able to adapt to listening through one device.

Medical Technology Assessment Committee (MTAC)

Bilateral Cochlear Implants

10/13/2004: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine the effect of bilateral cochlear implants on health outcomes compared to unilateral cochlear implants, in patients with severe to profound hearing loss.
Articles: The search yielded 19 articles. The empirical studies were small (sample sizes ranged from one to 20 patients) and laboratory based. They consisted of conducting speech tests of patients with bilateral cochlear implants, sometimes comparing results to one-ear only in the same patients. There were no studies that compared bilateral cochlear implants to experienced users of unilateral implants. There were also no studies that examined functional outcomes with bilateral vs. unilateral implants, such as the ability to use the telephone or perceive speech in a real-world setting.

The use of bilateral cochlear implants for severe to profound hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Bilateral Cochlear Implants

10/02/2006: MTAC REVIEW

Evidence Conclusion: The evidence base consists of small laboratory-based case series and one small randomized controlled trial. The RCT (Summerfield et al., 2006) compared quality of life outcomes in adults who received a second cochlear implant to a delayed treatment group. All participants were successful users of unilateral implants. The study found statistically significant improvement in spatial hearing and quality of hearing

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subscales of a QOL questionnaire in the bilaterally implanted group compared to the control group. However, there were no significant differences on six other quality of life measures and if the p-values had been corrected for multiple comparisons, none of the between-group comparisons would have been statistically significant. The study suggests that bilateral cochlear implants may be beneficial for improving some aspects of hearing in experienced adult users of unilateral implants, but findings are inconclusive. There is insufficient evidence on the effectiveness of bilateral cochlear implants compared to unilateral implants in children.
Articles: The evidence base consists of small laboratory-based case series and one small randomized controlled trial. The RCT (Summerfield et al., 2006) compared quality of life outcomes in adults who received a second cochlear implant to a delayed treatment group. All participants were successful users of unilateral implants. The study found statistically significant improvement in spatial hearing and quality of hearing subscales of a QOL questionnaire in the bilaterally implanted group compared to the control group. However, there were no significant differences on six other quality of life measures and if the p-values had been corrected for multiple comparisons, none of the between-group comparisons would have been statistically significant. The study suggests that bilateral cochlear implants may be beneficial for improving some aspects of hearing in experienced adult users of unilateral implants, but findings are inconclusive. There is insufficient evidence on the effectiveness of bilateral cochlear implants compared to unilateral implants in children.

The use of Bilateral Cochlear Implants in the treatment of severe hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hybrid Cochlear Implant

BACKGROUND

Sensorineural hearing loss (SHL) is the most common form of hearing loss occurring when there is damage to the inner ear or the nerve pathway from the inner ear to the brain. Causes are variable and range from aging and heredity, all the way to exposure to loud noises and drugs toxic to the inner ear. SHL typically results in difficulty hearing faint sounds, understanding people with higher-pitched voices, hearing certain speech sounds, and in some cases, hearing high-pitched emergency vehicle sirens or common safety alarms, such as smoke detectors. Any type of hearing loss can be debilitating and can affect people in various ways.
Conventional treatment options for hearing loss are dependent on the type and source of hearing loss. While hearing loss cannot be fully restored, a wide variety of technologies are currently available to improve hearing. These technologies utilize either air or bone conduction to transmit sound. Air conduction hearing aids (ACHA), for example, receive sound waves through a microphone which are then converted to electrical signals and amplified through a speaker in the ear. Alternatively, bone anchored hearing aids (BAHA) transmit sound vibrations directly to the inner ear through the skull, bypassing the outer and middle ear completely. In any case, both technologies come with strengths and limitations.
The Nucleus® Hybrid™ L24 Cochlear Implant System, developed by Cochlear® (Centennial, CO), combines the functions of both ACHA and BAHA in a single device. The device specifically uses acoustic amplification to amplify low frequency hearing, while taking advantage of cochlear implant technology to restore access to the high-frequency hearing allowing a near normal hearing experience. The hybrid technology requires surgical implantation, similar to that of a standard cochlear implant with the main difference being that the array is shorter and therefore not inserted as far into the cochlear.
The United States Food and Drug Administration (FDA) approved the first hybrid cochlear implant in March of 2014. The Medical Technology and Assessment Committee (MTAC) has not previously assessed hybrid cochlear implants and is currently reviewing the topic to support a coverage decision.

08/17/2015: MTAC REVIEW

Hybrid Cochlear Implant

Evidence Conclusion: *Effectiveness*: A multi-centered European study, carried out by Lenarz and colleagues, investigated hearing conservation in 66 patients with significant low-frequency residual hearing using the Nucleus Hybrid L24 cochlear implant. The investigators compared pre- and post-operative performance in speech recognition scores in both quiet and noisy environments were significantly improved for 65% and 73% of subjects, respectively. In addition, the mean speech spatial and quality subscale ratings were significantly improved by 1.2, 1.3 and 1.8 points, respectively ($p<0.001$). Ultimately, the investigators concluded that the hybrid cochlear implant preserved low-frequency residual hearing and improved speech perception (Lenarz, James et al. 2013). [Evidence Table 1] A similar study, conducted by Roland et al. in multiple centers across the US, included 50 individuals with severe to profound high-frequency hearing loss. In the same way as the European trial, pre- and post-operative performance was measured on consonant-nucleus-consonant words, AzBio sentence noise as well as self-assessment. At six months, the investigators reported that a majority of the patients had statistically significant improvements in word and sentence recognition leading the investigators to conclude that the Nucleus Hybrid L24 cochlear implant provides significant improvements to hearing (Roland, Gantz et al. 2015). [Evidence Table 2]

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Safety: The safety profile on these devices is not entirely clear. Both of the included studies detail a number of adverse effects including dizziness, irritation and tinnitus to name a few. Beyond that, the literature reports risk of permanent damage to residual hearing fibers from the surgery and placement of the electrode itself. A larger long-term concern is associated with future changes in hearing in the implanted ear. Specifically, should the patient experience additional hearing loss, will they need additional surgery using a longer standard electrode. Collectively, the evidence is limited by small sample sizes, lack of randomization and inadequate comparison groups. To add to this, neither of the studies provide a sufficient follow-up period. Finally, both of the studies are sponsored by the device manufacturer leaving the studies open to potential bias. Ultimately, the evidence does not adequately support the safety and effectiveness of the hybrid cochlear implant. The evidence base would benefit from large RCTs with extended follow-up to establish long-term performance and safety.
Conclusions: There is insufficient evidence to support the effectiveness of a hybrid cochlear implant with external hearing aid compared with a standard cochlear implant. There is insufficient to establish the safety of hybrid cochlear implant with standard cochlear implant.
Articles: The search returned a small variety of publications including retrospective analyses, small single arm prospective studies and one cross-sectional study (Golub, Won et al. 2012; Nguyen, Mosnier et al. 2012; Reiss, Turner et al. 2012; Szyfter, Wróbel et al. 2013; Jurawitz, Büchner et al. 2014). The literature was specifically screened for randomized controlled trials (RCTs) with the overall aim to compare hybrid cochlear implants with conventional cochlear implants. In the absence of RCTs with appropriate comparators, the best available evidence came from two prospective, single arm studies (one of which supported the 2014 FDA approval) were selected for critical appraisal. The following articles were selected for review: Lenarz T, James C, Cuda D, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. *International Journal of Audiology*. 2013; 52:838-848. See Evidence Table 1. Roland JT, Gantz BJ, Waltzman SB, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. *Laryngoscope.* 2015. See Evidence Table 2.

The use of hybrid cochlear implants does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Cochlear Implant - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
HCPC Codes	**Description**
L8614	Cochlear device, includes all internal and external components
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement

Hybrid Cochlear Implant - Considered Not Covered:

Same as listed above and billed with HCPC Code	Description
L8614	Cochlear device, includes all internal and external components

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03/20/1995	09/07/2010 MDCRPC, 10/05/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013 MDCRPC, 01/07/2014 MPC, 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/01/2022MPC, 02/07/2023MPC	07/05/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt updates to the Cochlear Implant criteria (KP-0177) Specific changes include but not limited to: • No longer indicates a need to place one implant at a time and that evidence supports concurrent bilateral implants specifically for adults • Added “replacement exclusion” language from commercial contracts Removed non-applicable CPT codes: 69714, 69715, 69717, 69718
03/02/2021	MPC approved the updated recommendations to the current hybrid criteria for Cochlear Implant to include indications for unilateral sensorineural hearing loss for ages 5 years old and older. Requires 60-day notice, effective date 08/01/2021.
07/05/2022	MPC approved to update the hybrid criteria (KP-0177) to include indications for single-sided deafness and include clarifying language for obsolescence/warranty. Requires 60-day notice, effective date 12/01/2022.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Collagen Meniscus Implant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Collagen Meniscus Implant (150.12) *This service is not covered per Medicare criteria.*
Local Coverage Determinations (LCD)	None
Local Coverage Article	Collagen Meniscus Implant CAG-00414N

For Non-Medicare Members

Kaiser Permanente has elected to use the Collagen Meniscus Implant (A-0643) MCG* for medical necessity determinations. Per MCG guidelines this is a non-covered service. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or specialist

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Background

The knee meniscus is a fibrocartilaginous crescent-shaped structure that plays an important part in the biomechanics of the joint. It functions as load bearing, shock absorption, lubrication, and stabilization of the joint. The avascular nature of the articular cartilage and its hypocellular composition make it incapable of self-repair after injury. In the past, total or subtotal meniscectomy was routinely performed for patients with meniscal tears. This was based on the assumption that removal of the meniscus did not lead to adverse effects. More recently however, repair of the meniscus has become the standard treatment for tears, after studies have shown that total or even partial removal of the meniscus is associated with increased joint pressure, mechanical changes, and ultimately hyaline cartilage degradation and irreversible joint damage. If the meniscus is irreparable, arthroscopic partial meniscectomy of only the torn segments is recommended. In cases of substantial damage, subtotal or total meniscectomy may be inevitable. Researchers have evaluated different materials to substitute for the removed meniscus in order to avoid the joint deterioration that may occur after its removal (Rodkey 1999, Yoldas 2003).

The first meniscal transplantation was performed in the early 1990s. Over the years, different graft types were used including autogenous tissue, allograft tissue, and artificial material. More recently, a group of scientists used

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tissue engineering techniques to develop a collagen meniscus implant which serves as a scaffold to support the production of a new meniscus-like tissue rather than artificially replacing it. Collagen meniscus implants (collagen scaffold) are fabricated from type I collagen derived from bovine Achilles tendons. The bovine collagen fibers undergo several chemical treatments and techniques to purify them, after which they are swelled in hyaluronic acid and chondroitin sulphate, homogenized, precipitated, dehydrated and manually oriented in a mold which undergoes other processes and sterilization before they are ready for use. Collagen meniscus implants are provided as a semi-lunar shaped device with a triangular cross-section. The surgeon assesses the defect and trims the implant to the size necessary for repair of the damaged or weakened soft tissue (Rodkey 1999, Steadman 2005, Rodkey 2008).

Collagen meniscal implant is not intended to replace the entire meniscus as it requires a meniscal rim for attachment. In a routine arthroscopic surgical procedure, partial meniscectomy is performed to remove only damaged or pathological tissue, leaving the native meniscus intact. A specially designed arthroscopic measuring device is then used to determine the dimensions of the total meniscus and the defect. On the surgical field the collagen implant is trimmed to fit the lesion then delivered into the joint through a cannula, manipulated into the prepared lesion and fixed to the host meniscus rim with nonabsorbable sutures (Rodkey 1999, Steadman 2005, Rodkey 2008).

ReGen Collagen Scaffold (CS), now called Menaflex, was cleared by the FDA in December 2008 to be used in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. The patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization. The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. CS is not a prosthetic device and is not intended to replace normal body structure. It is contraindicated in patients allergic to bovine or other animal derived products, with an overly sensitized immune system, systemic or local infection, evidence of osteonecrosis in the targeted area, medical history of severe degenerative osteoarthrosis, or without an intact meniscal rim and anterior and posterior horns.

Medical Technology Assessment Committee (MTAC)

Collagen Meniscus Implant

04/06/2009: MTAC REVIEW

Evidence Conclusion: The published literature to date, does not provide sufficient evidence to determine the short-term or long-term safety and efficacy of collagen meniscus implants in reducing pain, restoring the knee function, and preventing degenerative osteoarthritis in patients with irreparable damage to the medial meniscus. The only published randomized controlled trial on collagen meniscal implants had several threats to its validity which make it hard to draw any conclusion on the benefits and harms associated with the implant. In addition to the relatively small size, short follow-up duration, and industry funding, the trial had potential selection and observational biases including; the inappropriate randomization process, unblinding of the patients and surgeons, vast differences in the postoperative rehabilitation programs received by the two treatment groups, performing follow-up arthroscopy only among the meniscal transplant group, and assessing improvement in activity level based on historical data subject to recall bias. Overall, the results of the trial show insignificant differences between patients receiving the collagen meniscus implant and the controls in reducing their pain and improving and/or restoring function.

Articles: To determine whether using collagen meniscus implants in patients with medial meniscus defects would lead to better clinical outcomes than total meniscectomy or implanting an allograft. To determine if using collagen meniscus implants is safe for the patient and whether it leads to long-term joint damage. The search yielded 14 articles. There was one RCT that compared collagen meniscus implant with partial meniscectomy and 4 very small case series with less than 15 patients each. All studies were conducted by the same group of investigators who developed the implant, except for a small case series with 8 patients. The RCT was selected for critical appraisal: Rodkey WG, DeHaven KE, Montgomery WH, et al. Comparison of the collagen meniscus implant with partial meniscectomy. J Bone Joint Surg Am 2008; 90:1413-1426. See Evidence Table.

The use of Collagen Meniscus Implants for the reinforcement and repair of soft tissue injuries of the medial meniscus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

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CPT® or HCPC Codes	Description
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)

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Date Created	Date Reviewed	Date Last Revised
05/15/2009	07/06/2010[MDCRPC],05/03/2011[MDCRPC],03/06/2012[MDCRPC],01/08/2013[MDCRPC], 11/05/2013 [MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	11/22/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
11/22/2017	Added MLN article

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KAISER PERMANENTE®

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Clinical Review Criteria

Combined Hydrogen/Methane Breath Test

- Diagnosing Small Intestinal Bacterial Overgrowth (SIBO)
- Fructose or Lactose Intolerance

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Diagnostic Breath Analyses (100.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Services	Criteria used
Diagnosing Small Intestinal Bacterial Overgrowth (SIBO)	Hydrogen/methane breath test covered only when ordered by Gastroenterologist for possible SIBO
Fructose or Lactose Intolerance	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Small intestinal bacterial overgrowth (SIBO) is characterized by a malabsorption syndrome due to abnormally large amounts of bacteria within the small intestine (Gasbarrini, et al. 2007). Symptoms include diarrhea, abdominal pain or cramps, nausea, constipation, acid reflux, bloating, flatulence, dehydration and fatigue. SIBO can also cause more severe symptoms including steatorrhea, anemia, bleeding or bruising, night blindness, bone pain, fractures, leaky gut syndrome, autoimmune reactions, weight loss and “failure to thrive”. Due largely to uncertainty with regard to definition and detection, the true prevalence of SIBO and its relationship to a number of clinical disorders remains unclear (Dukowicz, et al. 2007).

Direct aspiration and culture of jejunal fluid have traditionally been considered the “gold standard” for SIBO diagnosis. With results expressed as colony-forming units per milliliter of jejunal fluid (cfu/ml), a SIBO diagnosis is

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most commonly defined as >105 cfu/ml, however, the thresholds vary throughout the literature (Abu-Shanab and Quigley 2009; Dukowicz, et al. 2007). To add to this, aspiration and culture is expensive, invasive and difficult to perform requiring the passage of a tube under fluoroscopic guidance through the nose, throat, esophagus and stomach. Breath tests, on the other hand, escape these limitations and have been proposed as a simple tool for diagnosing SIBO. Based on the fact that only bacteria in the gastrointestinal tract can ferment unabsorbed carbohydrates and metabolize them into hydrogen and/or methane, the gases are absorbed into the bloodstream and subsequently excreted in the breath (Levitt, et al. 2006; Simren and Stotzer 2006). Put simply, breath tests measure the levels of hydrogen and/or methane gas in a breath (Ghoshal, et al. 2006).

Breath tests can be performed at home or in a clinic and require that the patient fast for 12 hours prior to testing, after which, the patient provides a baseline sample breath. After establishing a baseline measurement, the patient ingests a small amount of substrate, either lactulose or glucose, and subsequently, provides breath samples every 15 minutes for three to five hours. At this time, hydrogen/methane breath tests have not been standardized with protocols differing in dose and concentration of the test substrate, and duration of test time intervals (Bures, et al. 2010). In the same way, there have been no accepted criteria for what constitutes a positive result.

Hydrogen/methane breath tests have not been approved by the Food and Drug Administration (FDA).

Medical Technology Assessment Committee (MTAC)

Combined Hydrogen/Methane Breath Test

6/16/2014: MTAC REVIEW

Evidence Conclusion: Evidence on the validity of the lactulose breath test for the diagnosis of SIBO is conflicting. In 1990, Corazza and colleagues performed complete microbiological analyses of jejunal aspirates in 77 patients thought to have SIBO. Those results were then compared to glucose and lactulose breath tests. In the results, the investigators reported sensitivities of 62% and 68% for glucose and lactulose, respectively and specificities of 44% and 83% (Corazza, et al. 1990). See Evidence Table More recently, however, Ghoshal and colleagues performed both glucose and lactulose breath tests on 83 patients on two separate days and reported that, when compared to culture of small bowel aspirate, both glucose and lactulose breath tests had lower sensitivities (glucose 44%, lactulose 31%) and higher specificities (glucose 80%, lactulose 86%). The authors propose several theories to explain the low sensitivities, including non-hydrogen producing patients, and patients with high basal breath hydrogen levels despite adequate preparation (Ghoshal, et al. 2006). See Evidence Table While none of the studies measured safety outcomes or recorded adverse events, most of the literature identifies breath tests as simple, safe, and lacking invasiveness (Dukowicz, et al. 2007). Despite these advantages, there is a lack of uniformity regarding their protocol and interpretation. Furthermore, hydrogen and methane levels are affected by a number of factors including smoking, exercise, chewing gum, breath mints, and antibiotic use. Above all else, differences in bacterial flora among patients can determine responses to breath testing with about 10-15% of patients lacking bacteria capable of producing hydrogen. Ultimately, the absence of an established interpretation of the gold standard, limits the ability to firmly establish the diagnostic accuracy of breath tests for diagnosing SIBO leaving the validity of the test in question. Conclusion: There is insufficient evidence to establish the diagnostic accuracy of the combined hydrogen/methane breath test for diagnosing SIBO. There is insufficient evidence to conclude that the hydrogen breath test is not harmful to patients. There is insufficient evidence to determine the impact of the test on patient management.

Articles: There is extensive literature on the use of breath testing to diagnose SIBO with many publications addressing the prevalence of SIBO among patients with irritable bowel syndrome. Generally speaking, there is a greater body of published literature on the use of hydrogen breath testing with less literature specifically addressing the use of methane breath tests and combination hydrogen and methane breath tests. Two studies were identified that assess the utility and accuracy of SIBO. The following studies were selected for critical appraisal: Corazza GR, Menozzi MG, Strocchi A, et al. The diagnosis of small bowel bacterial overgrowth: reliability of jejunal culture and inadequacy of breath hydrogen testing. Gastroenterology. 1990;98(2):302-309. See Evidence Table Ghoshal UC, Ghoshal U, Das K et al. Utility of hydrogen breath tests in diagnosis of small intestinal bacterial overgrowth in malabsorption syndrome, and its relationship with oro-cecal transit time. Indian J Gastroenterology. 2006;25(1):6-10. See Evidence Table.

The use of Combined Hydrogen/Methane Breath Test for Diagnosing Small Intestinal Bacterial Overgrowth (SIBO) does not meet the *Kaiser Permanente Medical Technology Testing Criteria.*

Applicable Codes

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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
91065	Breath hydrogen or methane test (eg, for detection of lactase deficiency, fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit)

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Date Created	Date Reviewed	Date Last Revised
07/01/2014	07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC] , 09/03/2019[MPC] , 09/01/2020[MPC] , 09/07/2021[MPC] , 09/06/2022[MPC]	12/06/2016

[MPC] Medical Policy Committee

Revision History	Description
12/06/2016	Added language to cover test if ordered only by GI for possible SIBO

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Clinical Review Criteria
Complications of Non-Covered Services

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Benefit Manual Chapter 16, 180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

All services related to the non-covered services are excluded from coverage. However, certain contracts, but not all, have provisions to cover specific complications of non-covered services for acute medical complications. Contracts that have coverage may allow for coverage of specific medically necessary interventions to resolve an acute, potentially life threating medical complication (not necessarily covering non-acute issues). Refer to the member specific contract language to determine the benefit coverage for non-covered services. Coverage does not include complications that occur during or immediately following the non-covered service. Additional surgeries or other medical services to resolve other acute medical complications resulting from non-covered services shall not be covered.

Examples of -Non-covered complications may include but are not inclusive of the following possible situations:

- A nasal obstruction after cosmetic rhinoplasty
- Desired cosmetic outcomes not achieved
- Scarring of surgical wounds arising from a cosmetic procedure
- Request for removal of breast implants due to contracture or leakage, when placed for cosmetic purposes

All requests that appear to involve complications of a non-covered services, or any from dental services should be sent to the clinical review physicians for review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

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Background

Most Kaiser Permanente contracts state "Excluded: non-covered surgical services." In applying this exclusion guidance was requested by staff making coverage determinations. The above criteria were developed to provide guidance.

Creation Date	Review Dates	Date Last Revised
09/24/2007	04/06/2010[MDCRPC], 02/11/2011[MDCRPC], 02/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018 [MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/03/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/01/2015	Revised LCD L34886 and L35008 Non-Covered Services.
11/12/2018	Updated KPWA criteria for Non-Medicare Members
12/5/2018	Revised ALL reviews must go to Medical Director Review
05/07/2019	MPC approved to adopt criteria for complications of non-covered services
08/04/2020	Added Medicare LCA A57642
08/03/2021	Removed retired Medicare LCD L35008 and LCA A57642.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Compression Garments – Stockings/Sleeves

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Surgical Dressings (L33831)
Local Coverage Article	Surgical Dressings (A54563)

For Non-Medicare Members

Kaiser Permanente has elected to use the Graduated Compression Stockings/Sleeves (KP-0336) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Elastic stockings are generally stockings of 18-20 mm or less and can be purchased over the counter.

***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 12 months of clinical notes from requesting provider &/or specialist

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Background

Compression garments are usually made of elastic material and are used to promote venous or lymphatic circulation. Compression garments worn on the legs can help prevent deep vein thrombosis and reduce edema and are useful in a variety of peripheral vascular conditions. Compression garments can come in varying degrees of compression. The higher degrees require a physician's prescription.

Evidence and Source Documents

2/12/1986: LITERATURE SEARCH

Articles: The use of JOBST products for the treatment of burns is medically appropriate.

12/31/1999: LITERATURE SEARCH

Articles: Effective Health Care, NHS Centre for Reviews and Dissemination, University of York, August 1997, Volume 3:4, ISSN: 0965-0288.

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Twenty randomized controlled trials evaluated different forms of compression bandaging on venous ulcer healing in a wide range of age groups. Two of these incorporated economic evaluations, 2 compared compression stockings with compression bandages and 2 evaluated intermittent pneumatic compression. Overall, the quality of trials is poor. Six RCT's assessed whether compression therapy was better than no compression. These showed that compression provided by either Unna's boot, 2-layer, 4 layer or short stretch bandages improve healing rates compared to treatment using no compression. One study showed that compression was more cost effective because of faster healing rates saving nursing time. High compression showed the best healing rates. A combination of 2 compression stockings has been shown to increase the rate of healing compared to a short stretch bandage.
Compression stockings have been found to be more effective than drug therapy in the prevention of recurrence of leg ulcers.

White Paper - Kaiser on Benefits of Compression Therapy:
Venous ulcers can be healed, and recurrence prevented through the use of compression therapy (not TED hose). Recommend coverage of two pair a year and patients must wear all day every day. Compression therapy can prevent serious complications of venous insufficiency and reduce treatment costs.
Federal Post-Mastectomy Reconstructive Surgery Mandate: December 21, 1998 AAHP memo:
The Federal post-mastectomy reconstructive surgery mandate was contained in the Women's Health and Cancer Rights Act of 1998 that was included in the FY99 omnibus appropriations act (P.I., 105-277, enacted October 21, 1998). Under the new law most plans and insurers that provide coverage for medical and surgical benefits in connection with a mastectomy are required to provide reconstructive surgery benefits. Coverage includes reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce symmetrical appearance, and prostheses and treatment of physical complications at all stages of the mastectomy, including lymphedemas.
Yasuhara MD, Hiroshi et al., A Study of the Advantages of Elastic Stockings for Leg Lymphedema, *International Angiology,* Vol 15:3, 272-277, September 1996 See Evidence Table
G. Bertelli, et al, An analysis of prognostic factors in response to conservative treatment of postmastectomy lymphedema, Surgery, Gynecology and Obstetrics, Volume 175: 455-460, November 1992 See Evidence Table
Bunce, Ian H et al, Post-mastectomy Lymphedema Treatment and Measurement, *Medical Journal of Australia,* Vol 161: 125-128, July 18, 1994 See Evidence Table

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A6501	Compression burn garment, bodysuit (head to foot), custom fabricated
A6502	Compression burn garment, chin strap, custom fabricated
A6503	Compression burn garment, facial hood, custom fabricated
A6504	Compression burn garment, glove to wrist, custom fabricated
A6505	Compression burn garment, glove to elbow, custom fabricated
A6506	Compression burn garment, glove to axilla, custom fabricated
A6507	Compression burn garment, foot to knee length, custom fabricated
A6508	Compression burn garment, foot to thigh length, custom fabricated
A6509	Compression burn garment, upper trunk to waist including arm openings (vest), custom fabricated
A6510	Compression burn garment, trunk, including arms down to leg openings (leotard), custom fabricated
A6511	Compression burn garment, lower trunk including leg openings (panty), custom fabricated
A6512	Compression burn garment, not otherwise classified
A6513	Compression burn mask, face and/or neck, plastic or equal, custom fabricated
A6530	Gradient compression stocking, below knee, 18-30 mm Hg, each
A6531	Gradient compression stocking, below knee, 30-40 mm Hg, each
A6532	Gradient compression stocking, below knee, 40-50 mm Hg, each
A6533	Gradient compression stocking, thigh length, 18-30 mm Hg, each
A6534	Gradient compression stocking, thigh length, 30-40 mm Hg, each
A6535	Gradient compression stocking, thigh length, 40-50 mm Hg, each
A6536	Gradient compression stocking, full-length/chap style, 18-30 mm Hg, each
A6537	Gradient compression stocking, full-length/chap style, 30-40 mm Hg, each

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A6538	Gradient compression stocking, full-length/chap style, 40-50 mm Hg, each
A6539	Gradient compression stocking, waist length, 18-30 mm Hg, each
A6540	Gradient compression stocking, waist length, 30-40 mm Hg, each
A6541	Gradient compression stocking, waist length, 40-50 mm Hg, each
A6544	Gradient compression stocking, garter belt
A6545	Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each
A6549	Gradient compression stocking/sleeve, not otherwise specified
L8010	Breast prosthesis, mastectomy sleeve

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
12/31/1999	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 06/04/2013[MDCRPC],12/13/2013 [MPC], 10/07/2014[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	10/03/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Date Last Revised	Description
07/28/2015	Codes added and description of elastic stockings
08/26/2015	Added new LCD link
01/27/2016	Added Medicare coverage article
10/03/2017	Revised criteria to include indication: *Documented history of venous stasis ulcer within the last 2 years*

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KAISER PERMANENTE®

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Clinical Review Criteria

Continuous 24-hour monitoring of Intraocular Pressure

- SENSIMED Triggerfish® telemetric contact lens sensor (CLS; Sensimed AG, Lausanne, Switzerland)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Continuous 24-hour monitoring of Intraocular Pressure" for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Glaucoma is the second leading cause of blindness worldwide. It is a chronic optic neuropathy characterized by the loss of retinal ganglion cells and its axons. If left untreated, the condition progresses leading to reduction of the visual field and eventually loss of sight. Elevated intraocular pressure (IOP) is the only proven modifiable risk factor for the development and progression of glaucoma. Results of a pivotal glaucoma trial suggest that a 1 mmHg increase in IOP is associated with an 11% increase in the hazard ratio for the progression of glaucoma. Thus, the accurate measurement of IOP and its efficient control are essential in the management of glaucoma (De Smedt 2012, Freiberg 2012, Lorenz 2013, Mansouri 2012, 2013).

Some investigators reported that IOP fluctuates throughout the day (defined as nyctohemeral rhythm) in healthy and glaucomatous eyes and that understanding the IOP behavior over time is important for the management and treatment decisions. However, the role of IOP fluctuation as an independent predictive factor for glaucoma progression is still controversial. The current gold standard for measuring IOP is the Goldmann Applanation Tonometry (GAT), but it only provides a snapshot of IOP at a given moment and is normally used in the office by

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an ophthalmologist. The 24-hour IOP profiles are of increasing interest, and the repeated IOP measurements over 24-hour period may be performed using portable tonometry, but this can only provide multiple static and non-continuous snapshots for the IOP; up to one measurement per hour at the best. This also requires awakening the patient during the nocturnal sleep period which may potentially lead to stress-related artifacts and sleep disturbances. The 24-hour continuous use of GAT for assessing the IOP profile is only possible in specialized centers with a sleep laboratory (Mansouri 2013, Lorenz 2013, and Mottet 2013).

The SENSIMED Triggerfish® telemetric contact lens sensor (CLS; Sensimed AG, Lausanne, Switzerland) was recently developed to continuously monitor the IOP pattern in glaucoma in an ambulatory setting. The device does not directly measure IOP but is based on the assumption that there is a correlation between IOP and the corneal curvature. Its key element is a soft disposable silicone contact lens with an embedded microsensor that captures spontaneous circumferential changes at the corneoscleral area, allowing the measurement of changes in corneal curvature which are considered by investigators to be representative for IOP changes. The adhesive SENSIMED Triggerfish® Antenna, which is placed around the eye, wirelessly receives the information from the contact lens. Three hundred data points are acquired during a 30-second period every 5 minutes providing a total of 288 measurements over a 24-hour period. The data is transmitted through a thin flexible cable from the antenna to a portable recorder worn on the patient's waist. This stores the acquired data during the monitoring session. At the end of the recording period, the data is transferred via Bluetooth from the recorder to the software previously installed on the practitioner's computer for analysis. The CLS measurement is made automatically for a maximum of 24 hours (Frieberg 2012, Lorenz 2013, Mottet 2013, Hollo 2014, Manufacturer's webpage).
As indicated earlier, the CLS is based on an assumption that there is a correlation between IOP, and the corneal curvature and it can only provide indirect measurement of the IOP through changes in the corneal curvature. In addition, CLS does not display the output signal in mmHg, but in arbitrary units (au) that are proportional to the electric signal generated by the contact lens-embedded strain gauge. Calibration of the CLS output to mmHg is a challenge as the simultaneous use of CLS and tonometry on the same eye is not feasible. Another limitation is that CLS provides 288 IOP data points instead of a single one measurement (or 8 measurements typically obtained in a diurnal tension curve) which poses a challenge to the clinician. Since the output signal of the CLS is dependent on changes occurring at the corneoscleral junction, non-IOP-related changed in the corneal shape, hydration, or thickness may potentially affect the device output. It is also reported that information on the clinical meaning and practical value of the CLS curves is limited (Mansouri 2012, 2013, Mottet 2013, Hollo 2014).

The contact lens sensor (CLS) may lead to similar side effects caused by the classic vision correction contact lenses. Among the reported adverse effects were innocuous superficial corneal staining, corneal edema, superficial keratitis, and others (Mansouri 2012).

SENSIMED Triggerfish® was approved for use by the European regulatory authorities. It has not been approved by the US Food and Drug administration to date.

Medical Technology Assessment Committee (MTAC)

Continuous 24-hour monitoring of Intraocular Pressure

6/16/2014: MTAC REVIEW

Evidence Conclusion: The role of IOP fluctuation as an independent predictive factored for glaucoma progression is still controversial and has not been proved in large, well-designed prospective studies, to date. Also, the assumption that there is a correlation between IOP, and the corneal curvature is not universally accepted. The SENSIMED Triggerfish® telemetric contact lens sensor was not validated in humans, only in ex vivo in enucleated porcine eyes. The largest published study on continuous 24-hour monitoring of IOP patterns with contact lens sensor was conducted by Mansouri and colleagues (2012). They examined the safety, tolerability, and reproducibility of the device among 40 patients with established (n = 19) or suspected (n = 21) glaucoma in 2 study sessions conducted approximately 1 week apart. After a baseline ophthalmic examination, the patients were fitted with the CLS and re-examined after a 24-hour monitoring session. All participants underwent a second 24-hour monitoring session approximately 1 week later. Complete ophthalmic examinations were performed after each monitoring session, and any change from the baseline ophthalmic examination was reported as an adverse event (AE). Complete data recording was obtained from 37 patients in the first session and 39 patients in the second session. Data were not available for 4 patients' due poor battery or disconnection of the device or other unknown reason. The calculated Pearson correlation was (r = 0.59, P = .12) indicating fair to good agreement between the 2 sessions. Patient comfort level was assessed by visual analog scale, which showed moderate to good tolerability of the device (mean score 27.2 + 18.5mm in the first monitoring session and 23.8 + 18.7mm in the second session). 49 device-related adverse events occurred among 38 study participants (Table). All AEs were transient and resolved within 24 hours of CLS removal. Adverse events (AEs) in patients undergoing 24-hour intraocular monitoring with CLS

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Adverse events	No. of even	No. (%) of patients with AEs
Mild		32 (80)
Blurred vision	58	30 (75)
Conjunctival hyperemia	52	13 (32)
Eye complications associat	17	5 (12)
with device	5	3 (8)
Superficial punctate keratitis	3	3 (8)
Eye irritation	3	1 (2)
Eye pruritus	2	1 (2)
Ocular discomfort	1	1 (2)
Conjunctival edema	1	1 (2)
Device intolerance		
Moderate		
Superficial punctate keratiti	1	1 (2)
Blurred vision	1	1 (2)
Severe		
Conjunctival edema.	5	2 (5)

A more recent very small study (Hollo 2014) evaluated 24-hour continuous intraocular pressure (IOP) monitoring with a CLS to detect prostaglandin-induced IOP reduction. The study included nine ocular hypertensive and primary open-angle glaucoma patients. After a washed-out from IOP-lowering medication for 6 weeks, one study eye per patient underwent 3 baseline 24-hour measurement curves 4 days apart: 2 curves with Sensimed Triggerfish CLS and 1 curve with standard tonometry (GAT). The patients then received travoprost monotherapy for 3 months. The 24-hour CLS and tonometry curves were repeated on the study eyes after 3 months. The results showed that a significant decrease in IOP measured by the 24-hour GAT, but no significant difference was observed in the means of the 3 CLS curves. There was a high correlation between the 3 CLS curves but no correlation was seen between the CLS and GAT values either at baseline or under treatment. The authors concluded that these results suggest that the current CLS technique cannot be clinically used to monitor IOP decrease induced by topical medication in glaucoma and has limited value in identification of transient IOP elevation periods. Impact on management was studied in a small case series (Mansouri 2011) with 15 glaucoma patients with worsening disease despite the controlled IOP values as measured by office GAT. The 24-hour monitoring with CLS found that 9/13 (69%) of the patients who completed the 24-hour monitoring had the highest IOP during sleep. Based on the CLS findings, the management plan was changed in 11 (73%) patients.
There is a lack of published literature on 24-hour IOP monitoring using contact lens sensors.
Articles: The literature search did not reveal any validation study of the CLS or any other study that compared its accuracy with the gold standard of 24-hour GA, or trial that evaluated its clinical utility in managing patients with glaucoma. There was only a limited number of very small observational nonrandomized studies or case series that examined the safety and tolerability of the CLS. The population sizes varied between 5-15 subjects with only one study involving 40 individuals. The published studies were mainly conducted in Europe, particularly in Switzerland, mostly by the same group of authors, and sponsored by the SENSIMED the manufacturer of the SENSIMED Triggerfish® telemetric contact lens sensor.

The use of Continuous 24-hour monitoring of intraocular pressure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/01/2014	07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019 [MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	07/01/2014

[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Continuous Glucose Monitor (CGM)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Home Blood Glucose Monitors (40.2)
Local Coverage Determinations (LCD)	Glucose Monitors (L33822) Implantable Continuous Glucose Monitors (I-CGM) (L38659)
Local Coverage Article	Glucose Monitor – Policy Article (A52464) Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) (A58138)

For Non-Medicare Members

Kaiser Permanente has elected to use the Continuous Glucose Monitoring (KP-0126 09012022) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

> **MCG* are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed for heart transplant eligibility, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

*Note – Requests for an insulin infusion pump used with continuous glucose sensing (HCPCS code E0787 or E0784 + K0554 for Medicare) will only be authorized if the patient meets both criteria for continuous glucose monitor as outlined in this criteria and all criteria outlined in the Insulin Pump clinical review criteria including that current device is no longer under warranty.

Documentation requirements to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (endocrinology, primary care)
- Last 6 months of lab work
- Last 1-2 months of legible home monitoring logs or a printout of CGM results

ORDER FORM

Request for Approval of Patient-Use Continuous Glucose Monitoring System (CGMS)

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

Diabetes mellitus is one of the leading causes of death in the United States. If poorly controlled, it causes accelerated both large and small artery diseases that predispose patients to a number of late secondary complications including heart disease, stroke, renal, disease, peripheral vascular disease, retinal damage, peripheral nerve damage, and others. Management of diabetes involves maintaining blood glucose levels close to the normal range. Currently, self-monitoring of capillary blood glucose (SMBG), and laboratory testing of HbA1c, to measure longer term glycemic control, are the standard methods for glucose testing. Blood glucose values are influenced by a number of changing variables, including food choices and portions, stress, insulin doses, physical activity, and rate of nutrient absorption. SMBG is important for monitoring and treating fluctuations in blood glucose level, but it provides only a snapshot of glucose status at a given moment, and even compliant diabetics do not do perform it frequently enough to identify all the fluctuations in the blood glucose level, especially those that occur at night (Evert 2009).

In hopes of gaining a more complete picture of blood glucose level, researches have thus developed technologies for monitoring blood glucose concentrations on a continuous basis. Among these are the continuous glucose monitoring systems (CGMS) which are capable of monitoring interstitial glucose levels every 1-5 minutes. These systems consist of a small needle which is inserted in the abdominal subcutaneous fat. On the tip of the needle there is a glucose sensor that measures the glucose levels in the fluid surrounding the fatty tissue. There are two types of CGMS: retrospective systems and real-time systems. Both systems measure glucose concentration during a certain time span; however, these systems differ with regards to when the information is accessed. With the retrospective system data is stored in a monitor to be downloaded for later use while the real-time system continuously provides the actual glucose concentration on a display. It is thought that CGMS may help diabetic patients reach a near normal blood glucose pattern, assist in preventing hypoglycemic events, reduce emergency room visits, and decrease long-term complications by improving glycemic control (Cemeroglu 2010, Chetty 2008, De Block 2008, Girardin 2009, Langendam 2012).

Early generations of CGMS e.g. the GlucoWatch Biographer, and the physician use device MiniMed Continuous Glucose Monitoring System were uncomfortable and difficult to use. In addition, their results could only be determined in a physician's office and when graphed provided useful, but retrospective information about within- and between-day blood glucose variations and the frequency of unrecognized hypoglycemia. When compared with venous plasma glucose values, the interstitial fluid glucose sensor yielded lower values when blood glucose concentrations were rapidly rising. More recent devices were developed to overcome some of the earlier limitations, and several products that provide real-time information on glucose levels to patients rather than requiring data download in a providers' office are now available. These newer systems, however, still measure glucose in the interstitial space, and it takes time for interstitial glucose to achieve equilibrium with blood glucose (Reach, 2008, Cox 2009).

All continuous glucose monitoring devices consist of the same basic components: 1. A disposable short-term glucose sensor (a fine wire about the diameter of two hairs) which is placed under the skin and is worn for 3-7 days depending on the system (3 days for Guardian RT, 5 days for FreeStyle Navigator, or 7 days for DexCom Seven), 2. A reusable transmitter that is wirelessly attached to the sensor and conveys data to a receiver within a 5-10 foot range of the sensor, and 3. A pager-size receiver that displays current glucose values and recent trends. The receiver can be worn on the belt or carried in a pocket or purse. The process is very fast with measurements made every 10 seconds and then aggregated to give a value on the glucose monitor every 1-5 minute. High and low glucose value thresholds can be customized for individual patients and fed into the system. When these thresholds are exceeded, an alarm will sound. The receiver displays directional arrows to show the rate of change in glucose levels, allowing the patient to predict and possibly prevent hypoglycemic episodes. CGMS can be used continuously, as long as the sensors are replaced according to manufacturer recommendations. Continuous readings over a 24-hour period for up to seven days allow the user to detect variations and identify trends. Patients must initialize and calibrate the system whenever a new glucose sensor is inserted. They also need to calibrate it every 8-12 hours and before adjusting insulin therapy (Peters 2009).

Continuous glucose monitors are intended to be used as an adjunct, not a replacement, for self-monitoring of blood glucose. They should not be used to make therapeutic decisions; any readings that indicate hypo-or hyperglycemia events must be verified by SMBG before taking action. CGM systems have several limitations including:

1. They are not suitable for use by all patients and those who are likely to benefit from them are the motivated patients who know the importance of strict metabolic control, participate in the care of their diabetes, and are able to use the technology. Those who have poor control because of reluctance to perform SMBG would not comply with CGMS and will not benefit from its use.

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2. Patients need to learn how to use the large amount of data generated by the real-time CGMS.
3. The patients also need to be aware of the limitations of the systems as regards the lag time and calibration issues, and check with a standard blood glucose meter before making medication adjustments. They also need to understand the time of onset and peak of their insulin so that they make appropriate adjustments.
4. The insertion of the sensor under the skin is at times painful, and if it fails to calibrate another one has to be placed. Moreover, it needs to be firmly attached to the skin using tape, which may cause skin irritation or infection, and may become loose especially with sweating and exercise.
5. The functional operability of CGMS is limited to 2-7 days which might not be sufficient to detect recurrent glycemic patterns throughout the day or night.
6. Providers will have to find ways to incorporate the technology into their already busy clinical practice (De Block 2008, Hrabchak 2010, Ives 2010).

As of the current review the FDA-approved CGM real-time systems include:

- Medtronic Guardian Real Time Glucose Monitoring System that records glucose values for up to 3 days.
- Medtronic MiniMed Paradigm Real-Time System which integrates real-time CGM with an insulin delivery device and records glucose values for up to 3 days.
- DexCom SEVEN PLUS records glucose values for up to 7 days.
- Abbott FreeStyle Navigator provides continuous measurement for up to 5 days.
- The iPro Continuous Glucose Monitor (Medtronic, Inc) used only by the health provider and provides an average blood sugar measurement every 5 minutes for 3 days at a time.

The SEVEN PLUS and the FreeStyle Navigator are FDA approved for adults only. Pediatric versions of MiniMed Paradigm and Guardian systems are approved for use in patients 7-17 years. All systems require a prescription.

Medical Technology Assessment Committee (MTAC)

Continuous Glucose Monitoring

06/07/2001: MTAC REVIEW

Evidence Conclusion: The published evidence is insufficient to draw conclusions about the effect of continuous glucose monitoring on health outcomes. According to MiniMed, a multicenter outcome study is underway.
Articles: The literature search yielded 20 articles. Excluding review articles and opinion pieces, articles on other types of glucose monitoring or other aspects of diabetes control, there were two empirical articles, both of which were case series. One article had a sample size of 11 children and the other had a sample size of 9 adults. Due to the small sample sizes, evidence tables were not created.

Continuous Glucose Monitoring for the management of unstable diabetes is approved by the FDA, but does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/11/2004: MTAC REVIEW

Continuous Glucose Monitoring

Evidence Conclusion: *Pediatric population* - Three studies with the pediatric population were reviewed. The DirecNet study, a relatively large study with nearly 100 patients, evaluated the accuracy of the CGMS in children during a 24-hour hospital stay. It did not specifically include children with diabetes management problems. The authors found a relatively low accuracy. According to Clarke error grid, 61% of the decisions using the CGMS would lead to clinically correct treatment decisions (Zone A). Newer modified sensors appeared to be more accurate (78% of measurements were in Zone A compared to 58% with older original sensors). The newer sensors were also more reliable than the original sensors, but measurement taken by two new sensors differed from one another by more than 20% about one-fourth of the time. The Ludviggson study, a randomized cross-over design, focused on changes in HbA1c during three months with the benefit of data from the CGMS and three months without CGMS data. Eligibility included an initial HbA1c ³6.8%. When each time period was examined separately, there was not a statistically significant benefit from having CGMS data available. When data from both periods were combined, there was a significant decrease in mean HbA1c in the study arm using CGMS data, but not the other arm. The authors did not compare the change in HbA1c in the arm using CGMS data versus the other arm and had several threats to validity including lack of a wash-out period. The Kaufman study included patients with glucose management problems. The study found that data from the CGMS leads to changes in the recommendation for patient management. However, the authors did not discuss the impact of these changes on health outcomes. In summary, the limited evidence suggests that the accuracy of the CGMS in children may not be sufficiently high. The evidence is insufficient to determine the effect of continuous glucose monitoring on improving health outcomes. *Adult population* - There is less published empirical evidence in the adult population and no high-quality studies on accuracy. The best available study (Yogev) was on pregnant women with type 1 diabetes (not on patients with uncontrolled diabetes). In this sample, continuous glucose monitoring detected

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hyperglycemia that was not detected by self-blood glucose monitoring in all 34 patients and nocturnal hypoglycemia in 26 (76%) patients. Recommendations to change insulin treatment were made for 24 out of the 34 (70%) patients. However, the authors did not present data on how the change in recommendations affected maternal or neonatal outcomes.
Articles: The Medline search yielded 52 articles, some of which were reviews or opinion pieces, were on technical aspects of glucose monitoring or had outcomes unrelated to the accuracy of the glucose monitor e.g. changes in blood glucose with a low glycemic diet. *Pediatric population* - The search yielded 5 empirical articles. One had a sample size of only 9 patients (Caplin, 2003). Another was a case series with 28 patients and appeared to be relatively weak methodologically (e.g. only included 28 out of the 44 children who used the monitor in the analysis, did not discuss management changes following use of the monitor) (Salardi, 2002). The remaining 3 studies, one of which was a randomized cross-over trial, were critically appraised: Diabetes Research in Children Network (DirecNet) Study Group. The accuracy of the CGMS in children with type 1 diabetes: Results of the diabetes research in children network (DirecNet) accuracy study. Diabetes Technol Ther 2003; 5: 781-789. See Evidence Table. Kaufman FR, Gibson LC, Halvorson M. A pilot study of the continuous glucose monitoring system. Diabetes Care 2001; 24: 2030-2034. See Evidence Table. Ludvigsson J, Hanas R. Continuous subcutaneous glucose monitoring improved metabolic control in pediatric patients with type 1 diabetes; A controlled crossover study. Pediatrics 2003; 111: 933-938. See Evidence Table. *Adult population* - The search yielded 4 empirical articles. One was specifically on diabetic patients needing dialysis and included only 8 patients. Two other studies each included only 18 patients. The remaining study, which studied pregnant women with type 1 diabetes, was critically appraised: Yogev Y, Chen R, Ben-Haroush A. Continuous glucose monitoring for the evaluation of gravid women with type 1 diabetes mellitus. Obstet Gynecol 2003; 101: 633-638. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/30/2005: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: The new studies published after our last review of 2/11/2004 were evaluated. There was only one RCT with just over 100 patients (Tanenberg 2004), that compared the hemoglobin A1c values between patients who used the CGMS to those who underwent self-monitoring. The difference between the two groups in the HBA1c was not statistically significant.
Articles: Tanenberg R, Bode B, Lane W et al. Use of the continuous glucose monitoring system to guide therapy in patients with insulin-treated diabetes: A randomized controlled trial. Mayo Clin Proc 2004; 79: 1521-1526. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/07/2006: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: There are no published studies to date that evaluate the impact of real-time glucose monitor use on diabetic complications. There are also no published studies evaluating the accuracy or effectiveness of the Medtronic MiniMed Guardian RT device, or the consistency of measurements of either the Guardian RT or DexCom STS when multiple devices are worn. One published empirical study on the DexCom STS system was identified. The study evaluated both device accuracy compared to self-monitoring of glucose measurements and impact on short-term glycemic control. In 47 patients, 95% of paired sensor-home monitoring data points over nine days were in Clarke error grid regions A (clinically accurate) or B (acceptable). In addition, compared to a control group (n=44) that used devices but did not receive display information, there was a statistically significant improvement in glycemic control (more time in target glucose range, less time in hypoglycemic and hyperglycemic ranges). Conclusions cannot be drawn about the intermediate or long-term impact of the DexCom STS on glycemic control-- patients were only followed during the nine days devices were worn. Another remaining issue is the 15-30-minute lag time between interstitial glucose readings and blood glucose levels when the blood glucose is rising or falling quickly.
Articles: No published empirical studies evaluating the Guardian RT were identified. One published empirical study on the subcutaneous DexCom STS was identified. This was a randomized controlled trial with 91 patients and was critically appraised: Garg S et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor. Diabetes Care 2006; 29: 44-50. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*
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08/04/2008: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: *Accuracy/Reliability* the Garg et al. (2006) study, previously reviewed by MTAC, found that the DexCom STS device was reasonably accurate compared to self-monitoring of blood glucose. >95% of 6,767 paired sensor-SMBG data points were in Clarke error grid regions A or B (clinically accurate or acceptable, respectively). An issue identified was the 15-30-minute lag time between interstitial glucose readings and blood glucose levels when the blood glucose is rising or falling quickly. Weinstein et al. (2007) also found >95% of paired sensor-venous blood sample data points were in Clarke error grid regions A or B when the FreeStyle Navigator was tested in an inpatient setting in adults. A smaller study of the FreeStyle Navigator in children (Wilson et al., 2007) identified a lag time, with Navigator readings lagging behind reference values during times of rapid rates of change in glucose levels. Impact: There is insufficient evidence on the impact of real-time continuous glucose monitor use on diabetic complications, hospitalizations and ER visits. There is fair evidence from one RCT (Deiss et al., 2006) that there are greater improvements in HbA1C levels of children and adults when a Guardian RT is worn continuously, but not intermittently, compared to self-monitoring of blood glucose. Limitations of the RCT were that it was sponsored by Medtronic, the device manufacturer, and the process for using glucose monitor data to make changes to patient treatment was not well described. There is insufficient evidence that other commercially available real-time continuous glucose monitors, the DexCom STS or Seven, and the Abbott FreeStyle Navigator, impact glycemic control. Only case series were available. A series of 140 patients (Bailey et al., 2007) found a significant reduction in HbA1c level after 12 weeks of continuous glucose monitoring with the DexCom STS. Significant reductions in HbA1c over 13 weeks were also found in small case series with children who were managed with the FreeStyle Navigator. The available evidence is insufficient to evaluate the impact of real-time continuous glucose monitors on detection of hypoglycemic episodes, larger sample sizes and longer follow-up are required.
Articles: No published empirical studies evaluating the Guardian RT were identified. One published empirical study on the subcutaneous DexCom STS was identified. This was a randomized controlled trial with 91 patients and was critically appraised: Garg S et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor. Diabetes Care 2006; 29: 44-50. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/21/2010: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion:
Conclusion: There is insufficient evidence to determine the accuracy and reliability of the 7-day continuous glucose monitoring systems. There is fair evidence that the use of CGMSs including the 7 day is associated with a significant reduction in HbA1c levels among highly selected motivated 25 years of age or older patients with type 1 diabetes. There is insufficient evidence to determine whether use of the 7-day real-time continuous glucose monitoring systems leads to better patient-oriented health outcomes (e.g. hospitalizations, ER visits, and microvascular and macro vascular diabetic complications).
Long-term studies are needed to confirm the potential benefits of CGMS in preventing hypo-and hyperglycemic episode, improving the patient's quality of life and potentially reducing the likelihood of complications that may develop.
Articles: Accuracy/Reliability of CGMS: The literature search revealed the STAR 1 trial (2008) evaluating the MiniMed Paradigm Real-Time System which is sensor augmented insulin pump, the Real Trend study (2009) on the Medtronic MiniMed Paradigm Real-Time System, the MITRE trial (2009) that used the MiniMed CGMS and GlucoWatch which is no longer available commercially and a small study (N=14) by Garg and colleagues (2010) that compared the SEVEN and FreeStyle Navigator CGMS, as well as a meta-analysis of studies published up to March 2007. Impact of CGMS on health outcomes:
The ideal study would be a randomized trial comparing health outcomes in patients managed using a real-time CGMS compared to standard self-monitoring. The literature search did not identify any published RCTs that evaluated the impact of CGMS on hospitalizations, ER visits, microvascular or microvascular diabetic complications. There was a relatively large trial by the Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Group (2008) that used change in the HbA1c as a surrogate outcome for diabetes control. This study was selected for critical appraisal. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Group. Tamborlane WV, Beck RW, Bode BW, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008;359:1464176 See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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08/20/2012: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion:
Conclusion: For CGM to be considered a useful technology, it needs to be accurate, reliable, and reproducible for reflecting a patient's plasma glucose values, especially in the lower glucose range to help avoid hypoglycemia and allow patients to achieve lower HbA1c with less hypoglycemia. However, current data do not allow this conclusion. Even when taking the average of four sensors worn simultaneously (an impractical approach for everyday use) results vary from the true plasma glucose value by 25 – 50% almost 20% of the time when patients true blood glucose values were less than 70 mg/dL. Additionally, most studies show no or only trivial improvement in HbA1c, that is not sustained overtime. Results from current data suggest that it is unlikely that everyday use of CGM will result in decreased hypoglycemia or lower HbA1c.
Articles: No studies were identified that addressed patient-oriented health outcomes. Several meta-analyses and three randomized controlled trials (RCTs) published after the meta-analyses were identified that addressed the effects of CGMS on glycemic control. The most recent meta-analysis, two RCTs, and an observational study published after the meta-analysis were selected for review. The other RCT was not selected for review due to methodological limitations (i.e., not stated if an intent-to-treat analysis was performed, power was not assessed, and baseline characteristic were not similar). The following studies were selected for critical appraisal:
Langendam MW, Luijf YM, Hooft L, Devries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database Syst Rev.* 2012;1:CD008101. See Evidence Table
Riveline JP, Schaepelynck P, Chaillous L, et al. Assessment of patient-led or physician-driven continuous glucose monitoring in patients with poorly controlled type 1 diabetes using basal-bolus insulin regimens: a 1-year multicenter study. *Diabetes Care.* 2012; 35:965-971. See Evidence Table**.** Castle JR, Pitts A, Hanavan K, et al. The accuracy benefit of multiple amperometric glucose sensors in people with type 1 diabetes. *Diabetes Care.* 2012; 35:706-710. See Evidence Table. Mauras N, Beck R, Xing D, et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. *Diabetes Care.* 2012; 35:204-210. See Evidence Table

The use of continuous glucose monitoring in the diagnosis of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/20/2017: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion:
Conclusion:
- Moderate evidence shows that the Continuous Glucose Monitoring system with the use of multiple daily insulin injection may be more effective in HbA1c and glycemic variability in adults with type 1 Diabetes Mellitus than self-monitoring blood glucose on the short term; no major adverse events were reported
- Moderate evidence shows that continuous Glucose Monitoring with the use of insulin pump may be more effective on HbA1c in adults with T1DM than self-monitoring blood glucose on the short term; no statistically significant difference in time spent in hypoglycemia was found
- In patients with T2DM, Hayes conclusion can be adopted: there is conflicting evidence concerning efficacy
- The technology is safe. Studies with longer follow-up are warranted.

Articles: Beck, R. W., Riddlesworth, T., Ruedy, K., Ahmann, A., Bergenstal, R., Haller, S., Polonsky, W. (2017). Effect of Continuous Glucose Monitoring on Glycemic Control in Adults with Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA, 317(4), 371-378. Benkhadra, K., Alahdab, F., Tamhane, S., Wang, Z., Prokop, L. J., Hirsch, I. B., Murad, M. H. (2016). Real Time Continuous Glucose Monitoring in type 1 diabetes: A Systematic review and Individual Patient Data Meta-Analysis. Clinical Endocrinology. Gu, W., Liu, Y., Chen, Y., Deng, W., Ran, X., Chen, L. Mu, Y. (2017). Multicentre randomized controlled trial with sensor-augmented pump vs multiple daily injections in hospitalized patients with type 2 diabetes in China: Time to reach target glucose. Diabetes Metab. doi: 10.1016/j.diabet.2016.12.009
Lind, M., Polonsky, W., Hirsch, I. B., Heise, T., Bolinder, J., Dahlqvist, S., Wedel, H. (2017). Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults with Type 1 Diabetes Treated with Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA, 317(4), 379-387. van Beers, C. A., DeVries, J. H., Kleijer, S. J., Smits, M. M., Geelhoed-Duijvestijn, P. H., Kramer, M. H., . . . Serne, E. H. (2016). Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. Lancet Diabetes Endocrinol, 4(11), 893-902. doi:10.1016/s2213 8587(16)30193-0.

Applicable Codes

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Continuous Glucose Monitor (not implanted)

Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102	Adjunctive continuous glucose monitor or receiver
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
E2102	Adjunctive continuous glucose monitor or receiver
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Implantable Continuous Glucose Monitors (I-CGM)
Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare – Considered not medically necessary

CPT® or HCPC Codes	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
A4238	A4238 Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102	Adjunctive continuous glucose monitor or receiver

Date Created	Date Reviewed	Date Last Revised
06/07/2001	07/06/2010[MDCRPC],04/05/2011[MDCRPC],07/05/2011[MDCRPC],05/01/2012[MDCRPC], 09/04/2012 [MDCRPC],07/02/2013[MDCRPC],08/06/2013[MPC],12/03/2013[MPC],10/07/2014[MPC], 11/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	01/09/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
08/04/2015	• Removal of with a negative C peptide an indication • "Criteria for current users and for annual evaluation" was changed to "For ongoing approvals of supplies and/or replacement of current CGM"
04/03/2018	MPC approved to revise indication to criteria: *Patient is motivated, and has monitored and documented blood glucose 4 or more times per day for 2 months (change to 1 month)*
08/27/2018	Added Free Style Libre non-coverage language
09/13/2018	Removed Medicare from the Free Style Libre language
03/11/2019	Clinical review is no longer required for 72-hour evaluation
12/03/2019	MPC approved to revise criteria to address pediatric population and avoid delays in receiving a continuous glucose monitor when a pediatric patients' condition warrants.
11/03/2020	MPC approved to revise hybrid criteria to remove specific qualifiers for hypoglycemia and type I diabetes, removed statement that Freestyle Libre not on formulary for non-Medicare members, updated CGM order form (link in criteria), and added note about combined insulin pump/CGM device
02/16/2022	Updated applicable codes
04/05/2022	MPC approved to update CGM criteria to remove the 4x/day blood glucose checks, added indications for patients with dexterity or visual impairments. Requires 60-day notice, effective date 09/01/2022. Updated applicable codes.
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
01/09/2023	Added new HCPC codes A4239 and E2103 effective 1/1/2023.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Restorative and Cosmetic Procedures

- Abdominoplasty
- Panniculectomy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 16 - General Exclusions from Coverage, Section 120
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Article	Billing and Coding: Plastic Surgery (A57222)

For Non-Medicare Members

Cosmetic Surgery is performed to reshape normal structures of the body in order to improve appearance in the absence of a specific functional improvement. Surgery performed to improve on "natural" appearance or performed purely for the purpose of enhancing one's normal appearance is not considered reasonable and necessary.

Reconstructive Surgery is performed to restore bodily function or to correct a deformity resulting from disease, injury, trauma, birth defects, congenital anomalies, infections, burns, or previous medical treatment, such as surgery or radiation therapy. The primary goal is to restore function. Reconstructive surgery is reasonable and necessary to improve the functioning of a malformed body part. Please refer to member's contract for specific coverage regarding congenital anomalies.

I. Abdominoplasty

1. Abdominoplasties are not covered as they are considered cosmetic.
2. Diastasis recti treatment - Treatment of diastasis recti is considered cosmetic as the separation/laxity of the muscles of the abdominal wall is not considered a true hernia and the treatment does not address a physical functional condition.

Panniculectomy: is covered when **ALL of the following** criteria are met:

1. Panniculus hangs below the level of the pubis (documented by photographs)
2. Documentation in the medical record of the presence of significant complications including one or more of the following, requiring at least two office visits for treatment:
   a. The excess skin is the primary cause of at least one episode of cellulitis requiring systemic (oral or intravenous) antibiotics

   OR

   b. Transdermal skin ulcerations in the skin folds that are recurrent or refractory to medical treatment.
3. If the procedure is being performed following significant weight loss, in addition to meeting the criteria noted above, there should be evidence that the individual has maintained a stable weight for at least six months. If the weight loss is the result of bariatric surgery, procedure should not be performed until at least 18 months after bariatric surgery.

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4. There is a functional deficit (interference with activities of daily living) due to a severe physical deformity or disfigurement resulting from the excess skin.
5. The surgery is expected to restore or improve the functional deficit.
6. BMI must be < 35
7. No diabetes, or diabetes with HbA1c < 7.5
8. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery
9. Not covered when performed in conjunction with abdominal or gynecological procedures (e.g., abdominal hernia repair, hysterectomy, obesity surgery) unless criteria for panniculectomy are met separately
10. Not covered to minimize the risk of hernia formation or recurrence

Procedures to remove excess skin in the arms, buttocks, hips, legs, thighs, or torso are considered cosmetic as these procedures do not address any physical functional condition.

I. Dental/orthodontic procedures for craniofacial anomalies – for baseline policy for all plans, as they renew on or after 1/1/2021, click here to view the policy.

See individual links below for the following potentially cosmetic procedures:

- Blepharoplasty
- Dermatology Services
- Dermal Fillers for Facial Lipoatrophy (Sculptra/Radiesse)
- Reduction Mammoplasty
- Rhinoplasty
- Breast Reconstruction
- Skin Lesions
- Vein Procedures

The following are considered cosmetic in nature and non-covered under member's contract:

- Cervicoplasty ("neck lift")
- Collagen injection
- Hair Transplant
- Canthoplasty ("outer eyelid lift surgery") except in the setting of skin cancer excision

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Kaiser Permanente coverage contracts exclude cosmetic procedures. However, some procedures may be medically necessary when certain clinical criteria have been met. This document has been created to provide guidance to physician's reviewers when reviewer requests to cover potentially cosmetic services.

Evidence and Source Documents

Member contract

Applicable Codes

Panniculectomy - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description

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15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy

Excision of Excess Skin
Considered Not Medically Necessary

CPT® Codes	Description
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area

Abdominoplasty

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)

Lipectomy

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

Cervicoplasty - Considered Not Medically Necessary:

CPT® Codes	Description
15819	Cervicoplasty

Canthoplasty - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
67950	Canthoplasty (reconstruction of canthus)

Otoplasty - Considered Not Medically Necessary:

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CPT® Codes	Description
69300	Otoplasty, protruding ear, with or without size reduction

Hair Transplant

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts

Tissue Expanders - Considered Not Medically Necessary:

CPT® Codes	Description
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant

Wrinkle Removers - Considered Not Medically Necessary:

CPT® Codes	Description
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap

Collagen Injections - Considered Not Medically Necessary:

CPT® Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Dates Reviewed	Date Last Revised
07/01/2005	07/01/2005[MDCRPC], 05/30/2006[MDCRPC], 11/20/2006[MDCRPC], 12/22/2006[MDCRPC], 10/15/2007[MDCRPC], 06/09/2008[MDCRPC], 04/13/2009[MDCRPC], 02/2/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 07/02/2013[MDCRPC], 03/04/2014[MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC] , 06/07/2022[MPC] 06/06/2023[MPC]	11/06/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
11/01/2015	Changed Medicare links
05/03/2016	Added definitions for Cosmetic vs. Reconstructive Surgery. Added a list of non-covered cosmetic services
12/19/2017	Added LCD 37020
05/18/2020	Added clarifying language to canthoplasty “except in the setting of skin cancer excision”
06/01/2021	Removed reference to retired LCD Cosmetic vs. Reconstructive Surgery (A52729) for Medicare as it was replaced with the Plastic Surgery LCD/LCA. Updated applicable codes.
09/07/2021	MPC approved to adopt updates to the clinical indications for panniculectomy and updated excess skin removal from the arms, buttocks, hips, legs, thighs, or torso to cosmetic/not medically necessary for Non-Medicare members. Requires 60-day notice, effective date February 1, 2022.
11/06/2021	Added clarifying language to Reconstructive Surgery definition “Please refer to member’s contract for specific coverage regarding congenital anomalies.”

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Date Sent: 6/28/23
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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Collagen Cross-Linking for the Treatment of Keratoconus

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Collagen Cross-Linking for the Treatment of Keratoconus*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

A. To qualify for photochemical cross-linkage using riboflavin and Ultraviolet A light **ALL** of the following must be met:
   1. Has a diagnosis of keratoconus
   2. Patient is not older than 50 years old
   3. Treatment is limited to a once in a lifetime

Notes:
Kaiser Permanente considers epithelium-off photochemical collagen cross-linkage using riboflavin and ultraviolet medically necessary for keratoconus. For any other diagnosis, such as keratectasia, collagen cross-linking is considered experimental and investigational, as the effectiveness has not been established. Epithelium-on (transepithelial) collagen cross-linkage and performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) is considered experimental and investigational.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

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Keratoconus is a disease of the cornea that is characterized by a gradual thinning and protuberance of the cornea resulting in visual damage. The cause of keratoconus is not known; its prevalence varies from 50 to 230 per 100,000 (Kennedy, Bourne et al. 1986, Heidecke, Burkert et al. 2008) and the association between African Americans and Latinos and keratoconus has been described (Woodward, Blachley et al. 2016). Several risk factors have been identified; these include eye-rubbing, contact lens use, systemic disorders (Down syndrome, Ehlers-Danlos syndrome, and osteogenesis imperfecta), family history, and environment (asthma, atopic disease) (Gasset, Houde et al. 1978, Rabinowitz 1998, Sugar and Macsai 2012, Woodward, Blachley et al. 2016).

Clinical characteristics include bilateral or unilateral visual impairment, sudden decrease in visual acuity, and/or astigmatism. Patient may also present with difficulty with visual correction and protrusion of the cornea with an indentation of the lower eyelid on downgaze. Disease progression is marked by corneal hydrops. Diagnosis can be done by slit lamp examination when the disease progresses. The mainstay of treatment is the correction of the vision which can be performed with spectacle correction, contact lens, surgical treatments or intrastromal corneal ring, keratectomy, keratoplasty (corneal implantation) and collagen crosslinking (CXL).

Corneal collagen crosslinking aims to slow the progression of keratoconus by increasing covalent bonds in the cornea. During the corneal crosslinking treatment, riboflavin drops saturate the cornea, which is then activated by ultraviolet light. In laboratory and clinical studies this procedure has been shown to strengthen the cornea. CXL is not a cure for keratoconus. The goal of this treatment is to stop the progression of keratoconus and prevent further deterioration in vision. The procedure consists of applying riboflavin every 3-5 minutes for 25-30 minutes and irradiating the cornea with UVA light after removal of the corneal epithelium. Then bandage lens is applied, and assessment of re-epithelialization is performed about one week after the treatment. The intervention lasts one hour to 90 minutes. Although no approval statement was found on the Food and Drug Administration website, Avedro, the manufacturer of Photrexa® Viscous, Photrexa® and KXL® System indicated that in 2016, the US Food and Drug Administration approved corneal collagen cross-linking using riboflavin and UV for progressive keratoconus (Avedro 2016). Collagen crosslinking is believed to flatten the cornea and improve vision.

Medical Technology Assessment Committee (MTAC)

Collagen Cross-Linking for the treatment of Keratoconus

09/19/2016: MTAC REVIEW

Evidence Conclusion: Two randomized trials were critically appraised. These studies assessed the efficacy and effectiveness of CXL. Comparison was made between CXL and no treatment or between CXL and riboflavin only. Baseline characteristics were similar between the groups and patients were followed up for one year. The results showed that CXL led to positive outcomes by reducing corneal steepness and asphericity. Adverse events were reported, and these include corneal opacity, eye pain, punctate keratitis, blurry vision, corneal striae and corneal epithelial defect. However, the open label nature of the design, the lack of clarification on how the sequence generation was performed, the lack of information of allocation concealment, the short follow-up (1 year), the small sample size, and the fact that the sponsor of one of the trials was the manufacturer compromise the validity of the studies. The body of evidence is also constituted of prospective and observational studies. The sample size in these studies varied from 13 to 97 and a reduction in keratoconus progression was globally observed. It is worth noted that the follow-up period varied from 6 to 24 months. No meaningful conclusion can be reached because these studies are non-comparative studies.

Conclusion:
The body of evidence is of low quality and there is insufficient evidence to determine whether CXL is effective and safe in stopping the progression of keratoconus as compared to the use of alternative treatments.

Articles:
The literature revealed a number of articles; the following articles were selected for critical appraisal:
Safety and Effectiveness of the UV-X System for Corneal Collagen Cross-Linking in Eyes with Progressive Keratoconus (NCT00647699)
https://clinicaltrials.gov/ct2/show/results/NCT00647699?term=corneal+collagen+crosslinking&rank=19&sect=X016 See Evidence Table 1 (not peer reviewed). Corneal collagen crosslinking for progressive keratoconus in Saudi Arabia: One-year controlled clinical trial analysis (Khattak, Nakhli et al. 2015) See Evidence Table 2.

The use of Collagen Cross-Linking for the treatment of Keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (Report medication separately)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/04/2016	10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/07/2020

[MPC] Medical Policy Committee

Revision History	Description
10/04/2016	Created document & added MTAC review
11/01/2016	MPC approved criteria of medical necessity for collagen cross linking for the treatment of keratoconus
07/09/2019	MPC approved to change age indication from 40 years old to 50 years old
07/07/2020	Removed LCD L35008 and added Kaiser Permanente Medical Policy statement for Medicare

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Clinical Review Criteria

Cryosurgery

- Cryosurgical Ablation (CSA) for Breast Cancer and Benign Lesions
- Cryosurgical Ablation (CSA) for Liver Tumors
- Cryosurgical Ablation (CSA) for Prostate Cancer
- Cryosurgical Ablation (CSA) for Renal Tumors
- Cryosurgical Ablation (CSA) for Lung Cancer

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Cryosurgery of Prostate (230.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	**For Breast Cancer and Benign Lesions*:*** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cryosurgery"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Indication	Criteria Used
Breast Cancer and Benign Lesions	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Cryosurgical Ablation (CSA) for Liver Tumors Cryosurgical Ablation (CSA) for Lung Cancer Cryosurgical Ablation (CSA) for Prostate Cancer Cryosurgical Ablation (CSA) for Renal Tumors	Medical necessity review no longer required.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Cryosurgery has been known for years, but the recent changes in the technology and the development of improved cryosurgery units are permitting its clinical use. Cryoablation is a technique that uses liquid nitrogen or argon gas to freeze and ablate tissues. Cryoablation is mainly performed laparoscopically under real time ultrasound guidance.

It is reported that the critical temperature that leads to cancer cell destruction is approximately –40°C. Normal and neoplastic tissues are ablated and rendered necrotic at temperatures of –20°C (Chosy, 1996). During cryosurgery, the temperature is lowest at the center of the iceball with an incremental increase towards the periphery. Thus, with a cryoprobe tip temperature of –185° to-195°C, the temperature will be approximately 0°C at outer edge of the ice ball, –20°C at a distance of 4mm, and –40°C at a distance of 6mm towards the center of the iceball. It is important that the edge of the cryolesion be 1 cm beyond the margin of the tumor to make sure that a lethal temperature of –40°C or less was achieved throughout the tumor. The effect of cryosurgery occurs in two phases, freezing and thawing. The freezing phase is performed rapidly, and passive thawing is performed more slowly for a maximum effect. A double freeze-thaw cycle is usually performed to ensure the extension of the iceball to approximately 1 cm beyond the tumor edge.

The size of the cryolesion depends on several factors, including the temperature at the tip of the cryoprobe, area of tissue contacts, freeze time, and tissue vascularity. The response of a tumor to cryoablation depends on its biological characteristics e.g. density, specific heat, thermal conductivity, and rate of blood flow (Gage 1992).

Evidence/ Source Documents

Breast Cancer/Lesions

Medical Technology Assessment Committee

Cryoablation for Breast Cancer or Benign Fibroadenomas of the Breast

BACKGROUND

Cryoablation has been used to treat liver and prostate tumors. It is also proposed a treatment for small breast cancers and benign fibroadenomas of the breast. Cryoablation kills tumor cells by alternately freezing and thawing a target tissue. Freezing injures individual cells at the time of treatment. In addition, the tissue as a whole is affected because microcirculation is damaged. Cell necrosis during cytoablation depends on the lowest temperature achieved and the hold time at subzero temperatures. It is believed that uniform ablation can be achieved when tissue is exposed to at least -40oC during two consecutive freeze thaw cycles (Whitworth & Rewcastle, 2005). The procedure for using cryoablation to treat breast tumors is as follows: Using ultrasound guidance, a cryoprobe is inserted through a 3mm skin incision into the center of the tumor. Ultrasound is used to guide the cryoprobe, and also to monitor the treatment. Once appropriate placement of the cryoprobe is confirmed, the machine it turned on “high.” When set to “high,” argon gas, the cooling agent, is allowed to flow continuously through the cryoprobe. The probe is cooled to -160oC which freezes the tumor, forming an “ice ball” around it. After the iceball is formed, the cryoablation unit set on “low” setting which allows argon gas to flow intermittently into the cryoprobe for 1 of every 10 seconds to preserve freezing temperatures. Generally, two freeze-thaw cycles are used. Helium is used as the warming agent between freezing cycles (Nurko et al., 2005; Visica, manufacturer’s Web site). Benign breast fibroadenomas are common, especially among young women. Approximately 10% of women will experience a breast fibroadenoma during their lifetime. Currently accepted treatments include excisional biopsy and conservative management. Conservative management may be a reasonable choice for this benign condition, particularly smaller fibroadenomas. Moreover, women may choose to avoid immediate intervention since an estimated 30% of breast fibroadenomas resolve spontaneously within several years. Excisional biopsy provides a definitive diagnosis, but a disadvantage is morbidity including possible cosmetic and/or ductal damage. Cryoablation is less invasive than excisional biopsy and is done on breast fibroadenomas after confirmation that the tumor is benign, generally with needle biopsy (Whitworth & Rewcastle, 2005; Houssami et al. 2001). A minimally invasive procedure, such as cryoablation, may also be useful for treating early breast cancers treated with breast-conserving therapy rather than mastectomy. Other thermal methods have been used to treat breast tumors. These include radiofrequency ablation, interstitial laser therapy and highly intensive focused ultrasound (Pfleider et al., 2005).

08/07/2006: MTAC REVIEW

Cryosurgery – Breast Cancer

Evidence Conclusion: There is insufficient evidence to permit conclusions the efficacy of cryoablation for treating benign breast tumors including fibroadenomas. No studies were identified that compared cryoablation to

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conservative management, an accepted approach for managing fibroadenomas. The available studies were case series. A limitation of the published series was that there was likely overlap among patients in the studies. The degree of overlap could not be determined. In addition, two of the three studies reviewed (not the registry) were funded by the manufacturer of the cryoablation system. The Kaufman et al. and Caleffi et al. studies found that a higher proportion of larger (>2.5cm) fibroadenomas than smaller fibroadenomas were palpable at 12 months. This suggests that the usefulness of cryoablation may be limited because there is likely more demand for intervention, rather than conservative management, with larger fibroadenomas. There is insufficient evidence to permit conclusions on the efficacy of cryoablation for treating early breast cancer. No studies were identified comparing cryoablation to other treatments such as radiofrequency ablation or interstitial laser therapy. The available studies were relatively small case series with sample sizes of 30 or fewer patients. In the series, cryoablation was followed by surgery 1-4 weeks later, at which time the tumor cells were evaluated. In one study, there was residual DCIS in 5 out of 30 patients and in the other study, there was residual invasive cancer or DCIS in 6 out of 27 patients. In the latter study, cryoablation was successful in all of the 10 patients with tumors <1.5 cm and with ductal or medullary cancer and no extensive intraductal component. Number of patients were too small to draw conclusions about sub-groups that might benefit from cryoablation for early breast cancer.
Cryoablation appears to be safe, although data on adverse effects are limited. No major complications were reported in any of the series that were reviewed.
Articles: No randomized controlled trials or other controlled trials were identified. Empirical studies were all case series. Three series on benign breast tumors, including fibroadenomas, were identified. Findings from one of the series, written by Kaufman and colleagues, were reported in three articles. Sample sizes were 63 patients in the Kaufman study and 102 and 29 in the other series. In addition, a registry of fibroadenomas treated by cryoablation was identified. The registry included 444 fibroadenomas (the number of patients was not reported, some patients contributed more than one fibroadenoma). The registry study and the two largest case series were critically appraised. All of the Kaufman et al. studies were included in the same evidence table. Four studies on cryoablation for breast cancer were identified. All included patients with small breast tumors ≤2.0 cm. Sample sizes in the studies were n=30, n=29, n=15 and n=9. The two larger case series were critically appraised. The series with n=15 appeared to report preliminary data for one of the larger studies. The studies reviewed were as follows: Kaufman CS, Bachman B, Littrup PJ et al. Cryoablation treatment of benign breast lesions with 12-month follow-up. Am J Surg 2004; 188: 340-348. (Kaufman CS, Littrup PJ, Freeman-Gibb LA et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. Breast J 2005; 11: 344-350. Kaufman CS, Littrup PJ, Freeman-Gibbs LA et al. Office-based cryoablation of breast fibroadenomas: 12-month follow-up, J Am Coll Surg 2004; 198: 914-923) v See Evidence Table. Caleffi M, Filho DD, Borghetti K et al. Cryoablation of benign breast tumors: Evolution of technique and technology. The Breast 2004; 13: 397-407. See Evidence Table
Nurko J, Mabry CD, Whitworth P et al. Interim results from the FibroAdenoma Cryoablation Treatment Registry. Am J Surg 2005; 190: 647-652. See Evidence Table. Pfleiderer SOR, Marx C, Camara O et al. Ultrasound-guided, percutaneous cryotherapy of small (≤15mm) breast cancers. Invest Radiol 2005; 40: 472-477. See Evidence Table
Sabel MS, Kaufman CS, Whitworth P et al. Cryoablation of early-stage breast cancer: Work-in-progress report of a multi-institutional trial. Ann Surg Oncol 2004 11: 542-549. See Evidence Table.

The use of Cryoablation in the treatment of breast cancer or benign fibroadenomas of the breast does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Cryosurgical Ablation (CSA) for Liver Tumors

BACKGROUND

The liver is a common site for primary and secondary malignancies. Hepatocellular carcinoma (HCC), the most common primary tumor, is the fifth most common cancer in the world, and the third most common cause of cancer-related mortality. It is responsible for more than half a million deaths across the globe each year. Treatment options for patients diagnosed with primary and secondary malignancies are limited. Less than 15% are candidates for surgical resection at presentation because of inadequate liver functional reserve, extrahepatic disease, anatomic constraints of the tumor, or medical co morbidities. The use of external beam radiation is limited due to the intolerance of normal liver parenchyma to tumoricidal radiation doses (the dose required to destroy solid tumors (>70 Gy) is much higher than the liver tolerance dose of 35 GY). In addition, systematic chemotherapy was found to have little impact on survival, and negative impact on the health-related quality of life due to the toxicity to other organs and systems. These limitations have led to the emergence of other therapies, such as radiofrequency ablation (RFA), cryosurgical ablation (CSA), percutaneous ethanol injections (PEI), hepatic arterial infusion chemotherapy, transarterial chemo-embolization (TACE), and selective intraarterial radioembolization therapy (Steel 2003, Salem 2005, Ibrahim 2008, Bult 2009, Riaz 2009, Bhardwaj 2010). Ablative techniques, such as RFA and CSA, improve the ability to treat patients with unresectable hepatic tumors. Thermal ablative techniques destroy tumors via a source that changes temperature to levels that are associated with cell death while causing minimal damage to adjacent, normal tissue. The choice of technique depends on
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equipment availability and physician preference. The most commonly used ablative technique in the United Stated is RFA. RFA causes tumor destruction through the use of alternating high-frequency electric current in the radiofrequency range (460-500 kHz). This current is delivered through an electrode placed in the center of a lesion. Ions within the cell follow the alternating current creating frictional heat producing local tissue temperatures that can exceed 100°C. This ionic agitation leads to tissue destruction via tissue boiling and creation of water vapors. Once temperatures greater than 60°C are reached, protein denaturation, tissue coagulation, and vascular thrombosis result in a zone of complete ablation. Partial tissue destruction can occur up to 8 mm in diameter from the zone of complete ablation. RFA can be delivered either percutaneously, laparoscopically, or through open approaches (laparotomy). Complications from RFA include: pleural effusion, hepatic abscess, biliary injury, liver failure, intra-abdominal hemorrhage, pneumothorax, and hypoxemia. The most troubling complications arise when a probe is placed too close to the diaphragm or intra-abdominal organ, resulting in ablation of the surrounding viscera with the accompanying complications of perforation, diaphragmatic injury, or pulmonary damage. Limitations of RFA include: treating lesions in perihilar areas or near large vascular structures, and real time monitoring of the ablative zone is difficult due to air released during heating (Yamane 2009, Arciero 2006). CSA is another ablative technique. CSA uses repetitive freezing and thawing to produce irreversible tissue destruction. One or more cryoprobes are inserted at the site of the diseased tissue and liquid nitrogen or argon gas is delivered through the probe to freeze the tissue. Rapid freezing of the tissue results in the formation of intercellular ice crystals. At temperatures of about -40°C lethal ice crystals begin to form in the cell. Ice crystals also form in the fluid outside the cell leading to cell dehydration. The combination cause tumor cells to burst. Additionally, ice crystals form in small vessels and block blood supply to the tumor. Normally, two freeze-thaw cycles are used. CSA is easy to monitor, and the area treated can be accurately visualized with ultrasound. This allows for accurate real-time visualization; however, it does not guarantee that there has been cell death. Two devastating complications that are associated with CSA are cryoshock, a complex of severe coagulopathy and multi-organ failure, and intra-operative hypothermia. Other complications include: hemorrhage from cracking of the frozen liver, subphrenic abscesses, bilomas, and biliary fistulae (Bhardwaji 2010, Arciero 2006). The cryoprobe that is used in CSA has received FDA approval for ablation of cancerous or malignant tumors, benign tumors, and as a palliative intervention. RFA has received FDA approval for generic tissue ablation and the ablation of unresectable colorectal cancer metastases. This technology is being reviewed based on a request from gastroenterology.

06/21/2010: MTAC REVIEW
Cryosurgery – Liver Tumors
Evidence Conclusion: It is difficult to compare the results of CSA with surgery or other ablative techniques, as most authors report data from studies where a variety of different treatment modalities were used in conjunction with CSA. Differences in patient selection, follow-up duration, types of tumors, and treatment approaches also make studies difficult to compare.
CSA vs. RFA: The empirical evidence comparing CSA to RFA consists of nonrandomized, case series, and cohort studies that examined multimodal therapies rather than CSA alone. The Pearson study was selected for critical appraisal as it was the largest prospective study (N=146). The objective of this study was to compare complication and local recurrence rates in patients treated with RFA or CSA. Patients with either primary or secondary hepatic malignancies were included in the study. Compared to patients treated with RFA, patients treated with CSA appeared to have higher local recurrence rates (22% vs. 3%). However, data was not adjusted for confounding factors that may influence the rate of recurrence. With regard to complications, a total of 27 complications occurred in 22 CSA patients, while a total of 3 complications occurred in 3 RFA patients. Patients treated with CSA had a higher incidence of intrahepatic abscess and symptomatic pleural effusion than patients treated with RFA. It is not clear who these results are generalizable to as only very limited demographic information is presented. There is a high probability of selection bias in the study, as it is not stated how patients were recruited for the study and treatment choice was based on preference and training of the individual surgeon. Additionally, a subset of patients underwent resection in combination with CSA or RFA.
CSA vs. CSA + resection: The Niu study was selected for critical appraisal as it was a large prospective study (N=315) that compared long-term results of resection combined with CSA with resection alone in patients with colorectal liver metastases. The study found that the combined treatment group (CSA + resection) had higher recurrence rate, but survival rates were not statistically different between the two groups. Results from this study should be interpreted with caution as treatment groups were not comparable at baseline, more patients in the combined treatment group were treated with chemotherapy, and results were not controlled for confounding factors. It is not clear who these results are generalizable to as only very limited demographic information is presented. Conclusion: There is insufficient evidence to determine the relative safety and efficacy of CSA compared to RFA. There is insufficient evidence to determine whether CSA combined with hepatic resection will improve recurrence and survival rates compared to resection alone in patients with liver metastases from colorectal carcinomas.

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Articles: No published randomized controlled trials or meta-analyses were found pertaining to the use of cryosurgical ablation for liver cancer. The literature consisted mainly of case series and cohort studies. Two prospective cohort studies were selected for critical appraisal. One study (Pearson 1999) assessed the relative safety and efficacy of CSA versus RFA and one study (Niu 2007) evaluated recurrence and survival rates of CSA combined with resection versus resection alone in patient with liver metastases from colorectal carcinomas.
The following studies were critically appraised:
Pearson SA, Izzo FI, Declan RY, Delrio P et al. Intraoperative radiofrequency ablation or cryoablation for hepatic malignancies. Am J Surg 1999; 178:592-599. See Evidence Table. Niu R, Yan TD, Zhu JC et al. Recurrence and survival outcomes after hepatic resection with or without cryotherapy for liver metastases from colorectal carcinoma. Ann Surg Oncol 2007; 14:2078-2087. See Evidence Table.

Cryosurgery for Prostate Cancer

BACKGROUND

Radical prostatectomy and external beam radiation therapy are considered standard treatments for localized prostate cancer. Both can result in significant morbidity such as incontinence and impotence. There is interest in other treatments that are of similar or greater effectiveness and have less morbidity. Cryosurgery (also known as cryoablation) was first used to treat prostate cancer in the last 1960s. Originally, clinicians used an open perineal approach that had high morbidity. The procedure was re-introduced in 1993 by Onik and colleagues using transrectal ultrasound (Onik, 1993). The technique continued to evolve and is now performed with modifications to the procedure introduced by Onik. In the basic modern technique, six to eight 3.4 mm diameter cryoprobes are inserted transperineally into the prostate guided by transrectal ultrasound. Temperature probes are placed in the right and left neurovascular bundles and the apex of the prostate gland to ensure that temperatures reach optimal levels in the margins of the gland. In addition, temperature probes are placed in the Denonvilliers' fascia and the external sphincter and are used to make sure that sensitive areas adjacent to the prostate are not frozen. A urethral warming catheter is used to prevent the urethra from being frozen. Patients are treated with one or two freeze-thaw cycles (two is used more often in recent procedures) using a target temperature of –40°C. When the target temperature is attained, the ice ball is maintained at a static size for up to 10 minutes if this is possible without endangering the rectal wall (Bahn et al., 2002). Cryosurgery is also used as salvage therapy to treat recurrent prostate cancer after radiation therapy. Salvage prostatectomy is the standard treatment, but about half of patients have positive surgical margins and there is significant associated morbidity (Cespedes et al., 1997).

06/11/2003: MTAC REVIEW

Cryosurgery – Prostate Cancer

Evidence Conclusion: Primary treatment of clinically localized prostate cancer - Only case series data were available, the lowest grade of evidence because there is no control or comparison group. In addition, the case series did not evaluate a standard intervention; instead, the procedure changed over time. Both case series reported an intermediate outcome, biochemical success, as their primary health outcome. Conclusions about the effectiveness of cryosurgery compared to standard treatments for prostate cancer (e.g. radical prostatectomy, external beam radiation therapy) or no treatment can be drawn. Randomized controlled trials testing cryotherapy as primary treatment for prostate cancer should be feasible. The case series data suggest that cryosurgery is associated with a high-rate of impotence. Among men potent before surgery, in Bahn, 95% became impotent after cryosurgery and 90% remained so at follow-up (a mean of 5.4 years) and in Donnelly, 100% became impotent after cryosurgery and 53% remained so at 3 years, even with the use of sildenafil.
Salvage treatment for recurrent prostate cancer- Only case series data were available, the lowest grade of evidence because there is no control or comparison group. In addition, the procedure was inconsistent and changed over time. In a series of 131 patients (Izawa), 5-year disease-specific survival was 79% and 5-year disease-free survival was 40%. The long-term post-cryosurgery incontinence rate was 29%. Conclusions about the effectiveness of cryosurgery as salvage therapy after radiation treatment for patients with recurrent prostate cancer, or associated morbidity, compared to an alternate treatment such as salvage prostatectomy cannot be drawn.
Articles: *Primary treatment of clinically localized prostate cancer:* There were no randomized or non-randomized controlled trials. The only empirical data were from case series. The two largest case series that had data both on outcomes and adverse effects were critically appraised: Bahn DK, Lee F, Badalament R et al. Targeted cryoablation of the prostate: 7-year outcomes in the primary treatment of prostate cancer. *Urology* 2002 (Suppl 2A): 3-11. See Evidence Table. Donnelly BJ, Saliken JC, Ernst S et al. Prospective trial of cryosurgical ablation of the prostate: Five-year results. *Urology* 2002; 60: 645-649. See Evidence Table.
Salvage treatment for recurrent prostate cancer: Three case series were identified. Two were from the same institution and reported different outcomes on virtually the same group of patients. These studies were critically appraised. The other case series, which had a smaller sample size and a shorter follow-up, was excluded. Cespedes RD, Pisters LL, von Eschenbach AC et al. Long-term follow-up of incontinence and obstruction after salvage cryosurgical ablation of the prostate: Results in 143 patients. J Urol 1997; 157: 237-240. See Evidence

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Table. Izawa JI, Madsen LT, Scott SM et al. Salvage cryotherapy for recurrent prostate cancer after radiotherapy: Variables affecting patient outcome. J Clin Oncol 2002; 20: 2664-2671. See Evidence Table.

The use of cryosurgery in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Cryoablation of Renal Tumors

BACKGROUND

With the widespread use of body imaging techniques as magnetic resonance imaging (MRI) and computed tomography (CT), there is an increasing number of incidentally detected small renal masses or lesions with unclear clinical significance. The standard treatment for renal masses is radical nephrectomy. Other available treatment options include watchful waiting or partial nephrectomy. Recently, with the current trend of minimally invasive surgery, nephron-sparing approaches have gained more acceptance. Open, percutaneous, and laparoscopic renal cryoablation, radiofrequency ablation, and high intensity focused ultrasonography (HIFU) have been performed but are still under development. These techniques only target selected, small renal tumors with a diameter of 4 cm or less. Cryosurgery has been known for years, but the recent changes in the technology and the development of improved cryosurgery units are permitting its clinical use. Cryoablation is a technique that uses liquid nitrogen or argon gas to freeze and ablate tissues. Cryoablation is mainly performed laparoscopically under real time ultrasound guidance. It is reported that the critical temperature that leads to cancer cell destruction is approximately –40oC. Normal and neoplastic renal tissues are ablated and rendered necrotic at temperatures of –20oC (Chosy, 1996). During cryosurgery, the temperature is lowest at the center of the iceball with an incremental increase towards the periphery. Thus, with a cryoprobe tip temperature of –185o to-195oC, the temperature will be approximately 0oC at outer edge of the ice ball, –20oC at a distance of 4mm, and –40oC at a distance of 6mm towards the center of the iceball. It is important that the edge of the cryolesion be 1 cm beyond the margin of the tumor to make sure that a lethal temperature of –40oC or less was achieved throughout the tumor. The effect of cryosurgery occurs in two phases, freezing and thawing. The freezing phase is performed rapidly, and passive thawing is performed more slowly for a maximum effect. A double freeze-thaw cycle is usually preformed to ensure the extension of the iceball to approximately 1 cm beyond the tumor edge. The size of the cryolesion depends on several factors including the temperature at the tip of the cryoprobe, area of tissue contact, freeze time, and tissue vascularity. The response of a tumor to cryoablation depends on its biological characteristics e.g. density, specific heat, thermal conductivity, and rate of blood flow (Gage 1992). Potential complications of renal cryosurgery include post-thaw hemorrhage, urine leakage due to caliceal cryoinjury, and fistula formation.

04/09/2003: MTAC REVIEW

Cryosurgery – Renal Tumors

Evidence Conclusion: There is insufficient published evidence to determine the efficacy, safety, and long-term outcome of cryoablation for the treatment of renal tumors. No randomized controlled trials or non-randomized comparative studies were conducted to compare the procedure to surgery or other alternatives and assess its long-term benefits. All studies were either case reports or case series with very small sample sizes. The case series reviewed included small numbers of patients, were subject to selection and observation biases, and had short follow-up durations. These series showed that after a mean follow-up of 9 months in Shingleton's study, 14 months in Lee's study and 16 months in Gill's study the ablated renal tumor was no longer detectable in 25-40% or reduced in size in 20-75% of the patients with available follow-up data. Large randomized controlled studies with long-term follow up duration will be needed to compare cryoablation to other alternatives, and to determine its efficacy, safety, and long-term benefits.

Articles: The search yielded 48 articles. Many were reviews or tutorials that dealt with the technical aspects of the procedure. There were no meta-analyses or randomized controlled trials. There were 13 case reports (with 1-9 patients), and 9 case series with a small number of patients (10 to 32 patients). The 3 largest series were selected for critical appraisal: Gill IS, Novick AC, Meraney AM, et al. Laparoscopic renal cryoablation in 32 patients. Urology 2000; 56:748-753. See Evidence Table. Lee DI, McGinnis DE, Feld R, et al. Retroperitoneal laparoscopic cryoablation of small renal tumors: intermediate results. Urology 2003;61: 83-88. See Evidence Table. Shingleton WB and Sewell PE. Percutaneous renal tumor cryoablation with magnetic resonance imaging guidance. J Urol 2001; 165:773-776. See Evidence Table.

The use of cryoablation in the treatment of renal tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Applicable Codes

Breast Cancer and Benign Lesions - Considered Not Medically Necessary:

CPT® Codes	Description
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma

Prostate Cancer –

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare - Medical Necessity Review not required

CPT® Codes	Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

Renal Tumors - Medical Necessity Review not required:

CPT® Codes	Description
50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy

Liver Tumors - Medical Necessity Review not required:

CPT® Codes	Description
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
47381	Ablation, open, of 1 or more liver tumor(s); cryosurgical

Lung Cancer - Medical Necessity Review not required:

CPT® Codes	Description
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
06/30/2003	08/03/2010[MDCRPC], 03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
08/04/2020	Added Kaiser Permanente Medical Policy statement under Medicare for Breast Cancer and Benign Lesions.

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Clinical Review Criteria
Cervical Fusion (Anterior or Posterior)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, *"*Cervical Fusion (Anterior or Posterior)*"* for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Effective December 1, 2022

**All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.*

NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery (unless there is evidence of cord compression, infection, malignancy or progressive neurologic deficit). For persons with recent nicotine use, documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to fusion in patients without progressive neurologic deficit or cord compression

I. ANTERIOR CERVICAL FUSION FOR DEGENERATIVE DISEASE

Single or multilevel anterior cervical discectomy and fusion (ACDF) is considered medically necessary for treatment of symptomatic degenerative disease when **EITHER of the following** criteria are met:

A. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy** (see below), resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management *** (see below)
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:

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- Herniated nucleus pulposus
- Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
- ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
- Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis

4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following**:
   1. Clinical diagnosis of myelopathy*(see below)
   2. Complex imaging studies (i.e., CT, MRI, Xray, Myelogram) demonstrate structural cord compression associated with cord signal change/myelomalacia on MRI imaging
   3. Physical examination findings and imaging studies correlate with each level being considered for the fusion

II. CERVICAL FUSION FOR INSTABILITY

Single or multilevel cervical fusion is considered medically necessary for **ANY of the following** indications when there is an associated spinal instability:

- Acute spinal fracture and/or dislocation
- Traumatic ligamentous disruption
- Epidural compression, fracture or vertebral destruction from spinal tumor or cyst
- Spinal decompression or debridement for infection (e.g., discitis, osteomyelitis, epidural abscess, TB)
- Spinal decompression for myelopathy or radiculopathy associated with subluxation in rheumatoid arthritis
- Cervical spinal deformity associated with neurological symptoms of myelopathy* or radiculopathy** (e.g., sagittal plane angulation of more than 11 degrees between adjacent segments, subluxation of >3.5 mm)
- As an adjunct to cyst excision of synovial facet cysts in the cervical spine
- Atlantoaxial instability (e.g., atlas and axis fracture, nonunion)
- Treatment of cervical spine fracture/dislocation associated with acute cervical radiculopathy** or myelopathy*
- Multilevel symptomatic spondylotic myelopathy with kyphosis and
- Imaging studies correlate with symptoms and demonstrates cord compression
- Cervical instability from any **ONE of the following**:
  - Klippel-Feil syndrome
  - Down's syndrome
  - Skeletal dysplasia or connective tissue disorder

III. CERVICAL FUSION FOR IATROGENIC INSTABILITY

Cervical fusion is considered medically necessary for anticipated intraoperative iatrogenic spinal instability of the level or levels involved resulting from **ANY of the following** surgical procedures:

- Removal of 50% or more of the facets bilaterally
- Removal of 75% or more of a single facet
- Following cervical corpectomy*, as part of a stabilization procedure

***Note:** Corpectomy is a procedure in which the at least 50% or more of the body of the vertebrae is removed.

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IV. POSTERIOR CERVICAL FUSION: SPINAL STENOSIS

Posterior cervical fusion is considered medically necessary for the treatment of spinal stenosis with laminectomy when **EITHER of the following** criteria are met**:**

C. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy**(see below) resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management ***
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
   - Herniated nucleus pulposus
   - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
   - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
   - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

D. Myelopathy, must meet **ALL of the following**:

1. Clinical diagnosis of myelopathy*
2. Radiographic evidence of **ANY of the following**:
   - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
   - Sagittal plane angulation of more than 11 degrees between adjacent segments
   - Structural cord compression associated with cord signal change/myelomalacia on MRI
   - Loss of normal cervical lordosis
3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

V. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY:

Cervical fusion is considered medically necessary for treatment of symptomatic adjacent or same segment stenosis following prior cervical surgery, when **EITHER of the following** criteria have been met:

A. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy** resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management ***
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
   - Herniated nucleus pulposus
   - Spondylosis/ foraminal stenosis due such as an osteophyte causing nerve root compression
   - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
   - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

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OR

B. Myelopathy, must meet **ALL of the following:**

1. Clinical diagnosis of myelopathy*
2. Radiographic evidence of **ANY of the following**:
   - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
   - Sagittal plane angulation of more than 11 degrees between adjacent segments
   - Structural cord compression associated with cord signal change/myelomalacia on MRI
3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

VI. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY: PSEUDOARTHROSIS

Cervical fusion is considered medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) of the cervical spine at the same level(s) when it has been at least 12 months from the prior surgery and **ALL of the following criteria** are met:

- Mechanical neck pain that correlates to the level of the pseudoarthrosis
- Imaging studies (e.g., radiographs, CT) confirm evidence of a pseudoarthrosis (e.g., lack of bridging bone, dynamic motion on flexion-extension radiographs)
- Failure of three (3) consecutive months of physician-supervised conservative*** management which includes exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy **AND**

VII. CERVICAL FUSION NOT MEDICALLY NECESSARY

Cervical fusion is considered not medically necessary for the following indications:

- anterior or posterior cervical fusion for chronic axial neck pain
- posterior cervical fusion performed with laminectomy in the absence of kyphosis (e.g., degenerative spine) or subluxation/translation of more than 3.5 mm

Isolated cervical facet fusion, with or without instrumentation, including facet joint implants and/or bone graft substitutes used exclusively as a stand-alone stabilization device is considered experimental, investigational or unproven.

***Cervical Myelopathy:** signs suggestive of *spinal cord* involvement:

- Upper limb weakness in more than a single nerve root distribution
- Lower limb weakness
- Loss of dexterity (eg, clumsiness of hands)
- Bowel or bladder incontinence
- Frequent falls
- Hyperreflexia
- Hoffmann sign (overreaction to flick of the fingernail)
- Increased extremity muscle tone or spasticity
- Spastic Gait/ataxic Gait
- Positive Babinski

**** Radicular pain/suspected radiculopathy** defined as:

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- Pain in a *nerve root* distribution (e.g., C6, C7)
- Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) *OR*
- EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

***__**Physician-supervised conservative medical management**__ defined as: Patients must have three months of non-operative treatment as demonstrated by a trial of **one or more of the following** medications:

- Non-steroidal anti-inflammatory drugs (oral or topical)
- Acetaminophen
- Epidural steroid injection of corticosteroids as appropriate

AND

- A trial of **All** of the following physical measures:
  - Supervised Physical therapy, attendance at >75% of sessions
- At least half of PT must be in person (not virtual)
  - Flexibility and muscle strengthening exercises
  - Reasonable restriction of activities
  - If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.
  - Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Neck pain occurs in many people and typically involves more than one component of the spine, such as the vertebrae, intervertebral discs, spinal nerves, other anatomic structures such as ligaments, muscles, and joints. Conditions that frequently result in neck pain include soft tissue injury, trauma, infection, herniated disc, degenerative spine conditions, neoplastic conditions, and deformities such as kyphosis. While the cause of neck pain is often multifactorial (e.g., originating from the vertebrae, discs, ligaments, tendons and muscles) the location of pain varies. Axial neck pain occurs along the spine, is of musculoskeletal or soft tissue origin, and is a non-radiating type of pain. The most common cause of axial neck pain is degenerative change to the cervical spine, which occurs as a natural consequence of aging. Radicular pain involves a nerve root, is due to nerve root compression, follows the nerve root distribution, and radiates to one or both upper extremities, and/or into the shoulder area. Radicular pain can include varying degrees of sensory, motor, and/or reflex changes related to nerve root(s) without evidence of myelopathy (North American Spine Society, [NASS], 2013). Myelopathy is a term that describes any neurological deficit related to the spinal cord and is often used to describe loss of function in the upper or lower extremities (NASS, 2013). Depending on the cause of neck pain associated symptoms may include numbness, tingling, weakness, and other types of neurologic dysfunction in the presence of spinal cord compression. Conservative measures for treatment of neck pain include analgesics, muscle relaxants, local injections, physical therapy, cervical bracing and home exercise. Conservative treatment is often effective for alleviating symptoms and typically lasts six to eight weeks. However, conservative therapy is not recommended in

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the presence of progressive neurological deficits, in the presence of unstable spinal fractures or dislocations, or for progressive spinal deformity. In the absence of progressive neurologic compromise, or when conservative management has been attempted and fails to relieve pain and disability, surgery may be required for conditions with underlying pathology confirmed by physical examination and radiological imaging. When spinal cord compression is present surgical methods to relieve the pressure on the nerves is often necessary and is referred to as decompression surgery. Decompression typically includes surgical procedures such as discectomy (removal of the disc), laminectomy (removal of the lamina), corpectomy (removal of the vertebral body), or osteotomy (removal of a piece of bone). When performed, these procedures may result in spinal instability. As such, decompression is often performed as part of cervical fusion in order to regain stability of the spine. For example, anterior cervical fusion is usually performed with decompression. Posterior cervical fusion is typically performed with stabilization (using rods, screws) although may be performed with decompression in some instances (NASS, 2014). Instability of the cervical spine can also result from trauma and/or disease, or a combination of all (White, Panjabi, 1980), which may or may not require a decompression. Instability of the cervical spine has been defined by White, Panjabi (1980) and is well-accepted in the medical literature as sagittal plane translation of >3.5 mm, and/or rotation between motion segments of 11˚, in addition to other notable factors such as destruction of elements or inability to function, a positive stretch test, spinal cord or nerve root damage, and abnormal disc narrowing (White, Panjabi, 1980). In the absence of instability, evidence in the published peer-reviewed scientific literature does not provide strong support that when used for this indication cervical fusion is clinically effective for reducing pain and disability. 2011; Persson, et al., 1997). Psychological assessment and treatment as part of a multidisciplinary approach to conservative pain management is recommended. Risk factors, such as drug or alcohol abuse and depression may act as a barrier to recovery following spinal fusion (Washington State Department of Labor and Industries, 2002; Hanley, David, 1999; Tang, et al., 2001). Authors have recommended psychological screening, and treatment if applicable, of patients with neck and/or back pain prior to surgery for identification of risk factors that may be associated with chronic disability. Cervical spinal fusion is in many situations an elective surgery; therefore it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. Modifiable risk factors and the influence on outcomes of spine surgery has been studied, modification of such risk factors can assist with improved patient selection for spine surgery and better postoperative management (Shahrestani, et al., 2021). Along with alcohol and opioid use, tobacco/nicotine increases the risk of perioperative complications, cardiopulmonary complications, pseudoarthrosis and infection (Shahrestani, et al., 2021) furthermore it is well-established that smoking is a preventable cause of morbidity and mortality. Tobacco use in particular is considered a risk factor for poor healing and has been associated with nonunion. Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudoarthrosis (Brown, et al., 1986). The American Academy of Orthopedic Surgeons (AAOS) supports avoidance and cessation of all tobacco products and cigarette smoking due to the harmful impact on musculoskeletal health, as well as overall health (AAOS, 2016).

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Cervical Fusion: Anterior

CPT® or HCPCS Codes	Description
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments

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Cervical Fusion: Posterior

CPT® or HCPCS Codes	Description
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
22600	Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional vertebral segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments

Considered Experimental, Investigational or Unproven when used to report isolated cervical facet fusion, including facet joint implants and/or bone graft substitutes used exclusively as stand-alone stabilization devices for treatment of facet joint pain:

CPT® or HCPCS Codes	Description
22899	Unlisted procedure, spine
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/05/2022	07/05/2022[MPC]	

[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Coronary CT Angiography

- Cardiac CT Angiography
- Cardiovascular Computed Tomography (CVCT)
- Cardiovascular Multislice CT (MSCT)
- Contrast Enhanced Computed Tomographic Angiography
- Multidetector Row Spiral Computed Tomography (MDCT Scan)
- Multislice Detector Computed Tomography
- Multislice Tomography

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	**(CPT codes 75572, 75573, 75574)** Noridian has retired LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search. LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease L38615) **(CPT 0501T, 0502T, 0503T, 0504T)**
Local Coverage Article (LCA)	LCA Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease A58097

For Non-Medicare Members

Cardiac CT Angiography (CTA) (CPT 75574)

Kaiser Permanente has elected to use the MCG* Care Guideline: Cardiac CT Angiography (CTA) (A-0483) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using

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these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (cardiology)

For screening see:
Coronary Artery Calcium Score with Computed Tomography (CT) - CPT 75571

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Coronary artery disease (CAD) is one of the leading causes of morbidity and mortality worldwide. Currently invasive coronary angiography is the gold standard for coronary artery lumen assessment. It provides high spatial resolution and accurately determines the location, extent, and severity of coronary obstructive lesions. It also allows immediate intervention if needed. Coronary angiography, however, is an invasive procedure, has a small risk of serious complications, and requires a period of observation for several hours in a monitoring unit. Moreover, it was reported that nearly 40% of these procedures result in normal findings. This has led to a growing interest in the development less invasive methods for evaluating coronary anatomy, especially in stable patients at low to moderate risk of disease (Vembar 2006, Miller 2008).

Numerous anatomic and functional noninvasive tests for detecting CAD have emerged and are rapidly developing. Among these are stress echocardiography, nuclear perfusion studies, SPECT, magnetic resonance angiography, and others. More recently, computed tomography has been used for the evaluation of CAD. Electron beam computed tomography (EBCT) was initially used to assess coronary artery calcium as a marker of atherosclerosis. The first generation of multislice computed tomography (MSCT), also known as multidetector computed tomography (MDCT) scanners were introduced in the 1990s. The 4-slice scanner was developed to provide noninvasive direct visualization of the coronary arteries and led to significant improvements in spatial resolution compared to EBCT. However, it had motion artifacts, low resolution, long acquisition time, and up to 22% of the segments were non-assessable. The 4-slice CT thus rapidly evolved to16, 32, 40, and 64-slice CT scanners. The 16-slice scanner has better spatial resolution, faster gantry rotation, and larger coverage resulting in significantly shorter breath hold and less motion artifacts than those with 4-slice. The 64-slice scan generation, introduced in 2004, further improved the resolution, decreased the slice thickness, and reduced the acquisition time to less than 10 seconds. The entire procedure can be performed in approximately ten minutes. Systems with 256 and 320 slices and others with 64 slices but with 2 x- ray tubes (dual –source CT or DSCT) have recently been introduced (Gertz 2006, Vembar 2006, Berman 2006, Min 2009).

With the newer scanners, electrocardiographically synchronized images can be taken through the entire heart in the time of one breath hold. Synchronizing the location of the peak of QRS complex in the ECG with the projection data allows the reconstruction and visualization of anatomy at various phases of the cardiac cycle thus making functional imaging possible (Cademartiri 2005, Vembar 2006, Budoff 2008).

MDCT technology, however, has its limitations; it does not have the ability to correctly identify and differentiate between functionally significant and nonsignificant stenosis, or allow for intervention during the examination if needed. Positive findings frequently require confirmation with selective cardiac catheterization angiography, or stress myocardial perfusion to evaluate the functional significance. One of the difficulties in imaging the coronary vessels is the constant motion of the heart, which leads to artifacts and influences the image quality even with the significant improvements in the technology. Reducing the heart rate to 50-60 bpm with beta-blockers, now routinely used by most investigators, increases the cardiac rest period and reduces, but does not eliminate motion artifacts. To date, it is not possible to perform CT angiography in patients with atrial fibrillation unless it is highly regular.

One other significant problem, even with the most recent generations, is the inability of the MDCT to assess the degree of luminal obstruction within a calcified zone when there is dense calcification of the coronary arteries. This may lead to relatively high rate of false positive results and overestimate the severity of the disease. The use of MDCT is also limited for in-stent visualization, for evaluation of distal anastomosis among patients with

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previous bypass graft surgery, and for patients with higher body mass index. Moreover, MDCT requires the administration of contrast material and exposure to ionizing radiation. The radiation dose used is equivalent to 2-3 times the dose typically used during an invasive angiogram. This may be considered a low radiation exposure but might be of concern among women in childbearing age, or younger individuals who may use the test repeatedly. History of severe allergic reactions to an iodinated contrast material or of impaired renal function (creatinine level >1.5 mg/dL) are contraindications to CT coronary angiography (Garcia 2005, De Roos 2006, Leber 2006, Berman 2006, Hoffmann 2006, Rixe 2009, Min 2009).

Medical Technology Assessment Committee (MTAC)

Virtual Coronary Angioscopy

04/03/2006: MTAC REVIEW

Evidence Conclusion: All published studies on MSCT scanners investigated the accuracy of MCST in patients with known or suspected CAD, who was referred for evaluation with catheter angiography. None of the studies evaluated the technology for screening healthy, asymptomatic, or low risk individuals. Schuijf and colleagues' meta-analysis (2006) included 24 studies with 1,300 participants that compared MSCT scans head to head with invasive catheter angiography in patients with known or suspected CAD. The studies used one of the 4, 8, or 16 slice CT scanners. Those evaluating the 64-slice CT scans were not published to the date of analysis. The results of the meta-analysis show that the 4,8, and 16 MSCT scan generations had an overall high specificity (95%) and negative predictive value (97%) but lower sensitivity (85%) and positive predictive value (76%) compared to invasive angiography as the gold standard. Published studies evaluating 64-slice CT scanners had some differences in the methodology and patient characteristics, but all used invasive catheter angiography as the gold standard, included only patients with known or suspected CAD, excluded those with cardiac arrhythmias and unstable conditions, defined significant coronary stenosis as >50% lumen narrowing, and the majority used beta-blockers to reduce the heart rate. The trials ranged in size from 35 to 84 patients, used the same Sensation 64 CT Siemens Medical Solutions scanners, and almost all reported analysis of sensitivity, specificity, positive and negative predictive values. Analysis of MSCT performance was limited to coronary segments > 1.5 or 2 mm in diameter, and most studies used individual coronary vessels or vessel segments as the unit of analysis. Not all studies reported on the performance characteristics of MSCT using the patient as a unit of analysis. The results of the studies critically appraised show that 4-13% of the coronary segments were non-evaluable due to motion artifacts, severe calcified plaques, and/or other technical imaging problems. The sensitivity and specificity of MSCT for detecting >50% diameter reduction in the evaluated coronary segments ranged from 73% to 95% and from 80% to 97% respectively. Only two studies reported on the performance characteristics of MSCT using the patient as a unit of analysis showing a sensitivity of 95-96% and specificity of 90-91%. The negative predictive values ranged from 92-100% when segments were used as the unit of analysis and 93% to 98% when analyses were per patients. The positive predictive value on the other hand was much lower (as low as 56 % per segment and 83% per patient). Leber et al (2005) went a step beyond assessment of stenosis and evaluated the 64-MSCT scan for detecting and quantifying coronary atherosclerotic plaque compared to intravascular ultrasound (IVUS), and reported a 84% sensitivity and 91% specificity. This, however, was studied on a very small subgroup of only 18 patients with stable angina. The overall results of the published studies may indicate that MSCT scanning may have a high sensitivity of diagnosing CAD, and a high NPV that would accurately rule out CAD among the selected symptomatic patients with a negative MSCT scan result. However, all studies were small, conducted in single, highly specialized centers, conducted among selected intermediate to high risk patients, with stable conditions, regular heart rhythm, and a high prevalence of CAD. These factors in addition to analyzing the diagnostic performance of the technology based on the evaluable segments of the vessels only, would overestimate the calculated accuracy and predictive values of the test, and in turn the results may not be generalizable to a broader population. In conclusion: There is insufficient evidence to support the use of MSCT as a method of screening for CAD among healthy, low risk populations, or asymptomatic patients with known risk factors. There is insufficient evidence that the technology is as beneficial as catheter angiography in the diagnosis of CAD. There is insufficient evidence to support the use of MSCT scanning in monitoring progress of the disease and its outcome after an intervention, in patients with confirmed disease. There is insufficient evidence that the technology improves health outcomes. A multicenter study (CorE 64), and study with long-term healthcare outcomes conducted by the Medical College of Wisconsin are underway.

Articles: The search yielded around 170 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. The search revealed several studies using 4, 8, and 16-slice CT scanners for the detection of coronary artery lesions. A recent meta-analysis of 24 of these studies was also identified, as well as seven studies that used the 64-slice CT angiography for detecting CAD stenosis and comparing the technology with invasive coronary angiography. The meta-analysis and four of the studies on the 64-slice scanners were critically appraised. Fine JJ, Hopkins CB, Ruff N, et al. Comparison of accuracy of 64-slice cardiovascular computed tomography with coronary angiography in patients with suspected coronary artery disease. Am J

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Cardiol. 2006; 97:173-174. See Evidence Table. Leber Aw, Knez A, von Ziegler F, et al. Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography. A comparative study with quantitative coronary angiography and intravascular ultrasound. J Am Coll Cardiol. 2005; 46:147-154. See Evidence Table. Raff G L, Gallagher MJ, O'Neill WW, et al. Diagnostic accuracy of noninvasive coronary angiography using 64-slice spiral computed tomography. J Am Coll Cardiol. 2005; 46:552-557. See Evidence Table. Ropers D, Rixe J, Anders K, et al. Usefulness of multidetector row spiral computed tomography with 6.4x0.6 mm collimator and 330 –ms rotation for the noninvasive detection of significant coronary artery stenoses. Am J Cardiol. 2006; 97:343-348. See Evidence Table. Schuijf JD, Bax JJ, Shaw LJ, et al. Meta-analysis of comparative diagnostic performance of magnetic resonance imaging and multislice computed tomography for noninvasive coronary angiography. Am Heart J. 2006; 151:404-411. See Evidence Table.

The use virtual coronary angioscopy of in the evaluation of coronary artery disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/05/2007: MTAC REVIEW
MDCT in the Treatment of Coronary Heart Disease
Evidence Conclusion: *Use of MDCT for the diagnosis of coronary artery stenosis* - The published studies evaluating the use of MDCT scanners in the diagnosis of coronary artery stenosis are all relatively small trials mainly conducted in single specialized centers, and among selected patients with stable conditions who were referred for invasive coronary angiography for a known or suspected CAD. The technology was not assessed for screening healthy, asymptomatic, or low risk individuals. The studies evaluated MDCT angiography in respect to its accuracy in identifying coronary stenosis (per segment, per-vessel and per- patient), but not its effect on the treatment decisions, patient management, and health outcomes. Certain segments or whole patients were excluded from the analysis due to nonassessable images, which would overestimate the accuracy of the test. Three recently published meta-analyses (Hamon 2006, Sun 2006, and Stein 2006) pooled the results of published individual small studies. There were some variations between the three meta-analyses in the inclusion/exclusion criteria, but many of the same studies were included in all three analyses. Hamon and colleagues' analysis included more up-to date studies, and only those using 16 or more slice MDCT scans. The other two meta-analyses included older studies with 4, 8, 12 as well as the newer 16 and 64-slice scans. The authors of all three meta-analyses performed per-segment, per-vessel, and per-patient analyses. The per-patient analysis would be the most relevant if the MDCT is intended for use as a substitute for invasive angiography. Overall, the results of the three meta-analyses show that MDCT angiography had a sensitivity ranging from 81-94%, and specificity ranging from 93-94% for the per-segment analysis. Analyses based on patients showed a sensitivity of 91 –95%, and specificity of 74-84%. The per-patient pooled positive likelihood ratios were 5.4 and 6 and negative likelihood ratios were 0.05 and 0.07 in the two analyses that reported them. Hamon and colleagues also pooled the results of the positive and negative predictive values which were 83% and 94% respectively for the per-patient analysis. Nikolaou and colleagues, 2006 evaluated the clinical value of the 64-slice computed tomographic (MDCT) in the diagnosis of coronary artery disease among 72 patients with and without a history of a known coronary artery disease (CAD) in a cardiology center in Germany. 40% of the participants had already been diagnosed with CAD and angiographically verified. Invasive coronary angiography was the gold standard and was evaluated by an independent observer blinded to the MDCT results. Scan results were analyzed by two independent experienced observers blinded to the invasive angiography results, and patients' history. 6% of patient-based and 10% of the segment-based CT angiograms were nonassessable. 64% of the assessable CT angiograms had a high image quality, 30% had moderate quality and 6% were poor. The results of this study showed a sensitivity of 86% and specificity of 94% for the per-segment analysis. These were 97% and 79% respectively for the per-patient analysis. The negative predictive value was 100% for patients with known CAD, and 93% for those with a suspicious disease. These rates were computed from very small number of patients with a high prevalence of CAD and would not necessarily apply to populations at a lower risk. *Use of MDCT to evaluate patients presenting to emergency rooms with acute chest pain:* The few studies that evaluated the use of the technology in the emergency room did not compare it to the gold standard of catheter angiography but used a combination of noninvasive tests and observations as a surrogate gold standard. Gallagher and colleagues, 2006 evaluated the diagnostic accuracy of the 64-slice multidetector computed tomographic (MDCT) coronary angiography compared to stress nuclear imaging for the detection of an acute coronary syndrome (ACS) or 30-day major cardiac adverse events. The study included 92 low-risk chest pain patients seen in the emergency department of a teaching hospital in Michigan USA. The participants had negative serial ECG and cardiac marker results at presentation to the ER. They were admitted to the emergency department observation unit for the chest pain diagnostic protocol (cardiac monitoring, serial ECG. and cardiac marker tests) 4 hours after arrival. Those with abnormal markers had repeat tests and ECG at 8 hours. If these latter tests were negative the patients received a stress nuclear imaging test followed by MDCT coronary angiography using 64-slice multidetector CT scanners. Patients were treated based on the findings of both tests, and then followed up for evidence of ACS or major adverse events within 30
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days of their initial visit. Those with positive tests suggesting unstable angina underwent cardiac catheterization to confirm the diagnosis. The authors used clinical markers and outcomes as a surrogate gold standard, and 7 (7.6%) of the study participants were not included in the analysis due to uninterpretable MDCT images. The numbers were too small and show a MDCT sensitivity of 86% specificity of 92%, NPV of 99% and a PPV of 50%. Hoffmann et al, 2006 also assessed MDCT angiography among 103 patients presenting to the ER with acute chest pain in a university hospital in Massachusetts. The participants had no ischemic ECG changes and negative initial biomarkers. They all underwent contrast enhanced 64-slice MDCT coronary angiography before admission. The results were not compared to the gold standard of catheter angiography. The diagnosis of acute coronary syndrome was made by an expert panel blinded to the results of MDCT, based on the results of serial ECGs, cardiac biomarkers, and subsequent cardiac testing including exercise testing, stress perfusion imaging, or cardiac cauterization during the index hospitalization and 5-months follow-up. The results of the study showed that MDCT had a sensitivity of 100%, specificity of 82%, negative predictive value of 100%, and a positive predictive value of 47% in detecting a significant stenosis. These, however, were not verified with catheter angiography for all patients. Two other studies (White et al 2005, and Sato et al 2005) also evaluated MDCT use in small numbers of patients (N=69 and 31 respectively) admitted to ER with chest pain. They used the older 4 and 16 row CT detectors. Patients included also had non-diagnostic ECGs and normal cardiac enzymes. Invasive angiography was not used as a gold standard. The reference standards used were similar to those discussed earlier. The sensitivities and specificities were 83% and 96% respectively in White's study, and 95.5% and 88.9% respectively in Sato's study. This relatively moderate accuracy indicates that some cases might be missed, and others may undergo unnecessary invasive angiograms based on the results of the MDCT.
In conclusion: The patient-based analysis of the results of the studies, as presented individually or pooled in meta-analyses show high sensitivity and negative predictive values, but lower specificity and positive predictive value of the MDCT angiograms in the diagnosis of CAD in selected patients. This indicates that the test may be useful in excluding CAD and avoiding a conventional angiography among some patients, but at the expense of up to 25% false positive tests among population groups with a high prevalence of CAD. The latter would overestimate the calculated accuracy and predictive values of the test, and in turn the results may not be generalizable to a broader lower-risk population. There is insufficient evidence to determine whether using the technology to diagnose coronary artery stenosis improves the net health outcomes. The published literature on the use of MDCT angiography in an ER does not provide sufficient evidence to determine the benefits and harms of the test in diagnosing patients presenting with acute chest pain. There are no published data to date on the effect of the using the technology on patient treatment or management decisions. A multicenter study (CorE 64) and a study with long-term healthcare outcomes conducted by the Medical College of Wisconsin are underway.
Articles: The search yielded around 55 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Three meta-analyses published after the last review were identified, as well as several small studies on MDCT with patient sizes ranging from 51 to 129. Four studies (Nikolaou 2006l, Plass 2006, Schuijf 2006, and Muhlenbruch 2006) compared the technology with invasive coronary angiography, Dewey et al, compared the 16-slice scanner with exercise electrocardiography, in one study and MRI in another study using the invasive angiography as the gold standard. Four published studies evaluating the use of MDCT for patients presenting to the ER with acute chest pain were identified. None of the latter studies compared the technology to the gold standard of invasive angiography, and only two used the 64-slice CT scans. All meta-analyses and recent studies were reviewed. The meta-analysis that included the most recent studies that used the newest generations of MSCT (> 16 slices), compared MDCT to invasive coronary angiography, and had a valid methodology was critically appraised. A recent study comparing the 64-slice MDCT with invasive angiography, and another evaluating its use in patients presenting to the emergency room with acute chest pain were also selected for critical appraisal. Hamon M, Biondi-Zoccai GG, Malagutti P, et al. Diagnostic performance multislice spiral computed tomography of coronary arteries as compared with conventional invasive coronary angiography. J Am Coll Cardiol. 2006; 48:1896-1910. See Evidence Table. Nikolaou K, Knez A, Rist C, et al. Accuracy of 64-MDCT in the diagnosis of ischemic heart disease. AJR 2006; 187:111-117. See Evidence Table. Gallagher MJ, Ross MA, Raff GL, et al. The diagnostic accuracy of 64-slice computed tomography coronary angiography compared with stress nuclear imaging in emergency department low-risk chest pain patients. Ann Emerg Med. 2006; See Evidence Table.

The use of MDCT in the treatment of coronary heart disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/01/2009: MTAC REVIEW
MDCT in the Treatment of Coronary Heart Disease
Evidence Conclusion: Use of 64-multidetector computed tomography (MDCT) for the diagnosis of coronary artery stenosis in nonemergent settings: The published studies that evaluated the use of MDCT scanners in the diagnosis of coronary artery stenosis had generally valid methodology but were relatively small and mainly
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conducted among selected patients with stable conditions who were referred for invasive coronary angiography for a known or suspected CAD. The technology was not assessed for screening healthy, asymptomatic, or low-risk individuals. The meta-analyses that pooled the results of the published studies had some variations in their inclusion/exclusion criteria, but a large number of same studies were included in all. The participants in ACCURACY (Budoff 2008) and CORE-64 (Miller 2008) studies, not included in the meta-analyses, were also patients with suspected symptomatic CAD referred for conventional coronary angiography. ACCURACY excluded patients with a known history of CHD, but no exclusions were made based on coronary artery calcium scoring or BMI. On the other hand, CORE 64 included patients with or without a history of CAD and excluded those with coronary artery calcium score >600 or BMI >40. Only coronary artery segments >1.5 mm was included in the analysis. These two studies as well as the other included in the meta-analyses performed patient-based and vessel-based analyses. Per-segment analyses were also performed in several studies. Accuracy of 64-slice MDCT. The patient-based analysis of the results of the studies, as presented individually or pooled in meta-analyses show high sensitivity (85-99%) and negative predictive values (95-100%), but lower specificity (83-91%) and positive predictive value (64-91%) of the MDCT angiograms in the diagnosis of significant (>50%) stenosis of CAD in selected patients. The technology was less sensitive (75-85%) but more specific (90-96%) in detecting stenosis per vessel. The accuracy of the test varied widely by artery and was highest for the left main artery followed by the left circumflex artery. These results indicate that the test may be useful in excluding CAD and avoiding a conventional angiography among some patients with a suspected disease. This however could be at the expense of more than 20% false positive tests among population groups with a high prevalence of CAD. Impact on management and health outcomes: There was insufficient evidence to determine the effect of 64-slice on patient management or net health outcomes. The published studies to date evaluated MDCT angiography in respect to its accuracy in identifying coronary stenosis, but not its effect on the treatment decisions, patient management, and health outcomes. Use of MDCT to evaluate patients presenting to emergency rooms with acute chest pain. The published literature on the use of MDCT angiography in emergency departments (ED) does not provide sufficient evidence to determine the benefits and harms of the test in diagnosing patients presenting with acute chest pain. Hoffmann 2009 (ROMICAT study), as well as earlier smaller studies that evaluated the use of the technology in the ED, did not compare it to the gold standard of catheter angiography, but used a combination of noninvasive tests and observations as a surrogate gold standard. The ROMICAT study aim was to determine the usefulness of MDCT angiography in patients with acute chest pain who presented to an emergency department and were admitted with low to intermediate risk for acute coronary syndrome. However, the results of the CT angiography findings were not provided to the physicians managing the patients, and thus it is not possible to determine whether the management or outcomes would have been altered based on the CT angiography findings. It is uncertain whether the clinicians would have performed less stress tests, more invasive angiograms, treated the patients more or less aggressively, or discharged the patients earlier had they known the results of the CT angiograms.
Articles: The search yielded around 325 articles on CT angiography. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Six meta-analyses published after the last review were identified. Four evaluated the diagnostic performance of the 64-slice CT scanners, one compared the performance of the 16 vs. the 64-slice scanners and another evaluated all 4, 16-slice, and 64 slice CT scanners. Two of the four meta-analyses on 64-slice scanners were performed by the same group of investigators (Mowatt and colleagues) and included the same studies. The literature search also identified two more recent multicenter studies (ACCURACY, and CORE 64) on the accuracy of the 64-slice CT scans in non-emergent settings, and one study on patients presenting to an emergency department (ROMICAT study). None was included in the meta-analyses. There were no published studies that prospectively compared MDCT to other noninvasive stress testing. The most recent valid meta-analysis that compared the performance of 64-slice scanners to invasive coronary angiography was selected for critical appraisal, as well as the newer studies ACCURACY, CORE 64, and ROMICAT. The references for the studies reviewed are: Mowatt G, Cook JA, Hillis GS, et al. 64-slice computed tomography angiography in the diagnosis and assessment of coronary artery disease: systematic review and meta-analysis. Heart. 2008; 94:1386-1393. See Evidence Table. Budoff MJ, Dowe D, Jollis JG, et al. Diagnostic performance of 64-multdetector row coronary computed tomographic angiography for evaluation of coronary artery stenosis in individuals without known coronary artery disease. Results from the prospective multicenter ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography) trial. J Am Coll Cardiol 2008; 52:1724-1732. See Evidence Table. Miller JM, Rochite CE, Dewey M, et al. Diagnostic performance of coronary angiography by 64-Row CT. N Engl J Med 2008;359:2324-2336. See Evidence Table. Hoffmann U, Bamberg F, Chae CU, et al. Coronary computed tomography angiography for early triage of patients with acute chest pain. The ROMICAT (Rule Out Myocardial Infarction using Computer Assisted Tomography) trial. J Am Coll Cardiol 2009; 53:1642-1650. See Evidence Table.

The use of MDCT in the treatment of coronary heart disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*
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Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report
0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

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Date Created	Date Reviewed	Date Last Revised
04/27/2006	04/03/2006, 02/05/07, 07/13/2009[MDCRPC], 06/01/2010[MDCRPC], 04/05/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 06/04/2013[MDCRPC], 10/01/2013[MPC], 4/1/2014[MPC], 01/06/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC],06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	03/06/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/01/2015	Revised LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137)
07/28/2016	Added retired LCD language
07/25/2017	Chest CT angiography no longer requires review
06/02/2020	Removed CPT code 71275 and reference for Chest CT Angiography since it does not require medical necessity review
03/06/2023	Addition of Medicare LCD, LCA links for Non-Invasive Fractional Flow Reserve (FFR) for stable Ischemic Heart Disease and applicable codes for Medicare added 0501-0504T.

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KAISER PERMANENTE®

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Clinical Review Criteria
Cardiovascular Risk Panel

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Biomarkers in Cardiovascular Risk Assessment (L36362)
Local Coverage Article	Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that Cardiovascular Risk Panels provide better long-term outcomes than current standard services/therapies.

Cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk (other than simple lipid panels*) are considered **not medically necessary**. Some examples of commercially available cardiovascular risk panels include but are not limited to the following:

- Applied Genetics Cardiac Panel
- Atherotech® Diagnostics Lab CVD Risk Panel and VAP Lipid Panel
- Berkeley Heart Lab (a Quest Diagnostics service) Cardio IQ® Lipid Panel
- Health Diagnostics Cardiac Risk Panel
- Boston Heart Diagnostics
- Genova Diagnostics CV Health Plus Genomics Panel
- Genova Diagnostics CV Health Plus Panel
- Metametrix Cardiovascular Health Profile
- Cleveland HeartLab CVD Inflammatory Profile
- Applied Genetics Cardiac Panel
- Genetiks Genetic Diagnosis and Research Center Cardiovascular Risk Panel
- Quest Diagnostics 4myheart
- Singulex Cardiac Related Test Panels
  - Cardiac Dysfunction panel
  - Vascular Information and Dysfunction panel
  - Dyslipidemia panel
  - Cardiometabolic

* A simple lipid panel is generally composed of the following lipid measures:
- Total cholesterol
- LDL cholesterol
- HDL cholesterol

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- Triglycerides

Certain calculated ratios, such as the total/HDL cholesterol may also be reported as part of a simple lipid panel. Other types of lipid testing, i.e., apolipoproteins, lipid particle number or particle size, lipoprotein (a), etc., are not considered to be components of a simple lipid profile.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Cardiovascular risk panels refer to different combinations of cardiac markers that are intended to evaluate risk of cardiovascular disease. There are numerous commercially available risk panels that include different combinations of lipids, noncardiac biomarkers, measures of inflammation, metabolic parameters, and/or genetic markers. Risk panels report the results of multiple individual tests, as distinguished from quantitative risk scores that combine results of multiple markers into one score. While the individual risk factors have in most cases been associated with increased risk of CV disease, it is not clear how the results of individual risk factors impact management changes, so it is also not certain how the panels will impact management decisions. Given the lack of evidence for clinical utility of any individual risk factor beyond simple lipid measures, it is unlikely that the use of CV risk panels improve outcome.

2010 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Recommendation for Assessment of Lipoprotein Concentrations, Other Lipoprotein Parameters, and Modified Lipids: “Measurement of lipid parameters, including lipoproteins, apolipoproteins, particle size, and density, beyond standard fasting lipid profile is not recommended for cardiovascular disease risk assessment in asymptomatic adults.”
http://circ.ahajournals.org/content/122/25/e584.full.pdf

Applicable Codes

Considered Not Medically Necessary when billed as part of a Cardiovascular Risk Panel:

This is not an all-inclusive list.

CPT® Codes	Description
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
81241	F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
81400	Molecular pathology procedure, Level 1(eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
81479	Unlisted molecular pathology procedure (when utilized with a description of KIF6, 9p21, 4q25-AF, LPA Aspirin, LPA-Intron 25)

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82163	Angiotensin II
82172	Apolipoprotein, each
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed
82397	Chemiluminescent assay (Leptin)
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen [not covered for cardiovascular disease risk]
82610	Cystatin C
82664	Electrophoretic technique, not otherwise classified
82725	Fatty acids, nonesterified [not covered for cardiovascular disease risk]
82777	Galectin-3 [not covered for cardiovascular disease risk]
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
83090	Homocysteine
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified [adiponectin] [leptin] [interleukin-6 (IL-6)] [tumor necrosis factor alpha (TNF-a)] [Oxidized phospholipids] [interleukin 17] [toll-like receptor 4 (TLR4)]
83525	Insulin, total [not covered for cardiovascular disease risk]
83695	Lipoprotein (a)
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)
83700	Lipoprotein, blood; electrophoretic separation and quantitation
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed
83719	Lipoprotein, direct measurement; VLDL cholesterol
83876	Myeloperoxidase (MPO)
83880	Natriuretic peptide
85384	Fibrinogen; activity
85385	Fibrinogen; antigen

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Date Created	Date Reviewed	Date Last Revised
01/25/2017	02/07/2017[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC] , 06/06/2023[MPC]	12/09/2022

[MPC] Medical Policy Committee

Revision History	Description
02/07/2017	MPC approved to adopt criteria to manage cardiovascular risk panels that are commercially available; 60 day notice effective May 1, 2017
06/07/2018	Added LCD – L36362
06/02/2020	Added LCA Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055)
06/01/2021	Updated applicable coding – removed deleted codes 0111T and 0126T
12/09/2022	Updated applicable coding – removed deleted codes 0423T

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Microinvasive Glaucoma Surgery (MIGS)

- Cypass (no longer available)
- iStent Device and Hydrus
- XEN Gel Implant (XEN® Gel stent) for Glaucoma

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Micro-Invasive Glaucoma Surgery (MIGS) (L38301)
Local Coverage Article	Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) (A57864)

For Non-Medicare Members

iStent Device and Hydrus – 66989, 66991	iStent Device and Hydrus will be considered medically necessary when **ALL of the following** are met: 1. Only used in conjunction with Cataract Surgery when the individual is currently being treated with an ocular hypotensive medication **AND/OR** had prior laser trabeculoplasty 2. Used to reduce intraocular pressure (IOP) of greater than 21, except when clinical circumstances would support a lower IOP (this rationale should be documented in the note) 3. 18 years old or over **AND** 4. Mild to Moderate primary open-angle glaucoma defined as how much vision loss via visual field testing 5. Eyes do **NOT** have the following* a. Prior significant trauma b. In eyes with abnormal anterior segment c. In eyes with chronic inflammation d. In glaucoma associated with vascular disorders e. In pseudophakic patients with glaucoma f. In uveitic glaucoma g. In eyes with prior incisional glaucoma surgery or cilioablative procedures h. In eyes with prior laser trabeculoplasty (LT) with selective LT within 90 days prior to screening or prior argon laser trabeculoplasty (ALT) at any time i. In patients with unmedicated IOP greater than 36 mmHg after “washout” of medications j. Plan for implantation of more than two stents

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	k. After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy required, corneal injuries, or complications requiring the placement of an anterior chamber IOL l. When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract Contraindicated in the following patients: • In eyes with angle-closure glaucoma. • In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle. • In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure *Exclusions include clinical circumstances that were not tested in the initial FDA approval.

Xen Gel Implant – 0449T, 66183	The use of Xen Gel Implant will be considered medically necessary when **ONE of the following** are met: 1. Refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues) **OR** 2. Previous surgical treatment has failed (angle-based procedures, laser trabeculoplasty) **OR** 3. Primary open-angle glaucoma **OR** 4. Pseudo-exfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy Should **NOT** be used if any of the following are met: a. Angle-closure glaucoma where the drainage angle of the eye has not been surgically open b. Glaucoma drainage device previously implanted c. Presence of conjunctival scarring, prior conjunctival surgery or other conjunctival pathologies (e.g., pterygium) in the target quadrant d. Pathologies of the conjunctiva (clear membrane covering the white outer layer of the eye) in the area needed for this implant Active iris neovascularization or neovascularization of the iris within six months of the surgical date (abnormal formation of new blood vessels on the iris) e. Eye inflammation (e.g., conjunctivitis, keratitis, uveitis) f. Artificial lens implanted in the anterior chamber (intraocular lens) g. Presence of intraocular silicone oil h. Vitreous present in the anterior chamber

Criteria adopted based on FDA premarket approval and input from KP Ophthalmology leadership.

Cypass device – 0474T
The Cypass device was taken off the market on 8/29/2018 by the manufacturer due to safety concerns. This device will no longer be covered for Kaiser Permanente members.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

The term micro-invasive or minimally invasive glaucoma surgery (MIGS) refers to a group of newer surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance and involve minimal trauma to ocular tissues. In contrast to external filtration surgeries such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries. Compared with traditional filtration surgery, MIGS holds the promise of faster recovery time and less severe complications.

It is this potentially improved safety profile that opened up the indications for MIGS to include patients with early-stage glaucoma to reduce the burden of medications and problems with compliance (due to eye drop application difficulty, cost, cosmetic effects, and frequency). Another area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

There are three FDA approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July 2016), and the XEN Glaucoma Treatment System (Nov 2016). The iStent is a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted into Schlemm's canal to augment the natural outflow system. CyPass is a 6.35 mm long fenestrated microstent made of biocompatible polyimide inserted into the supraciliary space, thus using an alternative outflow system. The XEN45 is a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space, bypassing the natural outflow system.

Both iStent and CyPass were FDA approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate OAG and a cataract that are currently being treated with medication to reduce IOP. XEN45 was granted FDA clearance for the management of refractory glaucoma, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

07/08/2019: MTAC REVIEW

XEN Gel Implant (XEN® Gel stent) for Glaucoma

BACKGROUND

Glaucoma is one of the leading causes of blindness affecting almost 65 million people worldwide. It is a progressive eye disease that causes an irreversible, but potentially preventable damage to the optic nerve leading to visual field and acuity loss. Glaucoma is a heterogeneous group of optic neuropathies, the most common etiology of which is primary open angle glaucoma (POAG) caused by either elevated intraocular pressure IOP-related) or an alternative mechanism (non-IOP-related) (Lavia 2017, Agrawal 2018, Buffault 2019).

Currently, the only proven treatment for IOP-related glaucoma is lowering the intraocular pressure with the aim of preventing additional damage to the ganglionic cells and the optic nerve. Treatment is typically initiated with topical ocular hypotensive medications. Surgery is performed for the treatment of patients with moderate to advanced glaucoma inadequately controlled by the maximally tolerated medical therapy. Currently trabeculectomy is considered the gold standard and most common surgical procedure used for uncontrolled glaucoma. It is an incisional (ab-externo) filtering surgery that lowers the IOP by creating a pathway for release of aqueous humor from the anterior chamber (AC) of the eye into a subconjunctival space known as the filtration bleb (FB). Trabeculectomy is highly effective at lowering the IOP but, is an invasive procedure that requires intense postoperative care and may be associated with complications including hemorrhage, hypotony, scarring, aqueous leak, inflammation of the bleb, and endophthalmitis (Kerr 2017, Hengerer 2017, Agrawal 2018, Yook 2018, Buffault 2019, Heidinger 2019).

Over the last several years, several new devices and less invasive procedures have been developed with the intention of achieving lower IOP with shorter surgical time, less risk, and faster recovery. These are collectively termed "minimally invasive glaucoma surgery (MIGS)" and include trabecular drainage devices (e.g. iStent, iStent inject, and Hydrus microstent), suprachondral drainage devices (such as Cypass and iStent supra), and

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subconjunctival drainage devices including Express shunt, InnFocus micro shunt, and XEN Gel implant. However, some investigators debate whether XEN Gel should be considered as a MIGS (Kerr 2017, Widder 2018).

The XEN®45 Gel implant or stent (Allergan plc, Dublin), the focus of the current review, is intended to decrease IOP by creating a permanent outflow pathway from the anterior chamber to the subconjunctival space through a scleral channel. It is a 6mm long, 45µm wide, soft hydrophilic tube made of a porcine gelatin cross-linked with glutaraldehyde. The implant is stiff when dehydrated but becomes soft and flexible within 1-2 minutes of contact with the aqueous humor, allowing it to conform to the ocular tissue, thus theoretically minimizing migration, erosion, and endothelial damage (Pillunat 2017, Gregorio 2018, Karimi 2018).

The XEN® Gel implant procedure can be performed under local or topical anesthesia. The device is inserted from the anterior chamber (ab-interno) using a pre-loaded disposable injector and implanted into the subconjunctival space opposite the incision with minimal conjunctival tissue disruption. The tube creates a conduit that is intended to maintain outflow of the aqueous humor at 2-2.5µL/min as calculated by Hagen-Poiseuille equation (where the diameter and length of the tube defines the amount of outflow). The channel created leads to the formation of a bleb that assists in the drainage of the aqueous fluid. The bleb is a significant risk factor for scar formation and thus an antimetabolite such as mitomycin C (MMC) at a concentration of 0.1-0.2 mg/ml is generally injected in the subconjunctiva approximately 20 minutes before the procedure to reduce the risk of scar formation. XEN Gel uses the same pathway as trabeculectomy, but with the difference of leaving a foreign body in the tissue. The implant is frequently used in combination with phacoemulsification and lens implantation. In that case, the implantation of the stent is performed after placement of the posterior chamber intraocular lens (IOL) (Pillunat 2017, Ker 2017, Gregorio 2017, Karimi 2018, Bufault 2019).

There are three generations of XEN Gel implants (diameter sizes 45, 63, and 140 µm), but XEN®45 Gel is the one currently recommended and available.

XEN® Gel Stent and XEN Injector received US Food and Drug Administration (FDA) approval in November 2016 for use in patients with refractory glaucoma who failed previous surgical treatment or in patients with primary open angle glaucoma, pseudo exfoliative or pigmentary glaucoma with open angle that are unresponsive to maximum tolerated medical therapy.

The use of XEN Gel stent is contraindicated in certain conditions including angle closure glaucoma; previous glaucoma shunt/valve in the target quadrant; presence of conjunctival scarring; prior conjunctival surgery; other eye pathologies e.g. pterygium in the target quadrant; active eye inflammation; active iris neovascularization; AC IOL; presence of intraocular silicone oil; vitreous present in the AC; impaired episcleral venous drainage; suspected or known allergy to any of the device components or the drugs used with the procedure; and /or a history of dermatological keloid formation (Gregorio 2018).

Reported adverse events associated with XEN Gel implant include hypotony, hyphema, choroidal effusion, choroidal detachment, leaking bleb, bleb inflammation, subconjunctival hemorrhage, conjunctival erosion, conjunctival perforation, stent obstruction, implant migration, extrusion, brakeage, and implant exposure, and the need for secondary interventions and/or intraocular surgeries. Serious complications such as endophthalmitis, and visual acuity loss due to retinal detachment have also been reported (Kerr 2018, Lapira 2018, Lim 2018, Arnold 2019).

Conclusion:

- There is no published high-quality evidence from randomized controlled trials (to date) to determine the comparative effectiveness and safety of XEN Gel implantation versus trabeculectomy or other minimally invasive procedure used to lower IOP in patients with open angle glaucoma uncontrolled with optimal local medications.

- Low quality evidence from several prospective and retrospective observational studies suggest that XEN Gel implant lowers the IOP and reduces the number of IOP- lowering medication used in selected patients with open angle glaucoma uncontrolled with optimal local medications. The results, however, must be interpreted with caution due to the non-randomized design, potential confounding, and other inherent limitations of observational studies.

- The success rates varied between studies from 37-68% depending on definition of success based on the level of IOP reached, duration of follow up, use of topical medications, and need for revision surgeries.

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- XEN Gel implant is associated with intra-and post- operative adverse events (AEs). Many were reported to resolve spontaneously without the need for intervention. However, few were serious and /or required immediate and inevitable interventions.

- More than one third of the eyes require additional surgeries after XEN Gel implant.

  Articles: The literature search did not identify any randomized controlled trials that compared the safety and efficacy of XEN45 Gel implant versus trabeculectomy or any other surgical procedure. The search revealed 3 systematic reviews with meta-analyses that pooled the results of the different of MIGS procedures, two studies (published in 3 articles on the earlier generations of the implant (XEN140 and XEN 63), around 10 observational studies with pre-post comparisons after XEN45 Gel implant with or without cataract surgery, and one retrospective observational study that compared the results the microstent implant to those of a trabeculectomy procedure.

  The meta-analyses of studies on MIGS as well as the studies using the earlier generations of XEN Gel (60 and 140) were excluded. The observational study with a comparison group (Schlenker, 2017) was critically appraised (Evidence table 1) and the larger prospective and retrospective observational studies were summarized in a following table. See Evidence Table.

The use of Xen Gel Implant as a surgical treatment for glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Xen Gel - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

iStent and Hydrus - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

Considered not medically necessary:

CPT® Codes	Description
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

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Cypass (no longer available) - Considered not medically necessary:

CPT® Codes	Description
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

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Date Created	Date Reviewed	Date Last Revised
02/06/2018	02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC] , 02/07/2023[MPC]	01/27/2022

[MPC] Medical Policy Committee

Revision History	Description
06/05/2018	MPC approved criteria for commercial members
10/08/2018	Non-coverage language for the Cypass device
11/14/2018	Language regarding iStent added
08/06/2019	MTAC review for Xen Gel was added
11/15/2019	Added all requests for Xen Gel must go to Medical Director for review
04/07/2020	MPC approved to adopt new coverage criteria for Xen Gel & iStent/Hydrus as surgical treatments for glaucoma, effective 08/01/2020.
08/12/2020	Removed Non-Medicare criteria prior to 08/01/2020
01/27/2022	Updated applicable coding (removed deleted codes 0191T, 0376T, added 66989, 66991, 0671T)

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Clinical Review Criteria

DaT-SPECT

(Dopamine Transporter-Single Photon Emission Computed Tomography)

- **Imaging with (^{123}I)Ioflupane, DaTscan, or (^{123}I)FP-CIT**

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Single Photon Emission Computed Tomography (SPECT) (220.12) *Medical necessity review no longer required
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Movement disorders are neurological conditions that affect the speed, fluency, quality, and ease of movement. They include a wide range of disorders including, but not limited to, Parkinsonian syndromes (PS) and essential tremor (ET). ET, the most common movement disorder, typically involves involuntary shaking movement with no cause. PS, on the other hand, is a group of neurodegenerative disorders that have similar features and symptoms, of which, the most frequent form is idiopathic Parkinson's disease (PD) accounting for 80% of all PS. Although ET and PS have different underlying etiologies, they present with similar clinical features, especially in the early stages of disease progression, thus complicating diagnostic differentiation. Accurate diagnosis of patients with suspected PS is critical for patient management because the disease course, therapy and prognosis greatly differ from non-degenerative diseases (Dauer and Przedborski 2003; de Lau and Breteler 2006).

Currently, the gold standard for the diagnosis of PS is post-mortem neuropathological examination. In practice, however, diagnosis is based on the presence of two or more classical motor features including bradykinesia, rigidity, tremor, and postural instability which can be atypical or mild in the early stages of the disease. Long-term clinical follow-up and good response to dopaminergic drugs have also been used to support clinical diagnosis (de

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la Fuente-Fernández 2012). Pathologic studies have shown that the lack of an objective diagnostic tool has resulted in an error rate of 10-30% (Rajput, Rozdilsky et al. 1991). Misdiagnosis can lead to unnecessary disability if effective treatment options are not initiated, and inappropriate therapies may unnecessarily expose patients to the potential side effects thus warranting an early and accurate diagnostic tool to ensure appropriate management.

DaTscan™ is a recent advance in imaging technology that supports the clinician in the differential diagnosis of PS and ET. While there is limited knowledge on the etiology of ET, the main pathological hallmark of PS is the loss of dopaminergic neurons in the substantia nigra, leading to striatal dopamine depletion (Dauer and Przedborski 2003). The DaTscan™ technology is able to determine the location and measure the amount of dopamine transporter (DaT) in the brain. More specifically, through small amounts of a contrast agent called (^{123}I)ioflupane and using a single photon emission computerized tomography (SPECT) scanner, DaTscan™ is able to demonstrate reduced striatal uptake of DaT where PS is present and, in contrast, normal striatal uptake in patients with ET. The results of DaTscan™ are not intended to differentiate between different PS disorders, but instead, should be used when diagnosis is inconclusive to rule out other movement disorders with similar presenting symptoms.

In January 2011, the U.S. Food and Drug Administration (FDA) approved the DaTscan™ for striatal dopamine transporter (DaT) visualization using SPECT brain imaging to assist in the evaluation of adult patients presenting with symptoms or signs suggestive of dopaminergic neurodegeneration. In these patients, DaTscan may be used to help differentiate ET from tremor due to PS and is intended for use as an adjunct to other diagnostic evaluations.

Medical Technology Assessment Committee (MTAC)

DaT-SPECT

02/10/2014: MTAC REVIEW

Evidence Conclusion: Marshall and colleagues conducted a prospective, longitudinal study. Among 102 patients with an early Parkinsonian syndrome with or without tremor (possible and probable) vs. a combination of patients with non-PD tremor (essential or dystonic tremor) and healthy volunteers. Clinical and DaTscan assessments were made at baseline, 18 months, and 36-month follow-up. The primary endpoint was the baseline DaTscan image assessment by three independent blinded readers as normal or abnormal. The standard of truth was the clinical diagnosis established by two independent movement disorder specialists in consensus, based on the assessment of patient's clinical examination videos at 36 months of follow-up. The standard of truth was used to judge whether or not a subject had a striatal dopaminergic deficit (Marshall, Reininger et al. 2009). Ultimately, the study concluded that in the 99 patients who completed all three assessments, on-site clinical diagnosis over-diagnosed degenerative parkinsonism at baseline (sensitivity was 93% and specificity was 46%) compared with the standard of truth clinical diagnosis (sensitivity 78% and specificity 97%). See Evidence Table. Vlaar and colleague's meta-analysis included eight studies that specifically assessed the diagnostic differentiation between PD and ET and concluded that SPECT with presynaptic tracers may accurately differentiate between patients with PD and ET with a reported sensitivity ranging from 88-100% and specificity of 80%-100%. Two of the included studies compared the diagnostic accuracy of the treating physician with the SPECT in its capacity to delineate PD from ET. Initial clinical diagnosis in these trials reached a sensitivity of respectively 76% and 87% and a specificity of 50% and 80%. More often than not, the included studies compared DaTscan diagnoses with clinical diagnoses, and it is not known how often the clinical diagnosis was wrong. Ideally, a study would follow patients until death to confirm diagnosis with autopsy (Vlaar, van Kroonenburgh et al. 2007). See Evidence Table *Risks of Diagnostic Test:* The Marshall et al. study, recorded adverse events (AE) at each follow-up visit. During the 36-month period, a total of 4 subjects died and 32 subjects (18%) experienced 71 nonfatal serious AEs, none of which were deemed to be related to the DaTscan. Only 24 (6.0%) AEs, reported by 13 subjects were considered to be related to the DaTscan. The most common AEs were headache (3%), nausea (2%), injection site hematoma (1%), dizziness (1%) and dysgeusia (1%) (Marshall, Reininger et al. 2009). Kupsch and colleagues also collected information on AE in their study which only resulted in two patients with AE that were considered related to the DaTscan. Both of the events, sleep disorder and headache, occurred following administration and prior to imaging and required no treatment (Kupsch, Bajaj et al. 2012). *Impact on Diagnosis and Patient Management:* In practice, clinical diagnosis is sufficient and accurate for many patients with advanced and typical manifestations of PD. There is a subset of patients, however, with suspected PS, particularly those with early-stage disease or atypical signs and symptoms, who theoretically may benefit from further diagnostic evaluation. The recently published, and rigorous evaluation of the impact of diagnostic test on clinical outcomes is a randomized, prospective, multicenter, global (US and Europe), controlled clinical trial conducted by Kupsch and colleagues in 2012. The study sought to demonstrate the impact of (^{123}I) Ioflupane on clinical management,

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diagnosis and confidence of diagnosis during a one-year follow-up in 273 patients with clinically uncertain PS of whom 138 were randomized to (^{123}I) Ioflupane and 135 randomized to no imaging. Significantly more patients in the (^{123}I) Ioflupane imaging group had at least one change in their actual clinical management after 12 weeks (p=0.002) and after 1 year (p<0.001) compared with patients in the control group. In addition, significantly more (^{123}I)ioflupane patients had changes in diagnosis and an increased confidence diagnosis at 4 weeks, 12 weeks and 1 year (all p<0.001) compared with control patients (Kupsch, Bajaj et al. 2012). See Evidence Table. Although the literature reports good accuracy with minimal safety concerns, the studies should be interpreted with caution. It is important to remember that throughout the literature, there was no autopsy confirmation of diagnosis, and thus no confirmed "gold standard". The interpretation of the imaging data is controversial due to inter-reader reliability and the target populations are poorly defined with many studies using clearly defined later-stage patients that are obviously not representative of the FDA indication. Even with the use of the DaTscan, the diagnosis of PS remains a clinical judgment based on imaging technology. Finally, it should be noted that the majority of the literature has received some sort of industry sponsoring. Conclusion*:* The evidence supports high sensitivity and specificity, but the lack of a gold standard limits the value of these numbers. There is evidence to indicate that the use of DaTscan™ can sometimes result in changes in diagnosis and treatment, however, there is no evidence to support that these changes result in improved health outcomes.
Articles: The literature search for studies on the accuracy of DaTscan in patients with suspected PS revealed almost 200 articles that assessed the DaTscan in a variety of differential diagnostic situations. This search was further narrowed down to include studies that specifically addressed diagnostic differentiation between PS and ET. For the most part, the literature was comprised of studies that were small with limited methodology due to a lack of gold standard for diagnosis.

The following articles were selected for critical appraisal:
Marshall VL, Reininger CB, Marquardt M et al. Parkinson's Disease is overdiagnosed clinically at baseline in diagnostically uncertain cases: A 3-year European multicenter study with repeat [^{123}I]-FP-CIT SPECT. *Movement Disorders*. 2009;24(4):500-508. See Evidence Table. Vlaar AM, van Kroonenburgh MJ, Kessles AG, et al. Meta-analysis of the literature on diagnostic accuracy of SPECT in parkinsonian syndromes. BMC Neurol 2007; 7:27. See Evidence Table. Kupsch AR, Bajaj N, Weiland F, et al. Impact of DaTscan SPECT imaging on clinical management, diagnosis, confidence of diagnosis, quality of life, health resource use and safety in patients with clinically uncertain parkinsonian syndromes: a prospective 1-year follow-up of an open-label controlled study. *J Neurol Neurosurg Psychiatry*. 2012; 83:620-628. See Evidence Table.

The use of DaT-SPECT does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare – Medical Necessity review not required
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day imaging
A9584	Iodine I-123 Ioflupane, diagnostic, per study dose, up to 5 mCi
ICD-10 Codes	**Description**
G20	Parkinson's disease
G25.0	Essential tremor
G40	Epilepsy and recurrent seizures

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03/04/2014	04/01/2014[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/07/2021

[MPC] Medical Policy Committee

Revision History	Description
09/01/2020	Removed deleted CPT code 78607 and added 78803.
09/07/2021	Added ICD-10 codes G20, G25.0 and G40.

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Clinical Review Criteria
Deep Brain Stimulation

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Deep Brain Stimulation (KP-0403) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

> ***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Neurology, Neurosurgery)

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies for the following:

- Refractory Obsessive - Compulsive Disorder
- Primary Headache
- Neuropathic Pain (see Background information in KP-0403)

(See also Occipital Nerve Stimulation for Primary Headache)

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Deep-brain stimulation (DBS) was first developed in the late 1980's. DBS involves ongoing electrical stimulation of a particular target in the brain and is designed to block the abnormal firing of neurons. The exact mechanism of action of DBS is not known. DBS has been used since the early 1990s to treat movement disorders such as Parkinson's disease, and, in 1999, the first report was published applying DBS to the treatment of refractory obsessive-compulsive disorder.

DBS consists of an insulated wire lead with four electrodes at its end that are surgically implanted into the affected area of the brain. A wire runs under the skin to a battery-operated pulse generator implanted near the

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collarbone or in abdomen. The generator is programmed to send continuous low voltage electrical pulses to the brain. It can be turned on or off when the patient swipes a special magnet over the generator. (Movement disorders patients typically turn off the device at night, because tremors usually stop during sleep.) The voltage can be adjusted in relation to the symptoms being treated.

To implant the electrodes, a neurosurgeon uses a stereotactic head frame and magnetic resonance or computed tomography imaging to map the brain and pinpoint the problem area. The patient's scalp is anesthetized before the procedure, but the patient is awake to report side effects while the electrodes are placed. This allows the lead to be placed for maximum effectiveness and minimum side effects.

Evidence and Source Documents

Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor
Globus Pallidus and Subthalamic Nucleus Stimulator Implant- Parkinson's
Refractory Obsessive-Compulsive Disorder
Primary Headache

Medical Technology Assessment Committee (MTAC)

Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor

BACKGROUND

Essential tremor is the most common form of tremor that affects more than 1 million patients in the US. It is defined as tremor which is postural, usually involving the upper limbs, absent at rest, not exacerbated by movement and not of cerebellar or extrapyramidal origin. One of the symptoms of Parkinson's Disease is tremor. Treatment for mild cases of tremor involves pharmacologic therapy with propranolol or L-dopa for Parkinsonian tremor. Severe debilitating tremor is usually treated with stereotactic surgical thalamic ablation (thalamotomy). However, thalamotomy can result in clinically significant neurologic side effects and once lesioned, no further tremor control is possible. The beneficial effects of thalamic stimulation on tremor were first identified when stimulation was used to localize the electrode prior to making a lesion in the thalamus for tremor control.

Electrical tremor control systems consist of an electrode implanted in the thalamus connected to an implanted radio-frequency pulse generator. The stimulator is programmed for optimal tremor control by a Neurologist and can be turned on or off by the patient using a magnet.

04/19/1999: MTAC REVIEW

Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor

Evidence Conclusion: Several case series have been published examining the role of thalamic stimulation in essential tremor and in Parkinson's disease. It is clear that stimulation reduces contralateral upper limb tremor to a clinically significant extent. In essential tremor improvement was noted when performing activities such as writing, drinking and eating. Although quality of life was not formally assessed the degree of change is likely to be clinically important. In Parkinson's disease the utility of reducing tremor is less clear, with no change in ability to write, dress, cut food, or speak. Perioperative complications occur in approximately 10%, and at 12 months neurologic complications related to stimulus intensity are common, each of the following occurring in 2-4%: dystonia, dysarthria, paresthesia, and disequilibrium.

Articles: Koller, W, et al, High Frequency Unilateral Thalamic Stimulation in the Treatment of Essential and Parkinsonian Tremor, *Ann Neurol.* 1997, 42:292-299 See Evidence Table**.** Limousin, JD et al, Multicentre European Study of Thalamic Stimulation in Parkinsonian and Essential Tremor. *J Neurol. Neurosurg Psychiatry.* 1999:66:289-296 See Evidence Table**.** Ondo, W et al. Unilateral Thalamic Deep Brain Stimulation for Refractory Essential Tremor and Parkinson's Disease Tremor. *Neurology*, 1998;51:1063-1069 See Evidence Table.

Members noted that patients who had debilitating non-tremor symptoms of Parkinson's disease such as rigidity and cogwheel movements would probably not show clinically significant improvements in their ability to eat, write or drink and therefore the benefits of thalamic stimulation would probably not outweigh the harms of this invasive surgical procedure in this population.

Electrical stimulation of the thalamus for the treatment of essential tremor meets GHC Medical Technology Assessment Criteria 1-5 for effectiveness and 6 for appropriateness and is therefore considered to be medically appropriate for patients who have failed maximal medical therapy for controlling their tremor.

Thalamic stimulation for treatment of Parkinsonian tremor also meets GHC Medical Technology Assessment Criteria 1-6 only for patients whose primary functional disability is tremor despite maximal medical therapy.

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10/03/2006: MTAC REVIEW
Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor
Evidence Conclusion: The evidence on deep brain stimulation for treating Parkinson's disease consists of two randomized controlled trials. Both studies had results favoring deep brain stimulation. The stronger study methodologically found a statistically significant reduction in motor symptom scores in the group assigned to deep brain stimulation in a double-blind comparison to no stimulation (Deep Brain Stimulation Study Group, 2001). However, Medtronic, the device manufacturer funded the study and was responsible for data collection and analysis. The other randomized controlled trial found more improvement in quality of life and symptom severity scores in patients assigned to neurostimulation compared to medical management (Deutschl et al., 2006). Limitations of the latter study are the study was not blinded and study participants had already failed medical management. The Deutschl study was not funded by Medtronic, but several authors had financial links with the company.
Articles: Deutschl G, Schade-Brittinger C, Krack P et al. A randomized trial of deep-brain stimulation for Parkinson's Disease. *N Engl J Med* 2006; 355: 896-908. See Evidence Table.

Evidence updated but not brought to MTAC as no change from previous review outcome.

Globus Pallidus and Subthalamic Nucleus Stimulator Implant
BACKGROUND
Deep brain stimulation (DBS) is a technique that is being used to treat symptoms of Parkinson's disease (PD). The main pharmacotherapy for PD is levodopa. Although levodopa is generally initially effective at reducing symptoms of PD, it eventually leads to side effects such as dyskinesias in many patients. Surgeries such as thalamotomy, pallidotomy are other possible treatments. An advantage of DBS is that, unlike other surgeries, it does not create lesions or destroy brain tissue.

Deep brain stimulation involves implanting an electrode into a specific region of the brain using stereotactic neurosurgical techniques. The electrode is connected to a programmable pulse generator that generates high frequency stimulation (>100 Hz) in a target nucleus. The pulse generator is implanted below the clavicle.

Thalamic stimulation, used to treat tremor, is the most well-established application of DBS with Parkinson's patients (thalamic stimulation for tremor met MTAC evaluation criteria in April 1999). Other targets are the internal globus pallidus and subthalamic nucleus which are believed to be effective for treating a wider range of PD symptoms, including bradykinesia, rigidity dystonia and gait disorder, as well as tremor.

Medtronic, Inc. manufactures the device that provides deep brain stimulation (the Activa System). The FDA approved a version of this device in 1997 for stimulation of the thalamus to control Parkinson's tremor and essential tremor. In March 2000, an FDA panel gave a premarket approval with conditions for bilateral DBS for the treatment of other Parkinson's symptoms.

10/10/2001: MTAC REVIEW
Globus Pallidus and Subthalamic Nucleus Stimulator Implant
Evidence Conclusion: The highest quality evidence consisted of one study that had a double-blind randomized component. In the double-blind randomized assessment, the study found a statistically significant reduction in motor symptom scores during deep-brain stimulation of the subthalamic nucleus or pars interna of the globus pallidus compared to no stimulation. The case series portion of the study found that symptoms improved significantly with stimulation 3- and 6-months post-implantation compared to pre-implantation. There were a substantial number of adverse effects but no comparison with adverse effects with other treatments or no treatment. A limitation of the study was that Medtronic, the device manufacturer, not only funded the study but also was responsible for data collection and analysis.
Articles: The search yielded 146 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were a number of small studies (n=25 or less), mainly case series; one was an RCT with n=10. The strongest study was published after the formal search was conducted. This study included a randomized double-blind assessment of outcomes and the sample size was over 100. This partially randomized study was critically appraised: Deep-brain stimulation for Parkinson's disease study group. Deep-brain stimulation of the subthalamic nucleus or the pars interna of the globus pallidus in Parkinson's disease. N Engl J Med 2001;345: 956-63. See Evidence Table.

The use of Globus Pallidus and Subthalamic Nucleus Stimulator Implant in treatment of Parkinson's Symptoms does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Refractory Obsessive-Compulsive Disorder

BACKGROUND

Obsessive-compulsive disorder is a common psychiatric diagnosis, affecting approximately 3% of people worldwide (Burdick et al., 2009). For initial treatment of OCD, the American Psychiatric Association (APA) recommends cognitive behavioral therapy (CBT), pharmacotherapy with SSRIs, or a combination of the two. For patients who do not respond to monotherapy, the next step is either switching medications, augmenting with another medication, or adding CBT if not already initiated (Harvard Medical Letter, 2009).

Approximately 20-40% of patients have worsening symptoms despite conventional treatment. Surgery is an option for patients who experience severe and incapacitating symptoms in spite of multiple medication trials and/or medication and CBT. Primary surgical approaches are subcaudate tractotomy (creating a lesion beneath the head of the caudate nucleus in the substantial innominata), cingulotomy (radiofrequency ablation of the anterior cingulum), limbic leucotomy (combination of previous two procedures), and anterior capsulotomy (interrupting fibers between the thalamus and the anterior frontal lobe) (Burdwick et al., 2009).

Another potential alternative therapy for treatment-resistant patients is deep brain stimulation (DBS). DBS involves chronic electrical stimulation of a particular target in the brain and is designed to modulate transmission of the neural circuit. The exact mechanism of action of DBS is not known and this is an area of active research. DBS has been used since the early 1990s to treat movement disorders such as Parkinson's disease, and, in 1999, the first report was published applying DBS to the treatment of refractory OCD. The optimal target for DBS in OCD patients is still being determined (Burdwick et al., 2009).

In February 2009, the FDA approved a humanitarian device exemption for a deep brain stimulator for severe OCD by Medtronic (Reclaim device). The humanitarian device exemption is an FDA classification signifying that the technology is used to treat conditions that affect fewer than 4,000 new patients per year. The FDA reviews the safety of the device but does not require that efficacy is established before approval. The FDA decision stipulates that deep brain stimulation is indicated for treatment of OCT in adult patients who have failed at least three SSRIs, and it can be used as an adjunct to medication. DBS is contraindicated in patients exposed to diathermy or MRIs, or who are unable to properly operate the brain stimulator. Medtronic plans to release the product commercially in the United States in mid-2009 (Medtronic website; FDA documents).

The Reclaim device by Medtronic includes a neurostimulator that is implanted subcutaneously in the upper abdominal region. The neurostimulator produces electrical stimulation pulses that are carried to an implanted set of leads via a lead extension. The leads are stereotactically introduced into the target area of the brain and are fixed at the skull with a burr hole cap and ring. The neurostimulator is battery-powered. There are sparse clinical data on battery life. According to Medtronic, the battery is expected to last 6-16 months, or longer depending on the neurostimulator setting used. When the battery is depleted, it can be replaced surgically. The primary clinical data submitted by Medtronic for FDA approval was a case series of 26 patients treated at 3 centers in the US and one in Europe (FDA and Medtronic documents).

06/01/2009: MTAC REVIEW

Deep brain stimulation for the treatment of refractory obsessive-compulsive disorder

Evidence Conclusion: There is insufficient evidence to draw conclusions about the safety and effectiveness of deep brain stimulation for patients with refractory obsessive-compulsive disorder. The empirical literature consists of case series with 10 or fewer patients.

Articles: The Medline search limited to a range of clinical trials yielded 10 articles. No additional articles were identified on the manufacturer's Web site. There were no randomized controlled trials or non-randomized comparative studies. The empirical literature consisted of small case series, with sample sizes ranging from 4 to 10. The studies do not meet MTAC criteria for reviewable evidence which requires that studies are published and, for case series, has a minimum sample size of 25.

The use of Deep brain stimulation for the treatment of refractory obsessive-compulsive disorder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Primary Headache

BACKGROUND

Headache is a major worldwide health problem disabling millions of people and resulting in considerable economic burden. Up to 40% of patients seen in major headache clinics suffer from chronic daily headache. Chronic headache disorders include migraine, cluster headache, cervicogenic headache, occipital neuralgia, and other types of primary headache (Maizels 1998, Jasper 2008).

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Cluster headache (CH), an excruciating headache syndrome, is the most common type of trigeminal autonomic cephalalgias, and is thought to be the most severe primary headache disorder. 10-20% of CH patients develop a chronic form in which the attacks persist for more than one year without remissions, or with remissions lasting less than a month. Acute treatment for the attacks includes injectable or intranasal triptans or oxygen inhalation. About one percent will become refractory to medical treatment and fulfill the criteria of intractable headaches. These patients may get some relief with attack treatments, but the disorder could be disabling and may be associated with depression and suicidality (Magis 2007, Leroux 2008).

Migraine headache is a chronic headache that affects about 15% of the population and is one of the most common problems seen in emergency departments and doctors' offices. Migraine is believed to result from changes in the brain and surrounding blood vessels. The attacks typically last from 4-72 hours and vary in frequency from daily to less than one per year. Transformed migraines are chronic daily or almost daily headaches (>15/month) that lasts more than 4 hours. There is no cure for migraine, and medications can only help reduce the frequency and severity of disorder (Bigal 2008).
Cervicogenic headache is a chronic hemicranial pain that usually occurs daily. It usually begins at the suboccipital region and spreads anteriorly to the ipsilateral orbital, frontal, and temporal areas. It is typically unilateral bur occasionally affects the two sides. It is believed to be due to convergence of upper cervical and trigeminal sensory pathways allowing pain signals to refer from the neck to the trigeminal sensory fields of the head and face. Treatments with pain medication, physical therapy, manipulative treatment, and surgical interventions may provide only some inconsistent temporary relief of pain (Naja 2006).

Various ablative surgical procedures targeting the trigeminal nerve, or the cranial parasympathetic outflow have been tried to treat these patients with intractable headaches. These include gamma knife surgery or root section of the trigeminal nerve, trigeminal tractotomy, microvascular decompression of the trigeminal nerve, glycerol injection of the Gasserian ganglion, and others. However, none of these procedures has a consistent effect, and many are associated with serious complications (Magis 2007).

Electrical stimulation of the brain was first attempted late in the 19th century, but its application for pain control began in the 1960s with spinal cord stimulation. The neurostimulation technique for ablating pain is based on the theory that peripheral nerve stimulation can produce specific focal analgesia and anesthesia. In addition, the technique may alter perception of pain by blocking cell membrane depolarization and axonal conduction with directly applied current (Shealy 1967, Lim 2007, Trentman 2008).

In the early 2000s, neurostimulation therapy emerged as a potential treatment option for a variety of different intractable primary headache disorders. This is an invasive device- based approach that has two broad types:
1. Peripheral therapy that involves branches of the occipital nerve: occipital nerve stimulation (ONS), and supraorbital nerve stimulation.
2. Central which refers to deep-brain stimulation (DBS) approaches e.g. hypothalamic deep brain stimulation used for chronic cluster headache (Schwedt 2009).

The occipital nerve stimulators (ONS) are implanted surgically in a 3-phase procedure: Phase 1. An incision is made over the occipital region at the level of the first cervical vertebra for the subcutaneous implantation of bilateral electrodes. These are tunneled in a cephalad direction so that they come to lie across the path of the greater occipital nerve on each side of the head. Phase 2. Confirmation of the electrode position by testing each separately by an external stimulator. The operator gradually increases the amplitude delivered to the electrodes from 0 to 4 v, and the patient is asked to locate and describe any sensation he /she feels. Correct placement is confirmed by the patient describing a vibrating sensation that radiates at least 4 cm cephalad from the base of the skull, on the side of the tested electrode, and Phase 3. Implantation of the stimulator battery in the pectoral, abdominal, or gluteal region, and connecting it to the electrodes via subcutaneously tunneled leads. The procedure is performed under sedation or general anesthesia, however during the second phase the patients are required to be awake and to be able to identify the position of the occipital electrodes when the electric stimulus is applied. Potential complications of the procedure include lead migration, infection, localized pain, muscle spasm, and lack or loss of effect (Lim 2007, Trentman 2008).

The deep brain stimulation (DBS) of the posterior hypothalamus has been investigated in patients with chronic cluster headaches or SUNCT (short-lasting, unilateral, neuralgiform headache attacks with conjunctival injection and tearing). DBS involves MRI guided stereotactic placement of an electrode into the brain (e.g. thalamus, globus pallidus, or subthalamic nucleus). It is typically implanted unilaterally on the side corresponding to the most severe symptoms. The use of bilateral stimulation using two electrodes has been investigated in patients with bilateral, severe symptoms. Initially, the electrode(s) is/are attached to a temporary transcutaneous cable to validate treatment effectiveness and, if effective, the patient returns to surgery several days later for permanent
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subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. After implantation, noninvasive programming of the neurostimulator can be adjusted to control the patient's symptoms. The procedures can be performed only by a highly experienced neurosurgeon and may be associated with a small risk of mortality due to intra-cerebral hemorrhage. Before implantation, all patients must undergo complete preoperative neuroimaging to exclude disorders associated with increased hemorrhagic risk (Leon 2006, Bartsch 2008).

Neither the occipital nerve stimulation nor the deep brain stimulators are approved to date by the U.S. Food and Drug Administration for the treatment or prevention of primary headaches.

08/03/2009: MTAC REVIEW
Deep Brain Stimulation for the Treatment of Primary Headache
Evidence Conclusion: The literature on brain stimulation for the treatment of chronic primary headache is limited and does not provide sufficient evidence to determine the efficacy or safety of either occipital or deep brain stimulation therapy for the prevention or treatment of chronic headache. There are no published randomized or nonrandomized controlled trials on the intervention to date. The empirical studies consist of a few very small case series with no comparison groups and a number of case reports. The outcome measures varied between studies as some reported change in pain and others reported on headache frequency intensity, disability and/or medication use. To date all published studies on hypothalamic deep brain stimulation are small case series and case reports with a combined total of 55 participants with refractory chronic cluster headache. Leone et al's series had the largest size (N=16) and follow-up duration (mean 23 months). The results of this study and other case series indicate that this invasive procedure has potential serious complications and is not always effective. Deep brain stimulation was not compared to another treatment or intervention to determine that the benefit observed was no a placebo effect.
Articles: The search yielded almost four hundred articles. The majority was review articles, opinion pieces, or dealt with technical aspects the procedure. DBS: The search identified 12 small case series and reports with a total number of 57 patients on deep-brain stimulation for chronic cluster headache. Leone M, Franzini A, Broggi G, et al. Hypothalamic stimulation for intractable cluster headache; long-term experience. Neurology 2006:67:150-152. See Evidence Table.

The use of Deep brain stimulation for the treatment of primary headache does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays

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61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
L8679	Implantable neurostimulator, pulse generator, any type
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

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Date Created	Date Reviewed	Date Last Revised
08/03/2010	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 05/07/2013[MDCRPC], 12/03/2013[MPC], 04/01/2014[MPC], 02/03/2015[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/02/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/02/2019	MPC approved to adopt indications for Mini-Mental State Examination with score of at least 24 and no evidence of severe depression

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Clinical Review Criteria
Defecography for Diagnosing Defecation Disorders

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (220.2)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Defecation is a highly complex physiologic process that requires normal colonic transit, ano-rectal sensation, expulsion force, and coordinated function of the pelvic floor for successful evacuation. A disturbance at any level of this process can lead to a defecation disorder (DD) (Maccioni 2013). DDs encompass a variety of clinical conditions including obstructed defecation syndrome, rectocele, rectal intussusception, rectal prolapse and enterocele. Patients typically report symptoms such as excessive straining, sensation of blockage, and a feeling of incomplete evacuation. Some patients even report a need to use digital maneuvers to defecate, and frequent use of enemas or suppositories. While the true prevalence of DD is unknown, the symptom of constipation is extremely common in the United States with a reported 5.7 million constipation-related physician visits in 2006 alone. While not life threatening, DDs can cause a considerable amount of morbidity and, in some cases, have devastating impacts on quality of life.

In most cases, diagnosis of DDs can be established accurately based on physical examination and detailed history. However, symptoms can be nonspecific and overlapping. While there is no gold standard for pinpointing the cause of DD, current practice guidelines from national bodies recommend physiological testing such as anorectal manometry (ARM) and rectal balloon expulsion tests (BET). In the event of equivocal results, however, direct visualization of the pelvic floor and lower bowel may be necessary (AGA 2013; Wald, Bharucha et al. 2014). Defecography, first described in 1952 by Wallden, was initially developed for the evaluation of outlet obstruction (Wallden 1952). Since then, however, defecography has evolved to not only detect structural abnormalities, but also to assess functional parameters. Although it has been recognized as a useful diagnostic technique, methods and interpretation of defecography have not yet been standardized. Conventionally, the technique involves placement of a contrast medium into the rectum, similar to the consistency of stool, and laterally imaging activity throughout defecation using fluoroscopy. Alternatively, defecography can also be performed in the supine or upright position with magnetic resonance imaging (MRI). In any case, interpretation of the imaging focuses on the anal rectal angle (ARA) at rest and during straining providing an indirect measurement of the function of the puborectalis muscle. Additionally, imaging can provide information about perineal descent, anal diameter, indentation of the puborectalis, and the amount of rectal and rectocele emptying.

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Medical Technology Assessment Committee (MTAC)

Defecography for Diagnosing Defecation Disorders

10/20/2014: MTAC REVIEW

Evidence Conclusion: A 2011 study conducted in France by Vitton and colleagues compared the accuracy of both MRI defecography and dynamic anal endosonography (DAE) using conventional defecography as the gold standard. The study involved 56 female patients with a history of dyschezia. Patients received each procedure randomly over a one-month period. Using conventional defecography as the criterion standard, the investigators calculated a range of sensitivities and specificities for detecting rectoceles, perineal descent, and enterocele. For both DAE and MRI, the sensitivities were highest in detecting rectoceles at 73.5% and 81.6%, respectively. For detecting perineal descent and enterocele the sensitivities were 61% and 58.3% for DAE and 46.3% and 66.7% for MRI. Specificities were 100% in both DAE and MRI for identifying enteroceles. The specificities were lower for perineal descent 73.3% (DAE) and 86.7% (MRI) and rectoceles 85.7% (DAE) and 85.7% (MRI). Although MRI defecography performed better than DAE no significant differences were observed between the diagnostic techniques and both correlated well with conventional defecography under the Youden index and the Yule correlation coefficient. Regardless, conventional defecography is an imperfect gold standard limiting the value of these results (Vitton, Vignally et al. 2011). Foti and colleagues also prospectively compared conventional and MRI defecography. In this study, 19 consecutive patients with outlet obstruction syndrome (OOS) underwent both conventional and MRI defecography. With the overall aim to develop a protocol for MRI defecography the comparisons between the two techniques showed no significant differences in sphincter hypotonia, dyssynergia, rectocele and rectal prolapse. Significant differences were, however, seen in descending perineum. Ultimately, the authors concluded that while MR imaging provides morphological and functional study of pelvic floor structures it cannot replace CD and may offer benefit if offered as a complementary tool to CD in evaluating OOSs (Foti, Farina et al. 2013). In a meta-analysis that sought to estimate the prevalence of abnormal findings associated with dyssynergic defecation across testing modalities, 79 studies including 7,581 patients were pooled and analyzed. The overall prevalence of any single abnormal dynamic pelvic floor test ranged from 14.9% to 52.9% with a median of 37.2%. The investigators note that the prevalence of abnormal tests tended to be lower in defecographic studies accounting for the lower end of this range. In addition to identifying a high prevalence of dyssynergic defecation in patients with chronic constipation, the investigators suggest that the lower prevalence of abnormalities found with defecography supports the use of ARM and BET for initial evaluation (Videlock, Lembo et al. 2013). None of the selected studies overtly assessed the safety and harms of defecography however, theoretically, the harms of conventional defecography include all those that we know to be associated with radiation exposure. In the study by Vitton and colleagues, patient tolerance and preference for assessment procedures was examined using a visual analogue scale. Tolerance was rated “high” or “very high” more frequently in the MRI defecography group (44.9%) than in the conventional defecography group (36.7%), although this difference was not significantly significant (P=0.9). This partiality was mirrored in a 2012 study, by Pilkington and colleagues, assessing patient acceptance of conventional and MRI defecography. In this study, the investigators administered questionnaires to 42 patients undergoing defecography (of these patients 25 patients completed for both conventional and MRI defecography). Over half of patients (62%) who underwent both procedures identified MRI proctography as the preferred technique. When asked why, all of these patients cited ‘less embarrassing’ as the reason for preference (Pilkington, Nugent et al. 2012). The clinical utility of diagnostic tests for constipation in adults was examined in a 2005 systematic review by Rao and colleagues. The investigators were able to identify ten case series related to the use of defecography. Although the results of the included studies did not allow for meta-analysis, the investigators found the results of the included studies to be conflicting citing significant overlap of findings between patients and healthy controls and poor correlation of symptoms with defecographic findings. Ultimately, defecography was recognized as a useful source of information regarding the anatomical and functional changes of the anorectum but concluded that the technique should only be regarded as an adjunct to clinical assessment and not relied upon as a sole diagnostic test. This study was not critically appraised due to lack of meta-analysis (Rao, Ozturk et al. 2005). Overall, the literature should be interpreted with caution. Beyond the heterogeneous nature of the populations across the literature, an inherent difficulty of evaluating the accuracy of defecography is that there is the lack of a true gold standard. To add to this, diagnostic criteria are continually changing inhibiting the ability to establish a standard technique or interpretation. Without adequately defined ranges for quantified measures and parameters interpretation relies on opinion rather than objective findings. Beyond that, no studies have been able to demonstrate that defecography contributes to improved diagnosis and more appropriate patient management.

Conclusions: There is insufficient evidence to conclude that defecography is accurate in the evaluation of DD. There is insufficient evidence to conclude that defecography is not harmful to patients. There is insufficient evidence to conclude that defecography contributes to improved diagnosis of DD. There is insufficient evidence to conclude that defecography leads to more appropriate management of patients with DD.

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Articles: The literature search revealed just over 200 publications addressing defecography, the majority of which were continuing medical educational materials, manuscripts or editorials. The remainder was comprised of small studies either describing various techniques or attempting to establish standards for interpretation. No studies were identified that aimed to assess the accuracy of conventional defecography by comparing the technique to other available techniques. The best available evidence came from two prospective studies comparing conventional defecography with MRI defecography and one meta-analysis comparing different testing modalities in the assessment of chronic constipation. The following articles were selected for critical appraisal: Vitton V, Vignally P, Barthet MB, et al. Dynamic anal endosonography and MRI defecography in diagnosis of pelvic floor disorders: comparison with conventional defecography. Diseases of the colon & Rectum 2011;(54) 11:1398-1404. See Evidence Table 1. Foti PV, Farine R, Riva G, et al. Pelvic floor imaging: comparison between magnetic resonance imaging and conventional defecography in studying outlet obstruction syndrome. Abdominal Radiology 2013;(118) 1:23-39. See Evidence Table 2. Videlock EJ, Lembo A, Cremonini. Diagnostic testing for dyssynergic defecation in chronic constipation: meta-analysis. Neurogastroenterology & Motility 2013;(25) 6:509-519. See Evidence Table 3.

The use of Defecography for Diagnosing Defecation Disorders does not meet the *Kaiser Permanente Medical Diagnostic Test Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary -

CPT® or HCPC Codes	Description
72195	**Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)**
72196	**Magnetic resonance (eg, proton) imaging, pelvis; with contrast material(s)**
72197	**Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences**
With diagnosis codes	
K59.00	**Constipation, unspecified**
K59.01	**Slow transit constipation**
K59.02	**Outlet dysfunction constipation**
K59.03	**Drug induced constipation**
K59.04	**Chronic idiopathic constipation**
K59.09	**Other constipation**
K59.4	**Anal spasm**
K62.89	**Other specified diseases of anus and rectum**

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/28/2014	11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/01/2022MPC	11/04/2014

MPC Medical Policy Committee

Revision History	Description

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Clinical Review Criteria

Dermatology Services

Cosmetic vs Medical for the following:

- Alopecia, Keloids, Laser Treatments, Benign Lesions
- Broad Band UVB Therapy
- Excimer Laser for Vitiligo
- Home Narrow Band UVB Therapy for Psoriasis
- Narrow Band UVB Therapy
- PUVA Therapy
- UV Lights

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Laser Procedures (140.5) Treatment of Psoriasis (250.1) Treatment of Actinic Keratosis (AKs) (250.4) Durable Medical Equipment Reference List (280.1)
Local Coverage Determinations (LCD)	Benign Skin Lesion Removal (Excludes Actinic Keratosis, and Mohs) (L33979) Plastic Surgery (L37020)
Local Coverage Article	Local Coverage Article: Additional Information Required for coverage and pricing for Category III CPT® Codes A55681- RETIRED 06/30/2020 Noridian retired **Local Coverage Article (LCA A55681).** These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on Kaiser Permanente commercial criteria or literature search. ***includes CPT 0479T, 0480T***

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Kaiser Permanente Medical Policy	For phototherapy requests other than Psoriasis (see above) such as Eczema 96900, 96910, as well as other dermatological conditions: Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **for in office or home UVB Phototherapy use Phototherapy, Skin (KP-0255 v2) MCG** for medical necessity determinations.

For Non-Medicare Members

1) The following treatments are considered cosmetic and are therefore not covered:
   a) Botulinum injections for treatment of wrinkles and facial imperfections (for covered indications for botulinum injections see the pharmacy prior authorization criteria)
   b) Tattoo removal (CPT 15783)
   c) Laser treatment of pigmented lesions, rosacea, superficial leg and face veins, cherry angiomas, telangiectasias, spider angiomas, or spider veins/venous ectasias
   d) Chemical peel (CPT 15788, 15789, 15792, 15793, 17360)
   e) Micro-dermabrasion (No codes specific for this service)
   f) Dermabrasion (CPT 15780, 15781, 15782, 15783, 15786)
   g) Acne scar repair (CPT 15780)
   h) Tattooing, depigmentation, and melanocyte transplant for vitiligo

2) The following treatments are covered and are not considered cosmetic when conditions are met:
   a) ***Alopecia treatment*** when the alopecia results from **ONE of the following**:
      - Infection (treatment is for the infection)
      - Autoimmune disorder
      - Discoid lupus
      - Low iron stores
      - Folliculitis decalvans

      Laser treatment services described in 2b no longer require medical necessity review (CPT: 17000, 17003, 17004, 17106, 17107, 17108, 17110, 17111, and 17250)
   b) **Laser treatment** for **ONE of the following**:
      - Port wine stain on head or neck
      - Telangiectasias scarring when caused by removal of skin cancer or radiation therapy
      - Facial angiofibroma secondary to tuberous sclerosis
      - Vascular lesions with history of spontaneous bleeding as documented in the patient's medical record
      - Actinic Keratoses (AK) for chemo sensitive agents

   c) **Excimer Laser** (CPT code 96920, 96921, 96922) is covered when **ALL of the following** are meet:
      1. Member must have **ONE of the following** conditions:
         a. Vitiligo: vitiligo on the face, neck or hands.
         b. Psoriasis: scalp, face, neck or hands
      2. There must be documentation of the failure of medical management with topical therapy

   d) **Scar/keloid revision**: Kaiser Permanente has elected to use the Scar Revisions (KP-0495) MCG* for medical necessity determinations.

   e) **Fractional Laser for burns and traumatic scars:** *Currently not covered due to lack of efficacy per the published medical literature (0479T, 0480T).*

   f) Removal of **benign skin lesions** (seborrheic keratoses, skin tags, milia, molluscum contagiosum, sebaceous (epidermoid) cysts, moles (nevi), acquired hyperkeratosis (keratoderma) and viral warts) are medically necessary and not cosmetic and are covered when **ONE or more of the following** criteria are met:
      1. The clinical diagnosis is uncertain, particularly where malignancy is a realistic consideration based on lesion appearance (non-responsive to conventional treatment or change in appearance).
      2. The lesion has **ONE or more of the following** characteristics:

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- Bleeding
- Intense itching
- Pain
- Has physical evidence of inflammation (purulence, oozing, edema, erythema, etc.)
- Clinically restricts an orifice or vision
- Is in an anatomical region subject to recurrent physical trauma and there is documentation of resulting pain, itching, or bleeding

g) **Laser/intense pulse light treatment** is covered for hair removal when the excess hair is a result of a documented endocrine abnormality confirmed by blood test. (commonly submitted with CPT 17999)

h) **PUVA:** Kaiser Permanente has elected to use the Skin Phototherapy (PUVA) (KP-0253) MCG* for medical necessity determinations. CPT code 96912, 96913

i) **UVB:** Kaiser Permanente has elected to use the Phototherapy, Skin (KP-0255 v2) MCG* for medical necessity determinations. CPT code 96900, 96910

j) **Home narrowband UVB phototherapy** is covered for qualifying conditions per Phototherapy, Skin (KP-0255 v2) MCG* when:
- The member has durable medical equipment coverage
- The light is ordered by a dermatology provider
- Home phototherapy requires initial support/teaching for frequency, dose of treatment to avoid over or undertreatment as well as follow up on a regular basis to ensure correct treatment, as arranged by the ordering provider

Related criteria:
Electronic Brachytherapy for non-melanoma skin cancer
Dermal Fillers for Facial Lipoatrophy

*** MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist (dermatology, surgery notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Dermatology services include a wide array of therapies. Some therapies are purely cosmetic, others are considered from a benefits standpoint to be "medically necessary" and relate to function and/or have an impact on an individual's physical, social and/or mental well-being.

The purpose of expanding the criteria set is to distinguish between dermatology services that are considered purely cosmetic versus those which are seen as medically necessary and are covered in part or whole. The creation of the criteria set incorporated what was previously found in coverage policy and other reference documents.

Medical Technology Assessment Committee (MTAC)

Home Narrowband UVB Phototherapy

BACKGROUND

Psoriasis is a chronic skin disease that affects 1-3% of the population. With psoriasis, the life cycle of skin cells is

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shortened from about a month to a few days. Consequently, cells build up rapidly on the outer layer of skin, forming thick erythematous plaques that are often pruritic. (Mayoclinic.com; BMJ clinical evidence). Treatments for psoriasis include: 1) self-care: baths, avoidance of alcohol, moisturizer; 2) topical medications: corticosteroids, vitamin D analogues, anthralin, retinoids; 3) oral medications: retinoids, methotrexate, azathioprine, cyclosporin, immunomodulator drugs (biologics); 4) phototherapy; 5) combination therapy e.g. phototherapy and oral medications. The biologic Etanercept is current covered by GHC for patients with extensive, severe psoriasis who meet the following criteria: failed topical treatments, failed at least one systemic agent (e.g. methotrexate), and failed a 12-week course of phototherapy. Phototherapy is one of the more commonly used treatments for psoriasis. The rationale behind phototherapy is that it causes photochemical reactions of endogenous absorbing molecules results in reduction of DNA synthesis that leads to a treatment effect. The therapy was first proposed in the 1920s by Dr. Goeckerman at the Mayo clinic who found a beneficial effect of natural sunlight in combination with coal tar. In the 1970s, it was shown that broadband ultraviolet B (UVB) radiation alone could treat milder clinical forms of psoriasis. After experimentation with different wavelengths, it was found that wavelengths between 311-313 nm were best at balancing the clearing of psoriasis while at the same time minimizing the adverse effect of erythema. The first well-designed lamp that emitted narrow-band radiation at 311-313 nm, the Phillips TL-01 fluorescent lamp, was introduced in 1984 (Kist, 2005; Honigsmann, 2001). The main treatment-limiting side effect of narrowband UVB is erythema, reported by 10-94% of patients depending on treatment regimen and definition of erythema. Other short-term side effects include dry skin with pruritis, blistering, and increased frequency of recurrent herpes simplex outbreaks. Long-term side effects, as with other types of phototherapy, include photo ageing and skin cancer. However, the incidence of skin cancer in patients with psoriasis treated with narrowband UVB is not well known (Kist et al., 2005, Naldi et al., 2005). The recommended initial treatment dose of narrowband UVB is 50-80% of a patient's minimal erythema dose (MED), established through phototesting. This is followed by increases of 10-40%, depending on the aggressiveness of the treatment and the patient's response (Kist, 2005; Honigsmann, 2001). The American Academy of Dermatology guidelines recommend giving up to 20-25 treatments of narrowband UVG, 2-3 times a week (Menter et al., 2008).

10/06/2008: MTAC REVIEW
Home Narrowband UVB Phototherapy
Evidence Conclusion: There is insufficient evidence to draw conclusions about the safety and effectiveness of home narrowband UV-B phototherapy for patients with psoriasis. There are no published randomized or non- randomized trials that use modern home phototherapy equipment. Findings from an RCT are expected to be published within the next 3-6 months.
Articles: A 2006 review article (Koek et al., 2006) on home ultraviolet B phototherapy for psoriasis identified 7 empirical clinical studies, 5 of which were published in English. 3 of the 5 studies in English were published between 1979-1983, before the introduction of the Phillips TL-01 fluorescent lamp. Thus, they did not use currently available phototherapy technology. Both of the more recent studies (Cameron et al., 2002; Feldman et al., 1996) were case series with fewer than 25 patients. One of the 3 older studies (Paul et al., 1983) had a comparison group, the others were case series. The Paul et al. study, which included 40 patients, compared the efficacy of a Metec-Helarium unit emitting low-intensity selective UV phototherapy (LISUP) at home to 3 times/week in-office UVB therapy. In-office UVB therapy was found to be more effective than home LISUP treatment; 90% (18/20) of patients in the UV-B group experienced clearing of psoriasis compared to 40% (8/20) of patients in the home LISUP group. No additional completed studies were identified that compared home UVB phototherapy to in-office UVB phototherapy or to a different type of treatment. A published protocol for an RCT was identified (Koek et al., 2006). This trial, called the PLUTO study, is a multi-center trial comparing home UVB treatment to in-center UV-B phototherapy in 196 patients with psoriasis. The home phototherapy treatments is Waldmann UV-100 unites with TL-01 lamps. According to the lead author (personal communication), a manuscript on the study outcomes is currently under review by the BMJ.

The use of Home narrowband UVB phototherapy in the treatment of psoriasis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/05/2009: MTAC REVIEW
Home Narrowband UVB Phototherapy
Evidence Conclusion: PLUTO study (Koek 2009) on home versus outpatient ultraviolet B phototherapy for psoriasis randomized 196 patients (in the Netherlands) with mild to severe psoriasis and clinically eligible for narrowband ultraviolet B phototherapy, to receive the treatment at home or in an outpatient setting. The trial had valid methodology and design as a noninferiority study. The patients and providers were not blinded, however assessment of the severity of and extent of the disease were evaluated by an independent research nurse blinded to the treatment arms. The results of the trial indicate that home phototherapy was not inferior to that provided in outpatient department, mainly for the self-administered psoriasis area and severity index (SAPASI) 50, 75, and 90 (i.e. proportion of patients achieving at least 50%, 75%, or 90% decline of baseline SAPASI at the end of therapy) as well as the psoriasis area and severity index (PASI) 90. However, the possible inferiority of home ultraviolet phototherapy to that provided in an outpatient setting,

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could not be entirely excluded for the primary outcome of PASI 50, or PASI 75, as the lower limits of the 95% confidence intervals were slightly lower than -15% preset noninferiority margin. The differences observed in SAPASI and PASI results may indicate a bias in the patient's self-assessment. The results of the trial also showed that patients in the home therapy group had a significantly higher mean number of irradiations, but an insignificantly higher cumulative dose at the end of therapy. 87% of the all participants had at least one occurrence of mild erythema, 58% a burning sensation, and 39% severe erythema with no significant differences between the two study groups. No significant differences were observed in the disease specific or generic quality of life among patients treated on outpatient setting or at home. The home therapy however, was associated with a lower burden of treatment and greater patient satisfaction.

Articles: A study on home versus outpatient ultraviolet B phototherapy for psoriasis was recently published in BMJ in 2009. Koek MB, Buskens E, vanWeelden H, et al. Home versus outpatient ultraviolet B phototherapy for mild to severe psoriasis: pragmatic multicenter randomized controlled non-inferiority trial (PLUTO study). *BMJ* 2009; 338: b1542 doi 10.1136/bmj. b1542

The use of Home narrowband UVB phototherapy in the treatment of psoriasis does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

Fractional carbon dioxide (CO_2) and erbium-doped yttrium aluminum garnet (Er:YAG) lasers are commonly used for treatment of excessive scarring. Laser therapy may be used to improve erythema, texture, pliability, and pain associated with burn and traumatic scars. Fractional laser ablation refers to the process in which a laser beam is split into hundreds of microbeams, which create small thermal injuries to the skin. It is believed that the injury caused by laser induces collagen formation and tissue remodeling. As opposed to ablative lasers, nonablative lasers induce coagulation only and do not cause epidermal injury and tissue vaporization.

Conclusion

An overall very-low-quality body of evidence is insufficient to draw regarding the efficacy and safety of CO2 fractional laser ablation or Er:YAG fractional treatment of burn or traumatic scars for functional improvement. Although most of the reviewed studies reported improved scar pliability following fractional laser treatment, this represents a surrogate outcome that does not directly address the primary Key Question. There is a large body of evidence on fractional laser ablation of hypertrophic scars and keloids; however, it primarily addresses cosmetic outcomes. The literature evaluating the impact of fractional laser treatment on functional outcomes is wholly comprised of case reports, which only supply anecdotal information. Large, well-designed trials of fractional laser treatment that directly address improvement of functional outcomes associated with scarring as a result of burns or trauma are needed.

Hayes Rating: D^2 --Insufficient Evidence: For carbon dioxide (CO^2) fractional laser ablation for functional improvement related to burn or traumatic scars. D^2 --Insufficient Evidence: For Erbium-doped yttrium platinum garnet (Er:YAG) fractional laser treatment for functional improvement related to burn or traumatic scars.

Hayes. Hayes Technology Assessment. *Fractional Laser Treatment of Burn and Traumatic Scars for Functional Improvement.* Dallas, TX: Hayes; May 11, 2021. Retrieved February 03, 2023, from https://evidence.hayesinc.com/report/htb.fractionallaser4442

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met (unless otherwise noted):

Alopecia Treatment

CPT® or HCPC Codes	Description
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
96902	Microscopic examination of hairs plucked or clipped by the examiner (excluding hair collected by the patient) to determine telogen and anagen counts, or structural hair shaft abnormality
With Diagnosis Codes	
L63.0	Alopecia (capitis) totalis
L63.1	Alopecia universalis

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L63.2	Ophiasis
L63.8	Other alopecia areata
L63.9	Alopecia areata, unspecified
L64.0	Drug-induced androgenic alopecia
L64.8	Drug-induced androgenic alopecia
L64.9	Androgenic alopecia, unspecified
L66.2	Folliculitis decalvans
L66.8	Other cicatricial alopecia
L66.9	Cicatricial alopecia, unspecified

Benign Skin Lesions

CPT® or HCPC Codes	Description
11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.5 cm or less
11401	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.6 to 1.0 cm
11402	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 1.1 to 2.0 cm
11403	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 2.1 to 3.0 cm
11404	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 3.1 to 4.0 cm
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter over 4.0 cm
11420	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.5 cm or less
11421	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.6 to 1.0 cm
11422	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 1.1 to 2.0 cm
11423	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 2.1 to 3.0 cm
11424	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 3.1 to 4.0 cm
11426	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter over 4.0 cm
11440	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less
11441	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.6 to 1.0 cm
11442	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 1.1 to 2.0 cm
11443	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 2.1 to 3.0 cm
11444	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 3.1 to 4.0 cm
14446	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter over 4.0 cm
11450	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with simple or intermediate repair
11451	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with complex repair
11462	Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with simple or intermediate repair
11463	Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with complex repair
11470	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with simple or intermediate repair

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11471	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with complex repair

Excimer Laser (Vitiligo & Psoriasis)

CPT® or HCPC Codes	Description
96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
96921	Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm
96922	Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm

Home Narrowband UVB Phototherapy

***Note: Code E0691 can be ordered more than once (e.g., scalp and hand/foot device) or billed with codes E0692-E0694.**

CPT® or HCPC Codes	Description
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel
E0694	Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection
A4633	Replacement bulb/lamp for ultraviolet light therapy system, each

Fractional Laser for burns and traumatic scars

Medicare – Considered not medically necessary

Non-Medicare – Considered not medically necessary

CPT® or HCPC Codes	Description
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Laser/Intense Pulse Light Treatment for hair removal

CPT® or HCPC Codes	Description
No specific codes – ***c**ommonly submitted with CPT code 17999 Unlisted procedure, skin, mucous membrane and subcutaneous tissue*	

PUVA

CPT® or HCPC Codes	Description
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)
96913	Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)

Scar/Keloid Revision

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CPT® or HCPC Codes	Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children
15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children
15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
23921	Disarticulation of shoulder; secondary closure or scar revision
24149	Radical resection of capsule, soft tissue, and heterotopic bone, elbow, with contracture release (separate procedure)
24925	Amputation, arm through humerus; secondary closure or scar revision
25907	Amputation, forearm, through radius and ulna; secondary closure or scar revision
25922	Disarticulation through wrist; secondary closure or scar revision
25929	Transmetacarpal amputation; secondary closure or scar revision
26121	Fasciectomy, palm only, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft)
26123	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft);
26125	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft); each additional digit (List separately in addition to code for primary procedure)
27594	Amputation, thigh, through femur, any level; secondary closure or scar revision
27884	Amputation, leg, through tibia and fibula; secondary closure or scar revision
31830	Revision of tracheostomy scar
67343	Release of extensive scar tissue without detaching extraocular muscle (separate procedure)
With Diagnosis Codes	
L73.0	Acne keloid
L91.0	Hypertrophic scar
L90.5	Scar conditions and fibrosis of skin

UVA

CPT® or HCPC Codes	Description
96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B

Considered not medically necessary:

Botulinum Injections

CPT® or HCPC Codes	Description
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64612	Chemodenervation of parotid and submandibular salivary glands, bilateral
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and

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	accessory nerves, bilateral (eg, for chronic migraine)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles

Tattoo Removal

CPT® or HCPC Codes	Description
15783	Dermabrasion; superficial, any site (eg, tattoo removal)

Chemical Peel

CPT® or HCPC Codes	Description
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
17360	Chemical exfoliation for acne (eg, acne paste, acid)

Micro-dermabrasion

CPT® or HCPC Codes	Description
No Specific Codes	

Dermabrasion

CPT® or HCPC Codes	Description
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)

Tattooing, Depigmentation, and Melanocyte Transplant for Vitiligo

CPT® or HCPC Codes	Description
No specific codes	

Acne Scar Repair

CPT® or HCPC Codes	Description
11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or

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	legs; excised diameter 0.5 cm or less
11401	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.6 to 1.0 cm
11402	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 1.1 to 2.0 cm
11403	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 2.1 to 3.0 cm
11404	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 3.1 to 4.0 cm
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter over 4.0 cm
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)
With Diagnosis Code	
L70.0	Acne vulgaris
L70.1	Acne conglobata
L70.2	Acne varioliformis
L70.3	Acne tropica
L70.4	Infantile acne
L70.5	Acne excoriee
L70.8	Other acne
L70.9	Acne, unspecified

Medical Necessity Review not required:
Laser treatment (described in 2b):

CPT® or HCPC Codes	Description
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion
17003	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)
17004	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions
17106	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); over 50.0 sq cm
17110	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
17111	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions
17250	Chemical cauterization of granulation tissue (ie, proud flesh)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Dates Reviewed	Date Revised

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07/25/2002	12/07/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC] ,07/02/2013[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023 [MPC]	04/18/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Review History	Description
05/21/2015	Added CPT codes
09/01/2015	Excimer Laser: added scalp psoriasis as indication
02/02/2016	Home UVB Phototherapy: Add psoriasis as a covered indication
08/02/2016	Home UVB Phototherapy: Add diagnosis of eczema will be reviewed on a case-by-case basis
12/19/2017	Added Plastic Surgery LCD (L37020)
06/17/2019	Added Eczema as an indication to Home Narrowband UVB phototherapy
08/06/2019	Minor changes were made to benign skin lesions criteria to allow removal of warts
12/01/2020	MPC approved to adopt updates to the existing hybrid Phototherapy, Skin criteria, KP-0255, to expand coverage for additional indications including Granuloma annulare and Pityriasis lichenoides chronica for in-office and home phototherapy. Members must have durable equipment coverage and requires initial support/teaching by the ordering provider for home phototherapy. Requires 60-day notice, effective date 05/01/2021.
04/28/2021	Added diagnosis codes covered by Medicare for home phototherapy; removed retired LCD L35008
05/04/2021	Laser treatment services described in 2b in criteria above, and represented by CPT codes: 17000, 17003, 17004, 17106, 17107, 17108, 17110, 17111, and 17250, will no longer require medical necessity review. Requires 60-day notice, effective date October 1, 2021.
03/01/2022	Updated applicable codes.
10/28/2022	Updated Medicare Policy to defer to KP Non-Medicare criteria for phototherapy for skin conditions other than psoriasis.
11/01/2022	Updated Medicare Policy to defer to KP non-Medicare criteria for phototherapy for all skin conditions including home UVB.
02/07/2023	Clarified criteria for Fractional Laser Treatment of Burn and Traumatic Scars for Functional Improvement. Added Hayes Technology Assessment dated May 11, 2021, to references.
04/18/2023	Added retired Medicare Retired Local Coverage Article A55681 for supporting documentation

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Diabetes Tests and Supplies

- Home A1c Test
- iPort Injection Port

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Diabetes Tests and Supplies" for medical necessity determinations. Refer to the Non-Medicare criteria below.

Service	Criteria
• Home A1c Test • i-Port/i-Port Advance Injection Port	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Diabetes Sentry Monitor (no longer available)
GlucoWatch Biographer™ (no longer available)
Home A1c Test
iPort Injection Port

Medical Technology Assessment Committee (MTAC)

Diabetes Sentry Monitor

BACKGROUND

There is evidence that tight glycemic control is associated with a lower incidence of diabetic complications including reduced rates of retinal, neurologic, and renal damage. Strict control of blood glucose, however, is associated with an increased risk of hypoglycemia (DCCT Research Group, 1993).

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Hypoglycemic episodes commonly occur at night. Mild episodes of nocturnal hypoglycemia are generally asymptomatic but may affect mood and well-being the following day. Recurrent exposure to nocturnal hypoglycemia may impair cognitive function. Severe episodes can cause convulsions and coma and may lead to cardiac arrhythmias resulting in sudden death. Strategies to reduce nocturnal diabetes include regular blood glucose monitoring, eating appropriate bedtime snacks, and use of short- and long-acting insulin analogues (Allen & Frier, 2003).

The Diabetes Sentry monitor is designed to monitor hypoglycemia and alert patients when they are experiencing physiological symptoms. The device was originally developed as the Sleep Sentry monitor in approximately 1980s. The device was later taken off the market and a re-designed version received FDA approval in 2003. In 2005, the FDA approved the name change to Diabetes Sentry. The device is manufactured by Diabetes Sentry Products in Bellingham, WA.

According to manufacturer's materials, the Diabetes Sentry monitors two symptoms of hypoglycemia: perspiration and drop in skin temperature (decrease of 2o F). Either of these symptoms will trigger an audible alarm loud enough to awaken most people. Patients are instructed that, when the alarm sounds, they need to verify whether they are in fact experiencing hypoglycemia with a blood glucose monitor. The company acknowledges that there are false-positive alarms since there are other reasons for nocturnal perspiration and temperature drop, for example, change in room temperature or a shift in blankets. The manufacturer estimates that there will be an approximately one false alarm per night. The device is designed for people with insulin-dependent diabetes who have a severe enough problem with nocturnal hypoglycemia that they are willing to accept false-positives.

Other potential limitations of the Diabetes Sentry monitor are that patients may forget to turn on the device and some individuals may not awaken when the alarm sounds. In addition, the device is not useful for patients with hypoglycemia unawareness since they may not perspire or experience a drop-in temperature during mild hypoglycemic episodes.

Unlike the Glucowatch, which is intended to measure blood glucose levels, the Diabetes Sentry measures symptoms of hypoglycemia (perspiration and temperature).

This is the first time that MTAC has reviewed the Diabetes Sentry.

Assessment objective: To evaluate the accuracy of the Diabetes Sentry for detecting hypoglycemic events. To evaluate the impact of device use on health outcomes (e.g. reduction in morbidity from hypoglycemia).

08/07/2006: MTAC REVIEW
Diabetes Sentry Monitor
Evidence Conclusion: There is no published evidence on the Diabetes Sentry approved by the FDA in 2003.
Articles: The search yielded 3 articles; all of these were small case series (n<25 each) and were published in the 1980s on the original Sleep Sentry device. There were no published articles evaluating the re-designed Diabetes Sentry device approved by the FDA in 2003.

The use of Sleep Sentry Monitor in the treatment of Diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

GlucoWatch

BACKGROUND

Intensive glucose control to maintain a lower level of blood glucose has been associated with fewer long-term complications of diabetes (e.g. UKPDS, 1998). Self-monitoring of blood glucose is an important part of a program to maintain tight glucose control. The standard procedure for self-monitoring of blood glucose involves frequent finger-stick measurements which can be painful and/or inconvenient for patients.

The GlucoWatch Biographer (Cygnus Inc., Redwood City, CA) is proposed as a non-invasive blood glucose self-monitoring device. The GlucoWatch Biographer was approved by the FDA to supplement (not replace) the information provided by standard finger-stick, glucose monitoring devices. The theoretical advantages of the GlucoWatch over standard self-monitoring procedures are increased convenience and less pain since patients could take fewer finger-stick measurements, increased accuracy of blood glucose levels through continuous monitoring and increased safety since the GlucoWatch has the capacity to sound an alarm when blood glucose reaches a dangerous level.

The GlucoWatch is worn on the forearm and has the appearance of a wristwatch. It extracts extracellular fluid by applying a low-level electrical current to the skin, a process known as reverse iontophoresis. The fluid is collected in gel discs on a single use component of the device, called the Autosensor. The fluid undergoes a chemical reaction after being catalyzed by glucose oxidate and. The GlucoWatch calculates a blood glucose level using the electrical signal produced by this chemical reaction, the strength of which is proportional to the glucose level.

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After a 3-hour warm-up period and calibration with a blood glucose level, the Autosensor provides up to 12 hours of glucose readings produced every 20 minutes. The Glucowatch displays the most recent glucose level and stores the remaining readings. It can be set to produce an audible alarm if the glucose level is above or below pre-specified limits. The alarm will also sound if the glucose level falls more than 35% compared to the last measurement, or if the device senses perspiration, which can interfere with functioning of the device and is also associated with hypoglycemia.
The FDA approved the GlucoWatch Biographer in March 2001 for individuals, age 18 and older. In August 2002, the GlucoWatch was approved for use by children between the ages of 7 and 17 years.

02/13/2003: MTAC REVIEW
GlucoWatch
Evidence Conclusion: *Children:* There is no published evidence on the efficacy of the GlucoWatch Biographer for monitoring blood glucose levels among children with diabetes.
Adults: There is no published evidence on whether use of the GlucoWatch Biographer improves health outcomes or glucose control among people with diabetes compared to standard self-monitoring techniques. The evidence on the accuracy of the GlucoWatch suggests that measurements are reasonably accurate compared to fingerstick measurements (approximately 70% of measurements would lead to clinically correct decisions and about 95% would lead to clinically acceptable decisions). However, the data may be biased because all studies were conducted by investigators affiliated with the device manufacturer, and most data were collected in a controlled clinical environment and accuracy may differ in a “real-life” setting.
Articles: The search yielded nine articles. One was an article reviewing several glucose monitoring devices, one was a report announcing the new technology, and the remaining seven were authored by the Cygnus Research Team. There were no studies reporting on the effect of glucose self-monitoring with the GlucoWatch on health outcomes e.g. macrovascular or microvascular complications of diabetes. There were also no studies reporting on the effect of glucose self-monitoring with the GlucoWatch on the ability to maintain tight glucose control. The empirical data all addressed the accuracy of the GlucoWatch to detect current blood glucose levels. All of the studies were conducted among adults. The two studies on accuracy with the strongest methodology were critically appraised. Features examined for study selection were sample size, thoroughness of methods description, setting (controlled environment vs. home setting) and comparison with finger-stick measurements. The following articles were reviewed: Tierney MJ, Tamada JA, Potts et al. Clinical evaluation of the GlucoWatch biographer: a continual, non-invasive glucose monitor for patients with diabetes. *Biosensors & Bioelectronics* 2001; 16: 621-629. See Evidence Table

The use of GlucoWatch in the evaluation of diabetic control does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Home A1c Tests
BACKGROUND
A1c (also known as hemoglobin HbA1c or HbA1c) gives information about the average blood glucose level over the previous 2-3 months and is the best measure of overall blood glucose control for patients with diabetes (Kaiser Permanente diabetes guideline). The A1c test measures the concentration of glycosylated hemoglobin in the blood. A1c forms when some of the glucose circulating in the blood binds irreversibly to hemoglobin A, forming a stable glycated hemoglobin complex. The A1c level is proportional to the amount of glucose in the blood over the life span of red blood cells. It does not fluctuate with daily blood glucose levels.
An HbA1c target of <7% is recommended for most patients with type 1 or type 2 diabetes. Research has found that, if a patient's HbA1c level is higher than 8%, reducing it by one-tenth (e.g., from 10% to 9%) will slow down damage to their body by about 50% from the current rate (DCCT Research Group 1997). The Kaiser Permanente diabetes glycemic control guideline recommends that people with diabetes routinely monitor their HbA1c every 6 months. For patients who have elevated blood glucose and are attempting to reduce their blood glucose levels, Kaiser Permanente recommends checking HbA1c every 3 months until the target level is reached.
HbA1c tests have traditionally been conducted in a health-care setting. Several in-home HbA1c tests have been cleared by the FDA. The FlexSite A1c At-Home test was FDA-approved in 1997 and is available over-the-counter. It includes a blood sample collection kit that uses treated filter paper for spotting blood. The patient provides one or two drops of blood to each of two target areas on the filter paper and lets the sample dry overnight. The dried blood sample is then mailed to the FlexSite lab where it is evaluated. Results are available by phone or mail. The manufacturer claims that its sample collection technique allows a dried blood sample to be transported for up to 12 days without significant artifactual in vitro glycation (manufacturer’s website; Parkes et al., 1999).
Another home A1c test was approved by the FDA in 2002 under the name Metrica A1cNow. It was cleared both for prescription and over-the-counter use. Beginning in 2004, the test has been distributed exclusively by Bristol-
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Meyers Squibb and it is now called the ChoiceDM A1c Home test. Unlike the FlexSite test, the Metrika A1cNow/Choice DM A1c Home test provides results at home. The test comes as a disposable, one-use device about the size of a pager. It incorporates microelectronics, optics and dry-reagent chemistry strips. Individuals collect a sample of whole blood via fingerstick or venipuncture, place the sample in a cartridge and mix it with the dilution solution provided by the manufacturer. The diluted sample is added to the monitor which activates the device (there are no buttons or switches, the device is self-activated). Activating the device causes blue microparticles conjugated to an anti-HbA1c antibody to migrate along the reagent strips. The amount of blue microparticles captured on the strips is proportionate to the amount of HbA1c in the sample. After about eight minutes, the results are displayed in numeric form on the digital display. Total hemoglobin in the sample is also measured (manufacturer's website; Kordella, 2002).

02/05/2007: MTAC REVIEW
Home A1c Test
Evidence Conclusion: No published evidence was identified on the Metrika A1cNow/Choice DM A1c Home test, the test that provides results to patients within minutes at home. In addition, there was no published evidence the ability of home A1c testing to improve clinical outcomes. One published study was identified on the FlexSite at-home A1c sampling kit, which requires mailing samples to a centralized laboratory. This study found that A1c levels using the usual method for analyzing in-home samples was highly correlated with two standard methods of establishing A1c levels. However, the accuracy e.g. sensitivity and specificity of any of the tests was not reported. In addition, the study involved having patients and staff collect blood samples, but the test results for the two types of samples were not reported in the analysis. The authors of the study had links to the test manufacturer which may have introduced bias.
Articles: No published studies were identified on the Metrika A1cNow/Choice DM A1c Home test. An FDA talk paper from 2002 states that the Metrica device was cleared for non-prescription use based on a study by the manufacturer comparing test results obtained by lay users to those obtained by medical professionals. The Medline search did not identify a published version of this study and the company did not respond to a request for the manuscript. One published study was identified on the Flexsite at-home test. This study was critically appraised: Parkes J, Ray R, Kerestan S et al. Prospective evaluation of accuracy, precision, and reproducibility of an at-home hemoglobin A1c sampling kit. Diab Tech Ther 1999; 1: 411-419. See Evidence Table.

The use of Home A1c tests in the treatment of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

I-Port™ Injection Port
BACKGROUND
The I-Port is a device that is placed on the skin, and through which patients can self-administer subcutaneous injections of prescription medications using a standard syringe and needle. A removable insertion needle allows placement of the body of the I-Port device on the skin. The device is held in place by an adhesive pad and a soft cannula. The I-Port body is 1.5" (38mm) in diameter and 1/3" (9mm) tall. The disposable I-Port can be worn for up to 72 hours and, during this time, up 75 needle sticks can be made through the soft cannula. During an injection of medication, the needle of the syringe remains above the surface of the skin. Medication is delivered through the cannula into the subcutaneous tissue. The I-Port is manufactured by Patton Medical Devices, a company founded by K.K. Patton, the inventor of the device. The I-Port was approved by the FDA in September 2005 as a class II device judged to be substantially equivalent to predicate devices. It is approved for marketing to adults and children who require multiple daily injections of prescription medication, including insulin.
The manufacturer materials warns consumers to use as specified by a health care provider and not to re-use the I-Port, not to use the same I-Port for longer than 72 hours and not to use a needle longer than 8mm or thicker than 28 gauge when injecting into the I-Port. In addition, the I-Port website Q&A section states that irritation, inflammation and infection are rare, but the potential for these exist, especially when the skin surface is not adequately cleaned before application or when the device is improperly applied to the body.
There was one adverse event report on the FDA Manufacturer and User Facility Device Experience Database (MAUDE) database. This was a device malfunction that occurred on July 24, 2007 with a life-threatening patient outcome. Details of the event were not included in the report.

10/01/2007: MTAC REVIEW
I-Port™ Injection Port
Evidence Conclusion: There is no published evidence to support the use of the I-Port and no published information on the safety of the device.

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Articles: No published articles were identified.

The use of iPort in the delivering of prescription medications does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Home A1c- Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use

iPort- Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
A4211	Supplies for self-administered injections

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
02/13/2003	02/13/2003[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	11/03/2020

[MPC] Medical Policy Committee

Revision History	Description
11/03/2020	Removed Diabetes Sentry Monitor and GlucoWatch Biographer from list of services as the specific products are no longer available.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Frequent Hemodialysis - Greater Than 3 Days a Week

- Facility
- In Home
- Nocturnal
- Short Daily

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Frequency of Hemodialysis (L37504)
Local Coverage Article	Billing and Coding: Frequency of Hemodialysis (A55676)

For Non-Medicare Members

Standard hemodialysis 3 days a week is covered for members with end stage renal disease. For home dialysis the following additional criteria must be met:

1. The member is stable on dialysis.
2. The member is free of complications and significant concomitant disease that would render home dialysis unsuitable or unsafe.
3. The member or caregiver is capable of completing a home dialysis training program and adhering to a prescribed treatment regimen.
4. Adequate caregiver is available during dialysis
5. Back-up arrangements have been made with the facility-based dialysis center.

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

End-stage renal disease (ESRD) is defined as an irreversible decline in kidney function that is severe enough to be fatal without treatment. In 2008, the prevalence of ESRD in the United States was 547,982 (Collins 2011). Treatment options for patients with ESRD include kidney transplantation and dialysis. Kidney transplantation is

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the preferred treatment for ESRD; however, the demand for kidney transplant exceeds the supply of transplantable organs (Pauly 2009). Of the 547,982 patients with ESRD, approximately 382,343 patients received dialysis (Collins 2011).

Dialysis filters blood to rid the body of harmful wastes, extra salt, and water. There are two types of dialysis peritoneal dialysis and hemodialysis. The majority of patients are treated using hemodialysis; however, there is no consensus on the optimal dose and frequency of hemodialysis. Difference hemodialysis regimens include: conventional hemodialysis, nocturnal hemodialysis, and short-daily hemodialysis (Toussaint 2010).

There are two types of dialysis: 1) Peritoneal dialysis: Removes waste products via the peritoneum, the membrane that lines the inside of the abdomen. The membrane is bathed in a special fluid called dialysate that is placed into the abdomen through a small tube, and after a designated period of time, the fluid is drained and replaced by new fluid. 2) Hemodialysis: Access is through surgical placement of an arteriovenous fistula, generally in the forearm, and less commonly by a venous catheter. After access is established, the fistula is connected to a hemodialysis machine that drains the blood, bathes it in dialysate solution and returns it to the bloodstream.

Conventional hemodialysis consists of three treatment sessions per week, with each session lasting 3 to 5 hours. Treatments can be performed in a dialysis center, hospital, or at home. Although this is a life-saving treatment, mortality in patients with ESRD is still remarkably high. Compared to the general population, mortality is four times higher in patients under 30 receiving dialysis and six times higher in patients over 65. Additionally, patients receiving dialysis often experience hypertension, fluid overload and the attendant cardiac sequelae, anemia, mineral and bone disorders, inflammation, poor nutritional status, poor functional status, and psychological disorders (Bayliss 2009, Ng 2010). Moreover, this approach to dialysis is inconvenient for patients receiving treatment in a dialysis center or hospital, who must travel to a dialysis unit several times a week.

Both nocturnal hemodialysis (typically 6-8 hours, 3-7 nights per week) and short-daily hemodialysis (typically 1.5-3 hours, 4-6 days per week) can take place at home or at a dialysis center. It is thought that increasing the frequency and duration of hemodialysis will lead to less fluid gain leading to improved blood pressure control, increased hemodynamic stability, and increased efficiency of solute clearance. A potential harm is an increased risk of vascular access complications due to more frequent use (Ng 2010, Toussaint 2010).

There are several hemodialysis devices approved by the FDA for home use. Some are large, non-portable devices that require modifications to the home electrical and plumbing systems. These include the Fresenius 2008K and the B. Braun Dialog Plus. Others are smaller and portable. The NxStage System One is specifically designed for home use; it does not require infrastructure changes.

Medical Technology Assessment Committee (MTAC)

Frequent Home Dialysis

08/04/2008: MTAC REVIEW

Evidence Conclusion: on home nocturnal or short daily dialysis versus in-center dialysis 3 times a week:
One RCT and two cohort studies were identified that compared nocturnal home dialysis to in-center dialysis 3 times a week. The RCT (Culleton et al., 2007) found statistically significant improvement in the primary outcome, LV mass, a surrogate marker for cardiovascular disease. Among other secondary outcomes, phosphate level was significantly lower in the nocturnal home dialysis group, and there was no significant between group differences in calcium level and anemia. Two cohort studies matched patients who received nocturnal dialysis to similar patients receiving conventional in-center dialysis 3 times a week. Bergman et al. (2008) found significantly lower dialysis-related or cardiovascular-related hospital admissions (the primary outcome) in the group converted to nocturnal dialysis, but no significant difference in all-cause hospitalization. Schwartz et al., (2005) also had significant findings for the primary study outcomes, increase in hemoglobin concentration and increase in the proportion of patients who were EPO-free after 12 months. None of the studies had mortality as an outcome.
There are fewer published studies on short-daily dialysis. A statistical analysis (Blagg et al., 2006) found a lower mortality rate in 117 patients who received short-daily dialysis either in-center or at home compared to national rates on patients receiving conventional hemodialysis (standardized mortality ratio=0.39). Patients who received short-daily dialysis may have differed from those in the national database, and there were financial links between the authors of this study and the home dialysis device used in the study.
Evidence on home nocturnal or short daily dialysis versus home dialysis 3 times a week:
No randomized controlled trials were identified, and there were no comparative studies with mortality as an outcome. The highest grade of evidence comparing different frequencies of home nocturnal dialysis is a retrospective cohort study by Mahadevan and colleagues (2006). The investigators evaluated biological

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parameters in 13 patients receiving nocturnal dialysis 6 nights a week and 21 patients receiving nocturnal dialysis every other night (3-4 times a week). After 3-6 months of follow-up, levels of urea, creatinine and PTH were all significantly lower in the group treated 6 nights/week, and there were no significant differences between groups in phosphate, calcium, albumin and homocysteine levels, or in use erythropoietin or phosphate binders. There were no significant differences at follow-up in the proportion of patients taking phosphate binders, calcitriol, blood pressure medications or erythropoietin. The evidence is limited due to lack of randomization (there may have been pre-existing differences between groups) and the small sample size (may be underpowered).
There is no high-grade evidence on health outcomes associated with short daily dialysis at home versus home hemodialysis 3 times a week.
Conclusions:
Objective 1:

- There is insufficient evidence that home nocturnal dialysis improves important health outcomes compared to in-center dialysis. An RCT found improvement in LV mass and phosphate level, intermediate outcomes, and mixed findings in QOL. There is weak evidence from a single cohort study that nocturnal dialysis lowers the rate of dialysis-related or cardiovascular-related hospitalizations. In this cohort study, all-cause hospitalizations did not decrease significantly.
- There is insufficient evidence that home short-daily dialysis improves health outcomes compared to in-center dialysis. One statistical analysis found a lower mortality rate with short daily dialysis compared to national rates, but patients may have differed in ways that affect outcomes, and there was potential financial bias.

Objective 2:

- There is insufficient evidence that home nocturnal dialysis 6 nights a week improves important health outcomes compared to home hemodialysis 3 times a week.
- There is insufficient evidence that home short-daily dialysis 5 or more times a week improves important health outcomes compared to home hemodialysis 3 times a week

Articles: Assessment objectives:

1) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional in-center dialysis 3 times a week.
2) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to home dialysis 3 times a week.

Important health outcomes are survival, hospitalizations and quality of life.
Objective 1: Comparison with in-center hemodialysis One randomized controlled trial (Culleton et al., 2007) and two cohort studies (Bergman et al., 2008; Schwartz et al., 2005) comparing frequent nocturnal home hemodialysis to in-center hemodialysis were identified and critically appraised. Case series were not reviewed due to the availability of higher-grade evidence. The studies on short-daily hemodialysis were all case series. Most were small (<15 patients) and or included patients who primarily received dialysis in-center and thus were not suitable for critical appraisal. The strongest study identified compared outcomes in 117 patients on short-daily dialysis (84% at home) to outcomes of patients from a national database receiving conventional dialysis (Blagg et al., 2006). The Blagg study was critically appraised. *Objective 2: Comparison with home hemodialysis 3 times a week*
One comparative study was identified, and critically appraised (Mahadevan et al., 2006). This was a small retrospective cohort study comparing outcomes in patients who received home nocturnal dialysis either six nights per week or on alternate nights (3-4 times a week). An RCT by the Frequent Hemodialysis Network (FHN) is underway comparing nocturnal home hemodialysis 3 versus 6 times a week. The study is currently recruiting patients; the estimated completion date is January 2010 (Clinicaltrials.gov). *Studies reviewed include:*
Blagg CR, Kjellstrand CM, Ting GO, Young BA. Comparison of survival between short-daily hemodialysis and conventional hemodialysis using the standardized mortality ratio. Hemodialysis International 2006; 10: 371-374. See Evidence Table Culleton BF, Walsh M, Klarenbach SW et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life. JAMA 2007; 298: 1291-1299. See Evidence Table Bergman A, Fenton SSA, Richardson RMA, Chan CT. Reduction in cardiovascular related hospitalization with nocturnal home hemodialysis. Clin Nephrol 2008; 69: 33-39. See Evidence Table Schwartz DI, Pierratos A, Richardson RMA et al. Impact of nocturnal home hemodialysis on anemia management in patients with end-stage renal disease. Clin Nephrol 2005; 63: 202-208. See Evidence Table Mahadevan K, Pellicano R, Reid A et al. Comparison of biochemical, hematological and volume parameters in two treatment schedules of nocturnal home hemodialysis. Nephrology 2006; 11: 413-418. See Evidence Table.

The use of home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Nocturnal Dialysis
04/18/2011: MTAC REVIEW

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Evidence Conclusion: *Short-daily dialysis compared to conventional dialysis*: A recent RCT that included 245 patients and evaluated whether short-daily dialysis (1.5 to 2.75 hours, six times per week) would improve patient outcomes compared to conventional dialysis (2.5 to 4 hours, three times per week). There were two composite primary outcome variables: death or 12-month change in left ventricle mass as assessed by cardiac MRI, and death or 12-month change in physical-health composite score from the RAND 36-item health survey. Compared to conventional dialysis, frequent dialysis was associated with favorable changes in both of the primary composite outcomes. As the mortality rate in both groups was low, the bulk of the treatment effect was seen in intermediate outcomes. The sample size was insufficient to determine the effects of frequent versus conventional dialysis on overall mortality, cause-specific mortality, or hospitalizations (FHN Trial Group 2010). *Nocturnal dialysis compared to conventional dialysis*: There is no high-quality evidence on health outcomes associated with nocturnal dialysis versus conventional dialysis. The majority of studies identified assessed intermediate outcomes such as mineral metabolism. Very few studies had mortality as an outcome. Results from these studies are inconsistent due to the low-quality of the studies. Conclusion: There is insufficient evidence to determine whether nocturnal dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional dialysis 3 times a week. There is fair evidence that short-daily dialysis leads to improvements in intermediate outcomes such as left ventricle mass and physical-health composite score compared to conventional dialysis 3 times a week. **Articles:** Studies were selected for review if they included at least 25 subjects and assessed the effect of nocturnal or short-daily dialysis on health outcomes. The majority of studies identified were non-randomized, observational studies. As these studies are more prone to bias, they were not selected for review. An RCT that compared the quality of life of patients receiving nocturnal dialysis to conventional dialysis was not selected for review as it did not have adequate power. A recent RCT comparing short-daily dialysis to conventional dialysis was selected for review.
The following study was critically appraised: FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *N Engl J Med 2010;* 363:2287-2300. See Evidence Table

The use of nocturnal dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Frequent Home Dialysis

08/20/2012: MTAC REVIEW

Evidence Conclusion:

Survival – There is lower quality evidence upon which to draw conclusions about survival with home versus in-center hemodialysis. Three observational studies specifically reported on death or measures of mortality and survival with home hemodialysis compared to in-center hemodialysis. One study had no deaths and therefore found no difference. The two other studies favored home hemodialysis but were either small or had a higher likelihood of residual confounding (Kaiser 2011).
Since the Kaiser review, a recent matched-cohort study was identified that included 11,508 subjects assessed the relative mortality between daily home hemodialysis and thrice-weekly in-center hemodialysis. Results from this study suggest that home hemodialysis may be associated with a reduction in all-cause mortality compared to thrice-weekly in-center hemodialysis (HR 0.87, 95% CI 0.78-0.97, P=0.01). Limitations of the study include: residual confounding, approximately 1 in 4 home hemodialysis patients switched to in-center hemodialysis, more patients in the in-center treatment group were dually eligible for Medicare and Medicaid, and the cause of death was unknown in 10-20% of cases (Weinhandl 2012).
Hospitalizations – There is lower quality evidence upon which to draw conclusions about hospitalizations with home versus in-center hemodialysis. One nested-case control study favored home hemodialysis in terms of hospitalizations per patients and two additional studies appeared to possibly favor home hemodialysis but were underpowered (Kaiser 2011).
Quality of life – The evidence is of insufficient quantity and quality to draw conclusions on quality of life with home versus in-center hemodialysis. Two small observational studies did not find differences in quality of life with home versus in-center hemodialysis. One study reported that both groups had about the same number of subjects working (Kaiser 2011).
Change in left ventricular mass – No studies were identified that evaluated this outcome (Kaiser 2011).
Blood pressure control – There is lower quality evidence upon which to draw conclusions. Two studies reported significant decreases in blood pressure measures with home hemodialysis compared to in-center hemodialysis. One study also appeared to favor home hemodialysis in terms of need for antihypertensive medications (Kaiser 2011).
Nutritional status and serum albumin – There are lower quality evidence upon which to draw conclusions. Three observational studies reported mixes results on measures of serum albumin, with one study significantly favoring home as compared to in-center hemodialysis. One study found no difference in intradialytic weight gain with home versus in-center hemodialysis (Kaiser 2011).

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Vascular access complications/ Safety – The studies evaluating vascular access complications have been very small and the results were somewhat mixed. One study evaluated the operations (per patient) due to vascular access and found no significant difference, but the data tended toward favoring home hemodialysis. Another small study appeared to favor in-center, but the study was not adequately powered to evaluate this outcome. In terms of other safety reports, one small study appeared to have more machine malfunctions with home hemodialysis, another study reported that a composite measure of intradialytic adverse events appeared to favor home hemodialysis, but this was not significant (Kaiser 2011).

Articles: In March 2011, Kaiser reviewed alternative approaches to hemodialysis. Since the Kaiser review three observational studies were identified. Two studies were excluded as they did not compare in-center hemodialysis to home hemodialysis. The remaining observational study was selected for review.

Several studies were identified that reanalyzed results from the FHN trial; however, they were not selected for review since the FHN trial evaluated whether short-daily in-center hemodialysis improved patient outcomes compared to conventional in-center hemodialysis, and whether nocturnal home hemodialysis improved patient outcomes compared to conventional home hemodialysis. The following article and medical technology assessment were selected for review: Kaiser Permanente. Alternative approaches to hemodialysis: short "daily" and nocturnal. March 2011. The committee voted to accept the Kaiser technology assessment. The studies were insufficient to draw conclusions on clinical benefit as compared to standard forms of dialysis.

Frequent Home Dialysis

10/12/2020: MTAC REVIEW

Evidence Conclusion:

- There is a lack of high-quality randomized controlled trials assessing the effectiveness of frequent home hemodialysis versus conventional in-center hemodialysis in patients with ESRD.

- The available evidence is of low quality, mainly from uncontrolled studies, and suggests:
  - Home hemodialysis may decrease mortality compared to in-center hemodialysis
  - No difference between groups in terms of all-cause mortality, hospitalization, cardiovascular mortality, access survival, and transplantation rate
  - Mixed findings regarding quality of life and adverse events.
  - Home hemodialysis may be comparable to in-center dialysis in patients with ESRD

The use of frequent home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Standard Hemodialysis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility - Considered Not Medically Necessary:

CPT® Codes	Description
99512	Home visit for hemodialysis
90999	Unlisted dialysis procedure, inpatient or outpatient

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Creation Date	Review Dates	Date Last Revised

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08/04/2008	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 10/02/2012MDCRPC, 08/06/2013MPC, 06/30/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC ,08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC	08/03/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
12/09/2015	Added Medicare and Noridian links
10/29/2018	Updated the Medicare links
08/04/2020	Added Medicare LCA A55676; Added CPT codes 90999 and 99512
08/03/2021	Added the October 12, 2020 MTAC review

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KAISER PERMANENTE®

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Clinical Review Criteria
Diaphragmatic/Phrenic Pacing

- Mark IV™ Breathing Pacemaker System
- NeuRx DPS RA/4 Respiratory Stimulation System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Phrenic Nerve Stimulator NCD 160.19
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or consult notes from the specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The diaphragm is a musculotendinous sheet separating the thoracic and abdominal cavities. Supplied by the phrenic nerve from the neck, it contracts rhythmically during respiration and is essential for adequate ventilation (Marieb, Mallatt et al. 2005). Interruptions to the diaphragms physiology from spinal cord injuries (SCI) or amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease) can be devastating leading to chronic hypoventilation. In many cases, mechanical ventilation has been used to generate a controlled flow of gas into a patient's airways which often times, adds a degree of complexity to care due to associations with a number of undesirable side effects such as infection and increased need for assistance. In addition, mechanical ventilation inhibits mobility and speech and can be expensive. Unfortunately, many patients cannot be weaned, and consequently, will require chronic mechanical ventilation.

Diaphragm pacing (DP; Synapse Biomedical, Oberlin, OH) was developed to reduce or eliminate the use of a mechanical ventilator allowing patients to breathe and speak more naturally. In addition, DPS also decreases the risk of complications associated with mechanical respirators such as infection. To a certain degree, DPS allows for an improved quality of life as the device does not inhibit the sense of smell and taste, reduces the reliance on external power source and allows the patient increased mobility making everyday activities such as bathing easier.

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The diaphragm pacing system (DPS) requires a minimally invasive procedure to implant four electrodes on the diaphragm where the phrenic nerves connect and an additional electrode just below the skin. The electrodes are then connected to an external battery powered system that provides ongoing electrical stimulation causing the diaphragm to contract and assist with breathing. With the overall goal to produce a training effect by repeated stimulation the DPS is advertised to have the potential of preventing progression of respiratory dysfunction.

The NeuRx DPS™ is manufactured by Synapse Biomedical, Inc. and received approval from the U.S. Food and Drug Administration (FDA) under the humanitarian device exemption in 2008 for treatment of respiratory insufficiency in high-level SCIs. More recently (2011), the indications for the device have been expanded for use in patients with ALS.

Medical Technology Assessment Committee (MTAC)

Diaphragmatic/Phrenic Pacing

04/21/2014: MTAC REVIEW

Evidence Conclusion: In 2008, Alshekhlee and colleagues evaluated 36 SCI patients who had chronic ventilation for more than a year. Prior to surgical implantation of the device, phrenic nerve conduction studies were conducted to confirm nerve viability. While successful implantation of DPS occurred years after injury, 96% of patients were able to pace and tolerate being off the ventilator for more than four hours per day. Fourteen of the patients (56%) were able to pace full time (24 hours/day) and six were able to pace part-time (12-24 hours/day). The remaining 5 patients (20%) were still in the conditioning phase (4+ hours/day) and had only been implanted within 2-5 months of final analysis. Only, one patient was unable to initiate conditioning due to muscle cramps. The authors concluded that DPS can help patients with cervical SPI to breathe unassisted by a ventilator. (Alshekhlee, Onders et al. 2008). [Evidence Table 1]. Most recently, Onders and colleagues published a final analysis of the pilot trial of diaphragm pacing in patients with ALS. Aimed to assess the safety and effectiveness of DPS in ALS patients the prospective open-label evaluation provided long-term analysis of DP in ALS patients. In this study, patients were their own controls with outcome measures being obtained at several visits before and after implantation. While not statistically significant, the efficacy endpoint of respiratory decline was promising with a -2.38±2.84% per month slope for decline pre-implant and a -1.34±1.49% per month slope following implant. In the same way, diaphragm thickness following surgery was greater than the thickness measured prior to implantation. The investigators concluded that long-term use of DP had no safety issues and can positively influence diaphragm physiology and survival (Onders, M et al. 2014). [Evidence Table 2]. Thus far, the body of evidence has flawed that complicate interpretation. All reports include small sample sizes and are not randomized. Given that the intervention involves surgery, selection bias may play a role with overall healthier patients referred for intervention limiting the generalizability of the results. Furthermore, methodological details on how some of the outcomes were measured and validated have not been well described. Lack of a comparator group is also a limiting factor in these studies. In terms of safety, while there were no reports of serious adverse effects attributable to the device, DPS relies on surgical implantation exposing patients to any risks associated with surgery including. Finally, it should be noted that Raymond Onders, MD, one of the primary investigators of both selected studies, is the developer of the DPS device. Conclusions: There is insufficient evidence to support the safety of DPS in carefully selected patients with SCI and ALS.

Articles: The search revealed numerous case reports and retrospective case series. The majority of the evidence focused on the use of DPS in patients with SCI or ALS. No randomized trials were identified. The initial FDA trial that led to the approval under the humanitarian device exemption was selected as well as the pivotal trial that led to the FDA approval of DP as a therapeutic option in ALS patients. The following studies were selected for review:

Alshekhlee A, Onders RP, Syed TU et al. Phrenic nerve conduction studies in spinal cord injury: applications for diaphragmatic pacing. Muscle & Nerve. 2008; 38:1546-1552. [Evidence Table 1]. Onders RP, Elmo M, Kaplan C et al. Final analysis of the pilot trial of diaphragm pacing in amyotrophic lateral sclerosis with long-term follow-up: diaphragm pacing positively affects diaphragm respiration. The American Journal of Surgery. 2014; 207:393-397. [Evidence Table 2.

The use of diaphragmatic/phrenic pacing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Non-Medicare – Considered Not Medically Necessary:

HCPC Codes	Description
L8696	Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each

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Date Created	Date Reviewed	Date Last Revised
05/06/2014	05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	05/06/2014

[MPC] Medical Policy Committee

Revision History	Description of Change

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Clinical Review Criteria
Digital Breast Tomosynthesis

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Criteria

For Medicare Members and Non-Medicare Members

Medical necessity review no longer required.

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Background

Mammography is the gold-standard for population-based breast cancer screening. The sensitivity of mammography in randomized trials is in the range of 68-88% (Elmore 2005). However, mammography is less sensitive in women with dense breasts (Brem 2008; Killela 2009). Because of these new technologies are being developed to improve detection and characterization of breast lesions. One of these technologies is digital breast tomosynthesis (Helvie 2010).

Digital breast tomosynthesis is a modified form of digital mammography. With digital breast tomosynthesis, multiple views of a stationary compressed breast are taken at different angles. These images are then reconstructed using an algorithm to create 3D radiographic images of the breast. It has been hypothesized that this technology may be able to decrease the number of false positive and false negative results and decrease recall rates. One limitation of digital breast tomosynthesis is that the specifications of many parameters including the number of projections, dose, angle, and post-processing algorithm differ across manufactures making clinical comparisons between manufactures difficult (Helvie 2010, Holloway 2010).

The Selenia Dimensions 3D System (Holistics, Inc.) has received approval from the FDA.

Medical Technology Assessment Committee (MTAC)

Digital Breast Tomosynthesis

12/19/2011: MTAC REVIEW

Evidence Conclusion: Based on evidence from observational studies, the Kaiser MTAT concluded that the evidence is of insufficient quantity and quality to conclude that digital breast tomosynthesis is more effective than any other technologies to screen for breast cancer in average-risk or high risk women, in evaluating those with equivocal/indeterminate mammography and/or ultrasound, or evaluating women considering breast conserving therapy. The current evidence base consists primarily of studies reporting diagnostic results of women with abnormal screening mammograms and is not representative of key populations under consideration. In addition, the sample sizes were too small and not powered to compare accuracy measures (Kaiser 2011). Conclusion: The evidence is of insufficient quantity and quality to conclude that digital breast tomosynthesis is more effective than any other technologies to screen for breast cancer.

Articles: The Kaiser Permanente Medical Technology Assessment Team (MTAT) reviewed digital breast tomosynthesis in 2009, 2010, and 2011. No additional studies were identified since the 2011 review. The

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following technology assessments were selected for review: Kaiser Permanente Interregional New Technologies Committee. Tomosynthesis. 2011; http://pkc.kp.org/national/cpg/intc/topics/04_04_116.html Kaiser Permanente Medical Technology Assessment Team. Breast Imaging: Digital Breast Tomosynthesis. 2010; See Evidence Table.

The use of digital breast tomosynthesis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/20/2015: MTAC REVIEW
Digital Breast Tomosynthesis
Evidence Conclusion: The external technology assessments by HTA, INTC, and TEC all concluded that there is insufficient evidence to determine that benefits of using breast tomosynthesis for screening asymptomatic women for breast cancer.
Health Technology Assessment (HTA), January 2015

Studies comparing DBT to DM for screening asymptomatic women
(Table reproduced from HTA Executive Summary)

Study	Sensitivity		Specificity	
	M %	DBT %	M %	DBT %
Ciatto, 2013 * (Italian STORM)	66.1	100	95.5	96.6
Skaane, 2013* (Oslo trial)	62.6	82.1	93.8	94.6
Haas2013 **‡	100	100	NR	NR
Friedwald, 2014 ‡	NR	NR	NR	NR
Rose, 2013 ‡	100	100	91.7	95.1
Destounis, 2014 ‡‡**	100	75	97.9	99.4
Lorenco, 2014 ‡‡	NR	NR	91.1	94.0
Greenberg, 2014‡	NR	NR	84.3	87.0
McCarthy,2014‡‡	NR	NR	NR	NR

M=mammography, DBT=digital breast tomosynthesis.
* Prospective studies
‡ Retrospective multicenter study
‡‡ Retrospective single center study
** US study
The majority of the studies compared DBT+DM vs DM alone.
There was population overlap between Greenberg, McCarthy, and Friedwald studies
All the trials had their limitations

Estimated yield of DBT in combination with digital mammography
Vs. digital mammography alone in women presenting for population screening
(Table reproduced from HTA review Executive Summary)

	DM	DBT+DM	Uncertainty
Recall rate /1,000	100-160	80-140	Moderate-high
Biopsy rate /1,000	14-22	12-27	Moderate
Cancer detection rate/1,000	3-5	4-6	Moderate-high
Positive biopsy among total biopsied	20-25%	25-30%	Low-moderate

The HTA review summary indicates that the 9 studies reviewed showed a substantial decrease in the recall rate with DBT vs. mammography and most found an increase in cancer detection. The evidence on biopsy rate was mixed, with the more recent studies showing an increase in the biopsy rate with DBT. Studies reporting on subgroups of women with dense and non-dense breasts found consistent findings.
There were limitations in the studies, including heterogeneity and differences among the screened populations, short follow-up duration, and lack of large prospective studies with patient outcomes. In addition, the only 2 prospective studies were conducted overseas, where the patterns of recall differ from that in the US. *Kaiser Interregional New Technologies Committee (INTC), November 2014* the evidence reviewed by the committee included 8 published comparative studies of DBT + mammography vs. mammography alone for routine screening (from a previous review) plus four more recent comparative studies. There were no published studies that investigated the impact of DBT screening on mortality or other health outcomes among women at low, average or high risk of breast cancer. The review concluded that there is insufficient evidence to determine that breast

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tomosynthesis is appropriate for screening asymptomatic women for breast cancer. The estimated absolute benefits in cancer detection and reduction in recall are small and the overall evidence is of low-to moderate quality. The review also concluded that the positive results observed may not translate to outcomes and there is insufficient evidence to determine that DBT prevents mortality or advanced disease from breast cancer, *Blue Cross Blue Shield/ Kaiser Permanente Technology Evaluation Center (TEC), January 2014* The addition of DBT to screening or diagnostic mammography did not meet the TEC criteria. The review included six studies that compared the use of mammography versus DBT with or without mammography for screening asymptomatic women. Four of the studies (Rose 2013, HAAS 2013, Skaane 2013, and Ciatto 2013) were also included in the HTA review. The two other studies included in the review were Rafferty et all's study (2013) and Good et all's study 2008 (Gur 2009). The TEC review did not include studies published in 2014 as the literature search was conducted in June 2013. TEC also evaluated the use of DBT for breast cancer diagnosis. The review concluded that the available evidence (at the time) on adding DBT to mammography for screening for breast cancer or to diagnostic mammography is insufficient to permit conclusions regarding the effect on health outcomes, or to determine the comparative benefit of adding DBT to mammography vs. mammography alone. *More recent published evidence after the HTA 2015 review* The literature search for more recently published studies identified a large (N=7,060) retrospective reading study embedded in a prospective study (TOMMY trial, Gilbert et al, 2015) that compared DBT plus 2D mammography vs. mammography alone, and a small (n=150) retrospective study (Thomassin-Naggara 2015) that evaluated the value of adding one view DBT to mammography to characterize breast lesions. TOMMY trial (Gilbert et al 2015 [Health Technology Assessment, NHS] Evidence table 1). This was a large retrospective reading study conducted by the UK National Institute for Health Research in six UK centers to compare the diagnostic accuracy of DBT in conjunction with 2D mammography or synthetic 2D mammography vs. standard 2D mammography among 6,021 women 47-73 years of age, for further assessment after routine breast screening, and 1,040 women 40-49 years with moderate/high risk of developing breast cancer attending annual mammography screening. All participants underwent a two-view 2D mammography of both breasts and two-view DBT imaging. Image-processing software generated a synthetic 2D mammogram from the DBT data set. Blinded readers reviewed 2D or 2D+DBT, or synthetic 2D+ DBT images for each case without access to the original screening mammograms or prior examinations. Sensitivities and specificities were calculated for each reading arm and by subgroup analyses. Overall, the results indicate that the specificity of DBT plus 2D mammography was statistically significantly higher than that of 2D mammography alone. The improvement in sensitivity by adding DBT to 2D mammography was minimal and statistically insignificant among all participants combined. Subgroup analyses however, showed significantly higher sensitivity with DBT+2D mammography vs. 2D mammography for women in the age range of 50-59 years, women with invasive tumors 11-20mm in diameter, those with breast density >50%, and in women with grade 2 invasive tumors. The analysis suggests that there was no significant difference in specificity of synthetic 2D +DBT versus 2D +DBT. As regards the sensitivity of synthetic 2D+DBT, subgroup analysis suggested that it had higher sensitivity than 2D alone in the detection of 11-20 mm invasive cancers, but lower sensitivity than 2D or 2D+DBT in the detection of microcalcifications and DCIS (ductal carcinoma in situ) 11-20mm in size. The study included women recalled for suspicious lesions on 2D mammography (only 5% of the screened women were recalled) as well as younger women at high risk. DBT was not used for 95% of the women screened by 2D mammography who were not recalled. This inherent selection bias of the study could overestimate the true effect of adding DBT to 2D mammography on the specificity and underestimate its impact on the sensitivity. The study was not a screening trial and its results cannot be generalized to screening populations. Thomassin-Naggara and colleagues' study (2015) found that adding DBT to mammography improved reproducibility and diagnostic performance especially for radiologists with lower experience in reading mammography. Conclusion: There is insufficient evidence to determine the comparative benefit of screening with DBT versus conventional mammography. The published studies suggest that the addition of DBT to DM has no or minimal effect on improving sensitivity especially with experienced film readers. The studies, however, suggest that the addition of DBT to DM may reduce the recall rates, but that would depend on the reading protocol, recall policy and experience of radiologists reading the images. There is no published evidence, to date, to determine the benefit of using DBT alone or in addition to digital mammography on long-term health outcomes.

Articles: The literature search revealed over 130 articles on digital breast tomosynthesis published after the last MTAC review. DBT technology was recently assessed by TEC for breast cancer screening or diagnosis in January 2014, by INTC in November 2014, and more recently by HTA in January 2015, for breast cancer screening in patients with dense breasts. The search for additional large screening studies published after the literature search dates of these reviews identified one large retrospective reading study (TOMMY trial) that compared the diagnostic accuracy of DBT in conjunction with 2D mammography or synthetic 2D mammography vs. standard 2D mammography, a small retrospective study (N=150) on the added value on DBT combined with DM according to reader experience, a post hoc analysis of the STORM study by Ciatto and colleagues' 2013 study (included in the HTA review), and a recent meta-analysis on the use of DBT as a diagnostic not a

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screening test. The TOMMY trial was selected for critical appraisal. Gilbert FJ, Tucker L, Gillan MG, et al. The TOMMY trial: a comparison of TOMosynthesis with digital MammographY in the UK National Institute for Health Research (NHS) Breast Screening Programme - a multicentre retrospective reading study comparing the diagnostic performance of digital breast tomosynthesis and digital mammography with digital mammography alone. Health Technol Assess. 2015 Jan;19(4):1-136. See Evidence Table.

The use of Digital Breast Tomosynthesis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medical necessity review no longer required

CPT or HCPC code	Description
77061	Diagnostic digital breast tomosynthesis; unilateral
77062	Diagnostic digital breast tomosynthesis; bilateral
77063	Screening digital breast tomosynthesis; bilateral
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral *(List separately in addition to 77065 or 77066)*

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/03/2012	01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 04/20/2015[MPC], 06/02/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC] , 10/01/2019[MPC], 10/06/2020[MPC] , 10/05/2021[MPC] , 10/04/2022[MPC]	02/28/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of Change
04/23/2015	Added CPT and HCPC codes
04/27/2015	Added April 2015 MTAC review
06/02/2015	MPC approved policy of insufficient evidence
08/25/2015	Added Medicare MLN MM8774 clarifying language
6/27/2017	Added WESCU rider language
02/28/2017	Medical necessity review no longer required.

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Clinical Review Criteria
Discography (Discogram) for Low Back Pain

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Discography (Discogram) for Low Back Pain***, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Low back pain is a great and growing problem in the Western countries as well as other parts of the world. It is the most common cause of disability in patients younger than 45 years old, and the loss of work, medical and disability costs can add up to at least $50 billion per year in the Unites States. Many factors are associated with back pain, but the exact causes of severe pain are unclear especially in the absence of a diagnosed anatomic pathology such as infection, tumor, deformity, or instability (Carragee 2001, 2004, Willems 2007).

Currently, there is no clinical test that could be used as a diagnostic gold standard for discogenic pain, and it is not possible to determine with absolute certainty that a particular disc is the spinal pain generator. Imaging methods such as radiography, magnetic resonance imaging (MRI), and computed tomography (CT) may detect disc degeneration but cannot confirm if it is symptomatic and relevant to the patient's pain syndrome. Plain radiographs provide data on bony alignment and deformity, signs of instability, and the general state of lumbar degeneration. Nuclear medicine scans may exclude tumors, fractures and infection, and magnetic resonance imaging (MRI) is used for the diagnosis lumbar degenerative disorders. MRI is considered the morphological imaging study of choice in patients with low back pain. It is non-invasive and allows assessment of more levels in one test. MRI findings might also provide some information to indicate that a positive test increases the likelihood of the disc as a source of patients' symptoms, yet the current evidence is insufficient to allow making an accurate prediction (Saal 2002, Hancock 2007, Willems 2007). Surgical exposure can confirm the presence of disc degeneration but cannot definitely confirm that it is the source of discogenic pain.

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Lumbar discography was first introduced in the late 1940s as a morphologic test. The term discography used to describe the technology, implies a strictly anatomic evaluation. Discograms do not image pain and hence do not provide insight into which neural pathways mediate discogenic pain. Imaging of intervertebral discs morphology usually does not change within a short interval, but discographic images may change after only 2 weeks. Concerns about the invasiveness of discography, radiation exposure, risk of infection, and the recent advances made in the high-resolution multi-detector CT and MRI of the disc, minimized the role of discography as an imaging tool. However, the frequent recurrence of familiar back pain during the discography led to the use of the test in evaluating lumbar discs as the origin of chronic low back pain, as well as pain in the cervical spine. Currently discography is used as a provocative test alleged to correlate symptoms with pathology (Buenaventura 2007).

Provocative discography is an invasive diagnostic procedure performed by the injection of a nonirritating radio-opaque dye, under x-ray guidance, into the nucleus of one or more lumbar discs. The dye is slowly injected into the center of the nucleus pulposus by a 22-25-gauge needle. The patient must be awake and cooperative and is supposed to be blinded to the time and level of injection. The distribution of the dye is noted, and the patient is asked whether each injection seems painful, and if the pain is similar “concordant” to the usual back pain he experiences. The patient is also asked to rate the pain on a visual analogue scale (VAS) or pain thermometer from 0-10 (or 0 to 5), with 0 denoting no pain and the higher end being unbearable pain. A completely intact disc will retain the dye in a central globular pattern, and is usually not very uncomfortable, even at high pressures. With more advanced disc degeneration on the other hand, patients may experience varying degrees of discomfort and pain as the dye is injected. A post discogram CT scan is often performed, and allows for a more thorough visualization, assessment, and identification of disc abnormalities (Saal 2002, Carragee 2001, Cohen 2005, Rowles 2005).

Discography has always been described as one of the most controversial tests in the management of degenerative painful lumbar spine conditions. Unlike MRI or CT scans, discography is used as a provocative test alleged to correlate symptoms with pathology. It seeks to confirm an impression that the back pain is discogenic and originating from a certain intervertebral disc. Some researchers found that healthy, previously pain free, patients can develop both back and leg pain from a provocative discogram as a result of the injection of irritants at different sites in motion segments. They also found that placement of the needle and injecting contrasts in the annulus fibrosus rather than the nucleus pulposus may induce back pain which should be regarded as false positive discography. Also, pain response to the discograms may vary widely among patients with chronic pain and somatization disorders. According to several investigators, psychological distress and pre-existing chronic pain processes may be stronger predictors of low-back pain than painful disc injections (Saal 2002, Carragee 2004, and Lander 2005).

One of the most feared complications of discography is discitis because of the poor blood supply of the intervertebral discs. Other reported adverse events include injury to the intervertebral disc, headache due to neuroaxial leak of the contrast, convulsions, meningitis, subdural or epidural abscesses, intrathecal hemorrhage, and others. Also, as indicated earlier discography may cause or worsen low back pain especially in patients with somatization disorder (Cohen 2005).

The suggested clinical indications for discography are wide-ranging and highly individualized (Carragee 2004). Guidelines published by specialized groups recommend that discography be reserved for use in patients with equivocal or inconsistent findings from MRI or other tests. Some investigators suggest its use for the evaluation of patients with chronic back pain for whom a surgical intervention is being considered.

Discography is being reviewed by MTAC based on a request from Dr. Kyle Kim. Considered as a procedure, discography is not regulated by the FDA; however, the devices and agents used for the test require FDA approval. Several of these devices and contrast material have been approved by the FDA.

Medical Technology Assessment Committee (MTAC)

Discography

10/01/2007: MTAC REVIEW

Evidence Conclusion: *Reliability of discography for patients with chronic lumbar disc disease:* There is no current consensus in the spine community of what constitutes a positive disc injection (Carragee & Hannibal 2004). In general, a positive discogram depends mainly on the production of the usual or concordant pain, which is a subjective measure and might not be a proper validation tool. Observer variability and bias in reading a discogram, as well as inter and intraobserver validation of pain response were evaluated only in a few studies. In a prospective trial involving 47 patients (Carragee 2000), the authors found that patients with abnormal

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psychological profiles have significantly higher rates of positive disc injections than either asymptomatic volunteers or symptomatic subjects with normal psychological screening. Agorastides and colleagues (2002) found an excellent interobserver and intraobserver agreement in applying Adams classification for discogram morphology but did not study the reliability of the test in diagnosing discogenic pain. These, as well as other published studies were small, had methodological flaws, and do not provide sufficient evidence to determine the reliability of discography. Diagnostic accuracy of discography: As indicated earlier there is no clinical test that could be used as a diagnostic gold standard for discogenic pain. Several studies investigated the accuracy of discogram and/or CT discograms in detecting disc disease based on surgical confirmation of the pathology. Other researchers evaluated the technology by comparing, and /or correlating its results with those obtained by various other techniques including CT, myelography, and MRI. Small series where experimental discograms (with no surgical confirmation) were performed on asymptomatic patients showed that the test might be associated with high false positive rates. Accuracy based on surgical confirmation of findings: Results of studies with surgical confirmation of disc degeneration (Jackson 1989, Bernard 1994, and others) showed that CT discography was more accurate than standard discography in identifying disc herniation. CT discography had a sensitivity ranging from 74% to 92% and specificity ranging from 60% to 80%, versus sensitivity around 80% and specificity as low as 31% for standard discography. Compared to other diagnostic modalities, CT discography seemed to be more accurate in identifying disc abnormalities. Combining it with MRI improved its sensitivity, but not the specificity in Bernard's study (See attached appendix table 1). Birney et al, 1992 (See evidence table) compared the findings of discography with MRI using surgical confirmation of disc herniation/degeneration as a gold standard among 90 patients (264 discs). All participants underwent an awake discogram by one radiologist and an MRI exam by another radiologist. 57 patients with 76 discs underwent surgical intervention. The study had its advantages and limitations. The authors evaluated discography as a morphologic test to examine the disc abnormality, but not as the cause of discogenic pain. The results of the study show 86% agreement between MRI and discogram. MRI was found to be more accurate in detecting disc herniation, while discogram was more accurate in detecting disc degeneration. The authors concluded that MRI and discography are equivalent in detecting degenerative disc disease; however, the study was not designed nor powered to detect equivalence. These studies determined the accuracy of discography in diagnosing disc pathology but did not confirm that the disc is the source of discogenic pain. Identifying a disc abnormality is not equal to identifying the cause of pain or that the disc is suitable for surgical intervention. Correlation of discography with MRI without surgical confirmation:
Studies that compared discography with MRI showed a varying agreement between the two tests. (See appendix table 2) Lim and colleagues (2005) studied the correlation between MRI and CT discography findings with pain response at provocative discography in 47 patients with discogenic back pain. MRI and discogram findings were analyzed based on concordant pain at discography. The study was small and had several limitations. Overall the authors reported a 68-89% accuracy of MRI in predicting pain, vs. 61% for discograms. Earlier in 1998, Ito and colleagues showed a 57% correlation between the two technologies in predicting pain. Several other investigators e.g. Gibson 1986, Linson 1990, Simmons 1991, Osti 1992, (See appendix table 2) as well as others studied the correlation between MRI and discograms in diagnosing a disc abnormality. The studies were small and had their limitations. Agreement rates were reported per patients, and/ or per discs. For patients it ranged from 55-75%, and for discs it ranged between studies from 71-94%. It is hard to determine if the lack of agreement between the tests was due lack of sensitivity (false negatives) or lack of specificity (false positives) in one or the other test. Diagnostic and therapeutic impact of discography on health outcomes: There were a number of published prospective and retrospective studies that aimed at correlating discography findings to surgical outcomes. The population sizes in these studies were small, and the mean duration of follow-up ranged from <2-6 years. Abnormal discogram was the basis for surgery, which was mainly spinal fusion, a procedure which is considered by many investigators as a controversial treatment. Willems and colleagues' (2007) study (see evidence table) evaluated whether preoperative status of the adjacent discs, as determined by provocative discography, had an impact on the clinical outcome of lumbar fusion in patients with chronic low back pain (LBP). The study included 209 patients with chronic LBP. They underwent outpatient routine diagnostic tests including radiography, MRI, CT, and provocative discography to determine the levels considered for lumbar fusion. The patients then underwent temporary external transpedicular fixation trial which was the final decisive factor for fusion. The latter was performed on 82 patients. They were followed up for a mean of 80 months and the primary outcome was the individual changes in pain on a visual analog scale (VAS), and patient satisfaction. A successful outcome was defined as 30% or more pain reduction. This rate was arbitrary, and according to the authors debatable. The study had other methodological flaws, and its overall results indicate that provocative discography had no significant impact on the clinical outcome after lumbar fusion. Carragee (2006) compared 5-year outcomes of two cohorts: 1 Discography (presumed discogenic pain) cohort, n=30, and 2: Unstable spondylolisthesis cohort of 32 patients used as a control group. The gold standard used for the diagnosis of discogenic pain by discography was clinical outcome after surgical intervention. Outcome measures included VAS for back and leg pain, Modems Lumbar Questionnaires, analgesic usage, work status, reoperation, and complications. The results show a surgical success rate of 27% among the patients with discography positive test, compared to a 72% success rate in the control group. The calculated positive predictive value of discography for achieving at least the minimum
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acceptable outcome was 43%. Earlier in 2002, Madan and colleagues studied the outcome of spinal arthrodesis among 73 patients with discogenic low back pain refractory to nonoperative management. Chronologically the first 41 patients had not undergone discography while the following 32 patients underwent surgery based on discographic findings. The primary outcome was satisfactory clinical outcome based on a visual analogue scale and other questionnaires including the Oswestry Disability Questionnaire after a mean follow-up of 2.4-2.8 years. The results showed that 75.6 % of the patients in the discography group had satisfactory outcomes versus 81% of those who did not have a preoperative discography. This observed difference in improvement was not statistically significant. The other published studies had their limitations, had potential selection, spectrum and observation bias, and used subjective measures as their outcomes. They also had conflicting results all of which makes it hard to determine if preoperative discography is of value in selecting patients for surgical intervention and/or predicting surgical outcomes. Conclusion: There is insufficient evidence to determine the reliability of discography in the diagnosis of discogenic pain among patients with chronic low back pain. There is insufficient evidence to determine that that discography is accurate for the diagnosis of discogenic pain. There is insufficient evidence to conclude whether or not the use of discography can improve selection of patients, predict or improve surgical outcomes in those with discogenic chronic low back pain.
Articles: The search yielded over 500 articles some of which dated back to 1966. There were three systematic reviews of the literature with no meta-analyses, and several small prospective or retrospective studies that aimed at determining the reliability, calculating the diagnostic accuracy, comparing, or correlating the findings of discography with MRI, CT scanning, myelograms or radiographs in symptomatic or asymptomatic patients. The search also revealed several relatively small studies that utilized health outcomes as a method for assessing the efficacy of discography. The ideal study would be a blinded independent comparison of discogram with a gold standard. However, to date, there is no known gold standard for discogenic pain. Some researchers determined the accuracy of discography by comparing it to other diagnostic modalities. Others used surgical findings and pathological disc morphology as their standard to confirm discographic results. These can confirm the presence of disc degeneration but cannot definitely confirm that it is the source of discogenic pain. Other groups suggested using clinical results of fusion as a gold standard to confirm whether the positive discogram injections were in fact true positives. Still many disagree on using a “controversial “treatment as the spinal fusion as a gold standard for a diagnostic test. One study that correlated discogram findings with MRI, and another that sought to measure its efficacy based on health outcomes were presented in evidence tables. Several other studies were grouped in table forms (see appendix tables 1 and 2) and/or discussed in the reviewer’s evidence summary section.
The studies critically appraised in evidence tables are Birney TJ, White JJ, Berens D, et al. Comparison of MRI and in the diagnosis of lumbar degenerative disc disease. J Spinal Disord 1992;5:417-423 See Evidence Table.
Willems PC, Elmans L, Anderson PG, et al. Provocative discography and lumbar fusion. Is preoperative assessment of adjacent discs useful? Spine 2007;32:1094-1099 See Evidence Table.

The use of discography in the treatment of lower back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Discography

12/14/2011: MTAC REVIEW

Evidence Conclusion: In 2007 we reviewed the evidence for lumbar provocative discography, and there was insufficient evidence to determine the benefits of the procedure. A quick literature search did not reveal any good quality or large studies on analgesic discography. The only more recent study discussed in that article is the Cooper et al's study presented in a meeting and not published in a peer reviewed journal.
There was a systematic review with no meta-analysis of studies on lumbar discography (Manchianti 2009) that concluded that the level of evidence on the technology is II-2 (i.e. evidence obtained from at least one properly designed small diagnostic accuracy study). The review indicated that there is a lack of literature, poor methodological quality and very few studies using IASP criteria. Carragee (2006) compared 5-year outcomes of two cohorts: 1 Discography (presumed discogenic pain) cohort, n=30, and 2: Unstable spondylolisthesis cohort of 32 patients used as a control group. The gold standard used for the diagnosis of discogenic pain by discography was clinical outcome after surgical intervention. Outcome measures included VAS for back and leg pain, Modems Lumbar Questionnaires, analgesic usage, work status, reoperation, and complications. The results show a surgical success rate of 27% among the patients with discography positive test, compared to a 72% success rate in the control group. The calculated positive predictive value of discography for achieving at least the minimum acceptable outcome was 43%.
Articles: A quick literature search did not reveal any good quality or large studies on analgesic discography. The only more recent study discussed in that article is the Cooper et al's study presented in a meeting and not published in a peer reviewed journal. There was an systematic review with no meta-analysis of studies on lumbar discography (Manchianti 2009) that concluded that the level of evidence on the technology is II-2 (i.e. evidence obtained from at least one properly designed small diagnostic accuracy study). The review indicated that there is a lack of literature, poor methodological quality and very few studies using IASP criteria.
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The use of discography in the treatment of lower back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
62290	Injection procedure for discography, each level; lumbar
62291	Injection procedure for discography, each level; cervical or thoracic
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/18/2007	10/01/2007, 10/15/2007 MDCRPC, 1/3/2012 MDCRPC, 2/7/2012 MDCRPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC , 02/01/2022MPC, 02/07/2023MPC	05/02/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/02/2017	Adopted KPWA policy for Medicare members

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Clinical Review Criteria
Device, Equipment and Supplies

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Durable Medical Equipment Reference List (280.1).
Local Coverage Determinations (LCD) Local Coverage Article (LCA)	Oxygen and Oxygen Equipment (L33797) "Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment." Oxygen and Oxygen Equipment – Policy Article (A52514) "Oximeters (E0445) and replacement probes (A4606) will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the beneficiary's treatment." **Please note that many individual DME items may have their own specific LCD and/or LCA.*

Noridian Jurisdiction D DME Supplier Manual
Noridian Same or Similar Chart

For Non-Medicare Members

Durable Medical equipment (DME) also known as home medical equipment (HME) may be considered medically necessary when **ALL** of the following criteria are met:

- The patient has a documented physical functional impairment or disability due to disease, trauma, congenital anomaly or prior therapeutic intervention and requires accommodation for basic activities of daily living (ADLs) that can be met by using a DME item; and
- Documentation in the medical record contains a clinical assessment and rationale for the requested DME item (see Required Documentation below); and
- The DME is prescribed by a health care practitioner; and
- It is an item with a published HCPCS code; and
- The piece of equipment meets the definition of DME (see Policy Guidelines) and
- The requested DME item is not considered to be not medically necessary, investigational or unsafe by a regulatory agency, excluded by plan benefits or contract exclusion; and
- When specific criteria exist, the patient has also met those criteria.

The following are considered not medically necessary:

- Accessory add-ons and upgrades when a basic DME item meets the member's functional needs
- Athletic/exercise/physical fitness equipment (e.g. treadmills, stationary bikes)
- Comfort or convenience items added to basic equipment

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- Deluxe equipment when basic (standard) equipment is available and meets the member's functional needs
- Duplicate equipment (e.g. a rolling walker, when the member has a properly fitted cane)
- Equipment and modifications/upgrades to equipment when used primarily for leisure or recreational activities (e.g. special wheelchair wheels for sport activities, prosthetic adaptations for beach use, skiing and others)
- Equipment used for environmental control or to enhance the environmental surroundings (e.g. air conditioners, air filters, humidifiers, allergy protective pillow/mattress covers, furniture [e.g. recliner chairs, over-bed tables], and others)
- First aid or precautionary equipment (e.g. automatic external defibrillator (AED), portable oxygen to back up an in-home oxygen system)
- Home modifications (e.g. bath grab bars, electronic door openers, elevators, Jacuzzi/whirlpools, ramps,)
- Institutional equipment (e.g. any DME that is used only in a medical facility and is not suitable for use in the home setting)
- Same/similar or back-up DME item(s) not used as the primary device to meet the member's functional needs (ie more than one of the same item of durable medical equipment).
- Devices that do not meet the definition of durable medical equipment (DME), because they are not primarily intended for medical purposes (e.g. desktop/laptop computers, smartphones, tablets, internet, phone services, any modification to a patient's residence for DME use)

*See below for specific exclusions

Required Documentation

Documentation from the clinical evaluation should include the following:

- An order/prescription from the physician/health care provider responsible for the patient's care that states the therapeutic purpose of the DME
- Details of the patient's physical functional impairment related to completing activities of daily living (ADLs) without the home medical equipment/DME; and
- The patient's medical condition that requires DME for long term use (i.e. 6-12 months or more) when applicable; and
- What assistive devices (e.g., canes, walkers, manual wheelchairs) the device has been trialed and found to be inadequate/unsafe or contraindicated to completely meet the patients functional needs (when applicable)

Note: Even when a provider orders or prescribes DME and deems the equipment necessary for the patient's functional needs, that does not mean that the item meets the criteria as listed in the policy. It also does not guarantee that the item will be considered medically necessary.

Definition of Terms

Activities of daily living (ADLs) – ADLs are self-care activities done daily within a member's place of residence and includes

- Dressing/bathing
- Eating
- Ambulating (walking)
- Toileting
- Transferring
- Hygiene/grooming

Durable Medical Equipment (DME) – DME is:

- Primarily and customarily used to serve a medical purpose and
- Not useful to a person in the absence of illness or injury and
- Ordered or prescribed by a physician or other qualified provider and
- Reusable (non-disposable) and
- Designed to withstand repeated use (durable) and
- Not solely for the convenience of the patient or caregiver
- The equipment is not for use exclusively outside the home setting.

Prosthetics are covered if:

1. The device replaces all or part of an internal body organ or

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2. Replaces all or part of the function of a permanently inoperative or malfunctioning internal body organ. **AND**
3. When specific medical criteria exist, the patient has also met those criteria.

The following items require review by Clinical Review:
1. Equipment with no HCPCS code
2. Equipment using miscellaneous code ****99, K0108, or L4205 in the absence of specific equipment/prosthetic codes
3. New technology
   a. Not yet FDA approved
   b. No specific HCPC for the service
   c. New FDA approval within 6 months
4. All equipment/prosthetics listed in Clinical Review Criteria
5. Duplicate items of equipment are being requested

Testicular prosthesis is considered medically necessary for replacement of congenitally absent testes, or testes lost due to disease, injury or surgery.
Testicular prosthesis may be covered when associated with transgender services when clinical criteria is met. Some plans do not cover transgender services.

ExoSyn Energy Storing AFO – CMS coding guidelines can be found here: Correct Coding - IDEO and ExoSym Energy Storing AFO
Medicare LCD L33686 – Ankle-Foot/Knee-Ankle-Foot Orthosis

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

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Background
In 2012 Kaiser Permanente plans developed a reference list for DME/prosthetic equipment/devices that would be covered. The criteria above were developed to augment the list in the determination of coverage for DME/prosthetic items in the absence of a specific medical policy document.

Evidence and Source Documents
Member contract

Applicable Codes
*To verify authorization requirements for specific DME items, please use the **Pre-authorization Code Check**.

Considered non-covered personal convenience item/not separately reimbursable in the home setting:

CPT® or HCPC Codes	Description
	Air Conditioners or Cleaners
A9280	Alert or alarm device, not otherwise classified
L3000-L3090	Arch support
E0160	Sitz type bath or equipment, portable, used with or without commode
E0161	Sitz type bath or equipment, portable, used with or without commode, with faucet attachment(s)
E0162	Sitz bath chair
E0235	Paraffin bath unit, portable
A4265	Paraffin, per pound
E0240	Bath/shower chair, with or without wheels, any size
E0241	Bathroom wall rail

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CPT® or HCPC Codes	Description
E0242	Bathroom rail, floor base
E0243	Toilet rail
	Bed Baths (home type)
E0273	Bed board
	Bed Lifters (bed elevators)
	Beds-Lounges (power or manual)
E0270	Hospital bed, institutional type includes: oscillating, circulating and Stryker frame, with mattress (not on Exclusions list in the General Criteria)
E0462	Rocking bed, with or without side rails
	Dehumidifiers
K1004	Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories
	Disposable sheets and bags
A4553	Non-disposable underpads, all sizes
A4554	Disposable underpad, all sizes
	Electric air cleaners
	Electrostatic machines
	Elevators
A9300	Exercise equipment
	Face masks (surgical)
E0218	Fluid circulating cold pad with pump, any type
E0191	Heel or elbow protector, each
A9273	Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type
	Humidifiers (not associated with PAP equipment, oxygen, IPPB, and Cool Air mist set ups)
A4520	Incontinence garment, any type (e.g., brief, diaper), each
E0221	Infrared heating pad system
A4639	Replacement pad for infrared heating pad system, each
E0481	Intrapulmonary percussive ventilation system and related supplies
L8499	Leg cover, realistic (Unlisted procedure for miscellaneous prosthetic services)
A9285	Inversion/Eversion correction device
	Leotards (does not include the burn leotards)
	Massage devices
A9270	Non-covered service
E0274	Over-bed table
	Parallel bars
E0625	Patient lift, bathroom or toilet, not otherwise classified
E0635	Patient lift, electric with seat or sling
E0640	Patient lift, fixed system, includes all components/accessories
E0639	Patient lift, moveable from room to room with disassembly and reassembly, includes all components/accessories
E0300	Pediatric crib, hospital grade, fully enclosed, with or without top enclosure
	Portable room heaters
A9281	Reaching/grabbing device, any type, any length, each
E0710	Restraints, any type (body, chest, wrist or ankle)
E0700	Safety equipment, device or accessory, any type
	Sauna Baths
E0172	Seat lift mechanism placed over or on top of toilet, any type
	Spare tanks of oxygen
	Speech teaching machines
	Stairway elevators
E0638 & E0641-E0642	Standing frame/table
A4490-	Surgical stockings

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CPT® or HCPC Codes	Description
A4510	
	Telephone alert systems
E0203	Therapeutic light box, minimum 10,000 lux, table top model
E0244	Raised toilet seat
E0245	Tub stool or bench
E0246	Tub rail attachment for transfer
E0247	Transfer bench for tub or toilet with or without commode opening
E0248	Transfer bench, heavy-duty, for tub or toilet with or without commode opening
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
	Treadmill exercisers
L8510	Voice amplifier
E0249	Pad for water circulating heat unit, for replacement only
E0950	Wheelchair tray
E1310	Whirlpool, nonportable (built-in type)
E1300	Whirlpool, portable (overtub type)
	White Canes
A9282	Wigs
A9286	Hygienic item or device, disposable or non-disposable, any type, each
A4606	Oxygen probe for use with oximeter device, replacement
E0445	Oximeter device for measuring blood oxygen levels noninvasively
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
V5275	Ear impression, each
V5281	Assistive listening device, personal FM/DM system, monaural (1 receiver, transmitter, microphone), any type
V5282	Assistive listening device, personal FM/DM system, binaural (2 receivers, transmitter, microphone), any type
V5283	Assistive listening device, personal FM/DM neck, loop induction receiver
V5284	Assistive listening device, personal FM/DM, ear level receiver
V5285	Assistive listening device, personal FM/DM, direct audio input receiver
V5286	Assistive listening device, personal blue tooth FM/DM receiver
V5287	Assistive listening device, personal FM/DM receiver, not otherwise specified
V5288	Assistive listening device, personal FM/DM transmitter assistive listening device
V5289	Assistive listening device, personal FM/DM adapter/boot coupling device for receiver, any type
V5290	Assistive listening device, transmitter microphone, any type

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Dates	Date Last Revised
01/22/2004	12/07/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 10/01/2013[MPC], 06/03/2014[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	10/28/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/1/2015	Added 2 Noridian links
10/27/2015	Added testicular prosthesis information

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02/02/2016	Expanded the policy for DME
09/28/2017	Added A9285 to non-covered
11/16/2017	Added ExoSyn language
02/28/2017	Added A4265 to non-covered list
05/23/2018	Added V codes for assistive listening devices to the non covered list
08/04/2020	Added devices not primarily intended for medical purposes (computers/phones/tablets, etc.) to the not medically necessary section
06/07/2022	MPC approved to add Home Pulse Oximetry codes to the DME list; 60-day notice required
10/26/2022	Retitled non covered item list
10/28/2022	Added E0765; Relief Band Device to the DME non-covered list

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KAISER PERMANENTE®

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Clinical Review Criteria
Driving Skills Assessment

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	Billing and Coding: Therapy Driving Evaluations (A52772) *Medicare does not reimburse evaluations performed solely to assess a beneficiary's ability to drive a vehicle. In order for a service to be covered, the service must have a benefit category in the statute Title 18 of the Social Security Act (SSA), it must not be excluded, and it must be reasonable and necessary. There is no benefit category for driving evaluations.*

For Non-Medicare Members

Treatments and/or therapies that are intended to specifically improve what are known as Instrumental Activities of Daily Living (IADL) are not covered because they are not considered treatment of disease. This includes driving skills assessments.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

OT is generally covered for members with eligible conditions that require improvement in Activities of Daily Living (ADLs). These include, but may not be limited to
bathing, communication, dressing, feeding, grooming, mobility, personal hygiene, self-maintenance, skin management, and toileting.

Treatments and/or therapies that are intended to specifically improve what are known as Instrumental Activities of Daily Living (IADL) are not covered because they are not considered treatment of disease. These include, but are not limited to: community living skills including balancing a checkbook, use of public transportation; home management skills including meal preparation, laundry; leisure activities including hobbies, sports or recreation of all types even if suggested as part of an OT treatment plan; motor vehicle driving evaluations and driving instruction - this includes automobiles, trucks, motorcycles and bicycles; or personal safety preparedness. This does not mean that a driving evaluation might not be helpful for a given patient, rather that the patient or family would be responsible for the cost.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
04/07/2020	04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/07/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt new non-coverage criteria, effective 08/01/2020.

KAISER PERMANENTE®

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Clinical Review Criteria
Dry Needling for Myofascial Pain

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Acupuncture (30.3) Acupuncture for Fibromyalgia (30.3.1) Acupuncture for Osteoarthritis (30.3.2) Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Myofascial pain syndrome (MPS) is a fairly common form of pain that arises from muscles or related fascia. The syndrome is usually characterized by palpable muscle tenderness and trigger points (myofascial trigger points or MTrPs). These are highly localized, hyperirritable spots in a palpable taut band of skeletal muscle fibers. When compressed, MTrPs can cause local and/or referred tenderness and pain, aggravation of existing pain, and /or autonomic phenomena. They can also contribute to impaired range of motion and increased sensitivity to stretch. Active MTrPs are associated with spontaneous local or referred pain and/or pain on movement, while latent MTrPs require direct stimulation to trigger pain symptoms. Palpating a trigger point or inserting a needle into it may elicit a localized twitch response, a brisk contraction of muscle fibers in and around the MTrPs. Trigger points may develop anywhere in the body in response to sudden injury, muscle overload, or repetitive microtrauma. Frequently affected sites include trapezius, supraspinatus, infraspinatus, teres muscle, lumbar paraspinals, gluteus, and pectoralis muscles. It is postulated that the injured muscle fibers shorten forming taut bands in response to the excessive amounts of calcium released from the damaged fibers or to the excessive amounts of acetyl choline released from the corresponding motor end plate. There are no laboratory or imaging tests to establish the diagnosis of MPS or to locate the trigger points. It has been suggested that spot tenderness, taut band, and pain recognition are the three important criteria for the diagnosis of MTrP, and that referred pain and local twitch response can be confirmatory signs for the diagnosis (Chou 2012, Dıraçoğlu 2012, Furlan 2005, Kietrys 2013, Ay 2010, Tekin 2013 Tough 2009).

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The primary goal of treating MPS is to inactivate the trigger points and loosen the taut bands. The most important strategy is to treat the underlying etiological lesion that causes activation of MTrPs. If the underlying pathology is not appropriately and completely treated, the MTrP is inactivated only temporarily not completely. Several treatment modalities have been used to alleviate the chronic myofascial pain, but no single strategy proved to be universally successful. These include the use of non-steroidal anti-inflammatory drugs (NSAIDs), NSAID gel or patch, thermotherapy, massage, physical therapy, spray and stretch techniques, exercise, ischemic compression, laser therapy, acupuncture, or local injections of substances as steroids or lidocaine. Trigger point injection with local anesthetic, saline, steroid, botulinum toxin, or even dry needling is believed to be the most effective method for treating MPS (Ay 2010, Chou 2012, Kalichman 2010).

Dry needling (DN) was initially developed to treat musculoskeletal disorders. It was widely used for the treatment of MTrPs in the last three decades after some investigators indicated that needling effect is distinct from that of the injected substance. Trigger-point DN (also called biomedical acupuncture) is different from acupuncture and is not based on the insertion of needles in traditional acupuncture meridian sites. DN is a procedure in which an acupuncture-like needle is inserted into the skin and muscle in the location of an MTrPs without the use of saline or any other liquid agent or medication. The needle is not left in situ but is removed after the muscle has finished twitching and the trigger point inactivated. This should be followed by exercises, usually stretching or ergonomic adjustments, in order to establish a painless full range of motion. It has been suggested that DN is most effective when local twitch responses are elicited, probably because of rapid depolarization of the involved muscle fibers which manifest as local twitches. The actual mechanism by which DN may produce an effect is being debated and several explanations were postulated. Some investigators explain that the localized twitch response that often occurs may interrupt the motor end-plate noise, producing an analgesic effect, while others suggest that eliciting a localized twitch response and stretching exercises relax the actin-myosin bonds in the tight bands. It is also postulated that the mechanical damage of the muscle fibers and nerve terminations leads to an increase of extracellular potassium, depolarization of nerve fibers, inhibition of central feedback mechanisms, local dilution of nerve-sensitizing substances, increasing vasodilatation, and formation of necrosis in trigger point area. A number of other mechanisms were postulated by different researchers. Adverse events associated with the DN include soreness after needling, local hemorrhages at the needling site, and syncopal responses (Ay 2010, Furlan 2005, Kalichman 2010, Kietrys 2013).

Several schools and theoretical models of DN have been developed during the last three decades. The most common are the radiculopathy (also known as intramuscular stimulation) and MTrP models. Dry needling techniques include superficial or deep needling and needling with or without paraspinal needling. In the superficial needling the needle is only inserted into the tissue overlying the MTrP to a depth of 5-10 mm for 30 seconds. At this level the needle does not necessarily reach the MTrP and local twitches are not expected. In the technique that involved paraspinal needling, needles are inserted at the trigger point as well as in the paraspinal muscle of the same segment that innervates the painful muscles. These last two techniques were the least investigated (Kalichman 2010).

DN is a minimally invasive skilled intervention performed by physical therapists (where allowed by state law) and requires advanced training. The states allowing the procedure to have to follow guidelines for education and competency standards for performing it.

Medical Technology Assessment Committee (MTAC)

Dry Needling for Myofascial Pain

02/10/2014: MTAC REVIEW

Evidence Conclusion: The results of the published randomized controlled trials (RCTs) and meta-analyses do not provide sufficient evidence to determine that DN is superior or equivalent to acupuncture, physical therapy, injections with lidocaine or botulinum toxin in reducing myofascial pain or increasing the range of motion. The published randomized controlled trials that compared the effect of DN to sham injections, injections with lidocaine, botulinum toxin, acupuncture, or physical therapy had small sample sizes, and insufficient power to detect significant differences between the study groups. The majority of trials were unblinded, had methodological limitations, and none was designed as an equivalence trial. The overall results of the studies show some improvement in pain and range of motion with lidocaine or botulinum toxin injections, physical therapy, or acupuncture, and some or no improvement with DN. Improvements were observed when the comparisons were made between pre-and post-treatment within each of the study groups. There were no significant between groups differences in the outcomes studied. Many of the authors interpreted the lack of difference between the study groups as equal effects. As indicated earlier, none of the trials were designed as equivalence study, and a lack of significant differences between study groups cannot be interpreted as equal effects as it might be due to the small sample sizes and insufficient power of the trials.

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Kietrys et al's (2013) meta-analysis (evidence table 1) pooled the results of 12 trials with a total of 696 participants that compared DN to either sham therapy or other active therapies (lidocaine injection, botulism toxin injection, or acupuncture) for upper quarter myofascial pain. The pooled results of the analysis indicate that DN may be superior to sham needling but less effective than the other active therapies. Tough and colleagues' (2009) meta-analysis pooled the results of 7 small trials, with significant heterogeneity, that studied the effect of acupuncture and DN of the MTrPs compared to no additional intervention, indirect local DN, or a sham therapy. Four of the included studies were rated to have poor methodological quality. The authors could perform a MA only for 4 (N=134 participants) studies that compared DN to sham needling. The pooled results of these trials showed that DN was not superior to sham therapy in reducing the myofascial pain (standardized mean difference =14.09 (95% CI, -5.81 to 33.99). The results of the two meta-analyses have to be interpreted with caution due to the small number and size of the trials as well as their methodological limitations, and significant heterogeneity between studies.
Conclusion: There is insufficient published evidence to determine that dry needling has a superior or equivalent effect as acupuncture, other therapies, or injections in reducing pain and improving range of motion (ROM) in patients with myofascial pain syndrome (MPS). The results of trials comparing DN to sham needling are conflicting, and may only provide weak evidence that DN performed by experienced physiatrists may be superior to sham needling in reducing the pain, but not improving the ROM. There is insufficient published evidence to determine the appropriate number of points to be injected. There is insufficient published evidence to determine the duration of pain relief after the injection. There is insufficient evidence to determine whether the patients would need to undergo another needling procedure, and the most appropriate interval between re-injections if needed.
Articles: The literature search revealed a number of small randomized controlled trials and 4 systematic reviews with or without meta-analyses (MA) on the use of DN in the management of myofascial pain. Kietrys and colleagues' 2013 meta-analysis examined the effectiveness of DN for the treatment of upper quarter myofascial pain. Tough et al's 2009 MA updated an earlier 2001 MA on the effect of DN on MPS in any location in the body. A Cochrane review (Furlan et al, 2005) pooled the results of studies on acupuncture and DN for low back pain. The three meta-analyses included the majority of the published RCTs that compared DN to sham needling, physical therapy, or injection of local anesthesia used for the treatment of myofascial syndrome in different locations in the body. The following most recent and larger meta-analysis and selected RCTs included or not included in the meta-analyses were critically appraised. Selection of the RCTs was based on their size, control groups, and methodological quality. Ay S, Evcik D, Tur BS. Comparison of injection methods in myofascial pain syndrome: a randomized controlled trial. *Clin Rheumatol*. 2010; 29:19-23. Dıraçoğlu D, Vural M, Karan A, et al. Effectiveness of dry needling for the treatment of temporomandibular myofascial pain: a double-blind, randomized, placebo-controlled study. *J Back Musculoskelet Rehabil*. 2012; 25:285-290. Irnich D, Behrens N, Gleditsch JM, et al. Immediate effects of dry needling and acupuncture at distant points in chronic neck pain: results of a randomized, double-blind, sham-controlled crossover trial. *Pain*. 2002; 99:83-89. Kietrys DM, Palombaro KM, Azzaretto E, et al. Effectiveness of Dry Needling for Upper-Quarter Myofascial Pain: A Systematic Review and Meta-analysis. *J Orthop Sports Phys Ther*. 2013; 43:620-34. Rayegani SM, Bayat M, Bahrami MH, et al. Comparison of dry needling and physiotherapy in treatment of myofascial pain syndrome. *Clin Rheumatol*.2013 Dec 19.DOI 10.1007/s10067-013-2448-3.Tough EA, White AR, Cummings TM, et al. Acupuncture and dry needling in the management of myofascial trigger point pain: a systematic review and meta-analysis of randomised controlled trials. *Eur J Pain*. 2009; 13:3-10. Tekin L, Akarsu S, Durmuş O, et al. The effect of dry needling in the treatment of myofascial pain syndrome: a randomized double-blinded placebo-controlled trial. *Clin Rheumatol*. 2013; 32:309-315.

The use of dry needling for myofascial pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

For dry needling (DN), typically coupled with exercise or stretching, for the treatment of adults with mechanical neck and/or trapezius muscle pain associated with trigger points (TrPs).

Conclusion

An overall low-quality body of evidence suggests that DN appears to be safe and may be somewhat effective for the treatment of neck and/or trapezius pain when combined with exercise, but it is unclear whether it provides additional benefits beyond those provided by standard therapy alone.

- Two sham-controlled trials found no difference in improvement in pain or physical function between DN plus exercise relative to sham DN plus exercise. This suggests that DN does not confer benefits beyond those attained by exercise or stretching.

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- In 6 studies, DN coupled with exercise resulted in statistically and clinically significant improvement in pain relative to pretreatment levels; findings in 5 of these studies were mixed as to whether use of DN improved physical function relative to baseline.
- In 4 studies, DN coupled with exercise resulted in improved pain and function relative to exercise alone, but there were no differences between DN alone or coupled with exercise and manual therapy relative to manual therapy alone. The clinical significance of these results is unclear.

Additional studies are needed to address the remaining questions regarding the clinical significance of DN treatment, its long-term effectiveness, and its effectiveness versus other standard therapies.

Hayes Rating: C

Hayes. Hayes Technology Assessment. Dry Needling for Mechanical Neck and/or Trapezius Muscle Pain in Adults. May 18, 2023. Retrieved May 23, 2023, from https://evidence.hayesinc.com/report/dir.needling2835

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscles

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
04/01/2014	04/01/2014[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	05/23/2023

[MPC] Medical Policy Committee

Revision History	Description
06/02/2020	Added NCD's: Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3) and Acupuncture (30.3)
05/23/2023	Added Hayes Technology Assessment for Dry Needling for Mechanical Neck and/or Trapezius Muscle Pain in Adults

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Radiation Therapy for Palmar Fibromatosis

- Radiotherapy
- Dupuytren's Contracture

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Radiation Therapy for Palmar Fibromatosis," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Dupuytren's contracture (DC) is a fibrotic tissue disorder affecting the hands. It is a benign condition characterized by thickening connective tissue in the palm eventually progressing to the formation of nodules and cords. Symptoms typically occur in both hands and progress gradually over time at variable rates. The lumps or dermal pits can be present for extended periods of time before a cord may develop causing the fingers to contract. The contracture, however, may not become troublesome for years or may never progress at all.

DC has a global prevalence of 3-6% primarily affecting males and Caucasian populations. Most patients will present with symptoms in middle age (Rizzo, Stern et al. 2013). Typically diagnosed upon physical examination, the etiology of DC is unknown, however, there is believed to be a strong genetic component as it most commonly occurs in people of Northern European or Scandinavian ancestry and often runs in families. The literature has also suggested associations with diabetes, seizures, smoking, alcohol, trauma and beta-blockers.

At present, there is no cure for DC. Available treatment options include both invasive and noninvasive modalities and typically focus on managing the disability and preventing progression (NICE 2010). Stretching, massage and splinting are frequently recommended while corticosteroid injections and fasciectomy have been used in more

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extreme and developed cases. In any case, most treatment options have limited effectiveness as 20% of patients experience recurrence of symptoms.

Radiation therapy or radiotherapy (RT) is a non-surgical treatment option that is reported to halt or slow the progression of DC in its early stages. Aimed to prevent or postpone the need for surgical intervention, the mechanism for action is unclear, but it is thought to affect the development and growth rate of fibroblasts within the palmar fascia. RT treatment of the affected nodules and cords can be performed with either superficial x-rays or electron beams. The technique is typically carried out over several consecutive visits until the intended radiation dose has been achieved.

Medical Technology Assessment Committee (MTAC)

Radiotherapy for Dupuytren's Contracture

10/20/2014: MTAC REVIEW

Evidence Conclusion: The most recent study, published by Zirbs and colleagues in September of 2014, included 355 patients with DC who had undergone soft X-ray between 1999 and 2008 at one of two sites in Germany. Participants were asked to respond to a structured questionnaire addressing family history, predisposing factors, occupation, disease characteristics, progression, treatments, effects, side-effects, and satisfaction using a visual analogue scale (VAS). Over half (58%) of patients responded to the questionnaire and, of those, almost 80% reported no progression of symptoms after receiving treatment and were satisfied with therapy. The investigators noted a significantly higher improvement in patients with who had experienced symptoms for less than 20 months, supporting the hypothesis that early stages of DC are treated more effectively. Ultimately, the authors concluded that radiotherapy was well-tolerated and prevented further disease progression in most patients (Zirbs, Anzeneder et al. 2014). In the only RCT identified, Seegenschmiedt and colleagues compared two different radiation techniques with the overall aim of optimizing radiation dose. The study included 129 patients (198 hands) who were randomly assigned to receive one of two RT schedules (30 Gy vs. 21 Gy). Subjective responses, DC stage, nodule number, size and consistency, as well as, cords and finger mobility were assessed at two follow-up appointments. At one year, the investigators reported that objective symptom assessment showed indications of regression in over half (56%) of the hands treated with 30 Gy of radiation. Similarly, of the group treated with 21 Gy of radiation, 53% of hands showed signs of regression. Subjective symptom assessment also indicated regression of DC in both groups with 65% and 53% of patients in groups A and B, respectively. The investigators, however, do not indicate if this difference was significant. Ultimately, the authors conclude that both tested regimens are well accepted and tolerated by patients. (Seegenschmiedt, Olschewski et al. 2001). Betz and colleagues present a case series of 135 patients (208 hands) who were irradiated with orthovoltage in two courses of five daily fractions of 3.0 Gy (total dose of 30 Gy) separated by a six to eight-week interval. The investigators were able to follow-up 76% of hands treated at 13 years and reported complete relief of symptoms in 16% of patients, good relief in 18% and minor relief in 32% patients. Ultimately, the investigators concluded that radiotherapy is effective in prevention of disease progression and improves patient's symptoms in early stage DC. (Betz, Ott et al. 2010). In terms of safety, theoretical adverse events could be anything that we already know to be associated with radiation such as skin dryness, scarring/hand stiffness, and long-term potential for developing radiation induced cancer. The included studies list both acute and chronic symptoms such as dryness and desquamation, skin atrophy, lack of sweating, telangiectasia and sensory affection. Seegenschmeidt and colleagues also detailed a higher acute toxicity in the low-dose group receiving (21Gy) when compared to the medium-dose group (30 Gy) siting the dose-time factor as the cause. In any case, all three studies ultimately concluded that the radiation therapy was well tolerated. On the whole, the body of evidence is limited and should be interpreted with caution. First and foremost, none of the included studies used an adequate comparator. In two of the selected studies no comparison group was used, and in the one study that did make comparisons, no sham group was included. To add to this, each study utilized different radiation doses at different regimens without identifying an ideal or standard dose. The inclusion criteria may also be a limiting factor as all three of the studies included patients who had previously received treatment limiting the ability to exclude the effects of prior treatment. Finally, only one of the studies, by Betz and colleagues, provides adequate follow up (13 years) to assess progression of symptoms and long-term safety. Conclusions: There is insufficient evidence to support the effectiveness of radiation therapy for patients with DC. There is insufficient evidence to support the safety of radiation therapy for the treatment of DC.

Articles: The literature was searched for publications assessing the safety and effectiveness of RT for DC. Several publications were revealed, many of which were published in languages other than English (primarily German). There were no randomized controlled trials (RCTs) comparing the effectiveness of RT with surgical intervention or any other medical intervention for that matter. One RCT was discovered that compared the effectiveness of two different radiation doses. In addition, two recent case series were included to address safety. The following articles were selected for critical appraisal: Zirbs M, Bruckbauer AH, Hoffman H, et al., Radiotherapy with soft X-rays in Dupuytren's disease – successful, well-tolerated and satisfying. European

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Academy of Dermatology and Vernereology. 2014. See Evidence Table 1. Seegenschmiedt MH, Olschewski T, Guntrum F. Radiotherapy optimization in early-stage dupuytren's contracture: first results of a randomized clinical study. Int J Radiation Oncology Biol Phys. 2001; 49(3):785-798. See Evidence Table 2. Betz N, Ott OJ, Adamietz B, et al. Radiotherapy in early-stage Dupuytren's contracture. Strahlenther Onkol. 2010;186(2): 82-90. See Evidence Table 3.

The use of Radiotherapy for Dupuytren's Contracture does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
With diagnosis code	
M72.0	Palmar fascial fibromatosis [Dupuytren]

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/28/2014	11/07/2014[MPC], 09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	12/24/2019

[MPC] Medical Policy Committee

Revision History	Description
12/24/2019	Added guidelines for Medicare members to use commercial criteria.

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Clinical Review Criteria
Dynamic Spinal Visualization

- Cineradiography
- Digital Fluoroscopic Video of the Spine
- Dynamic Motion X-ray
- Spine Digital Motion X-ray

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Dynamic Spinal Visualization*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Dynamic spinal visualization addresses different imaging techniques that allow the simultaneous visualization of movement of internal body structures with corresponding external body movement. These include dynamic or digital motion x-rays and video fluoroscopy (also known as digital fluoroscopic video or cineradiography). These imaging technologies use x-rays to create images either on film, video monitor, or computer screen.

Video fluoroscopy is a procedure that uses fluoroscopy to create real-time video images of internal structures of the body. Unlike standard x-rays that take one picture at a time, fluoroscopy provides motion pictures of the body that can be displayed on a video monitor during the procedure and also recorded for further or later evaluation. Digital motion X-ray is a fluoroscopic x-ray that integrates today's digital and optic technology to produce an x-ray movie of the body while in motion. It involves the use of either film x-ray or computer-based x-ray snapshots taken in sequence as the patient moves; to image the cervical spine; for example, patients are asked to perform flexion, extension, right and left lateral flexion and left and right rotation exercises to document range of motion. The

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snapshots are then digitized, put in order using a computer program and played on a video monitor creating a moving image of the inside of the body. Both digital motion x-rays and video fluoroscopy can either be examined by the physician with or without using special computer software to evaluate several aspects of the body's structure such as intervertebral flexion and extension, to determine the presence or absence of abnormalities.

The technology has been used for decades in the diagnosis of various conditions, mainly swallowing disorders, and have been proposed for the evaluation of spinal disorders including low back pain, and segmental lumbar spinal instability to determine the presence or absence of abnormalities.

Medical Technology Assessment Committee (MTAC)

Dynamic Spinal Visualization

10/17/2011: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence, to date, to determine the clinical utility of dynamic spinal visualization for the diagnosis or management of patients with spinal disorders. The published studies mainly evaluated the spine kinematics and motion patterns of the lumbar segments in symptomatic patients and asymptomatic volunteers. Others studied the correlation of total sequence of movement observed by cineradiography with the conventional radiographs taken at the extremes of spinal motion. No studies examined the effect of using the technology on managing the patients, impact on health outcomes, or an incremental value over conventional imaging methods. Reviews made by other health plans including Blue Cross, Blue Shield, Regence, Anthem, and several others, all came to the same conclusion that dynamic spinal visualization is considered investigational, and that there is insufficient published data to support the use of digital motion x-rays or cineradiography/video fluoroscopy of the spine for any indication.

Articles: The literature search revealed a limited number of small studies that compared the spine kinematics in patients with neck or back pain versus asymptomatic controls. No studies evaluating the effect of using the technology on managing the patients with back pain or other spinal disorders were identified.

The use of dynamic spinal visualization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
76120	Cineradiography/videoradiography, except where specifically included
76125	Cineradiography/videoradiography to complement routine examination (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/01/2011	11/01/2011[MDCRPC],10/02/2012[MDCRPC],08/06/2013[MPC],06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC] ,07/10/2018[MPC], 07/09/2019[MPC] ,07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	11/01/2011

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Electroconvulsive Therapy (ECT)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare National Coverage Determinations Manual, Chapter 1, Part 2 (Section 160.25)
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Care Guideline: Electroconvulsive Therapy (B-802-T) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Electroconvulsive therapy (ECT) is a procedure where electrodes are positioned on the patient's scalp, and a measured electrical current is passed through to the brain, inducing generalized seizure activity. ECT is typically administered by a psychiatrist, with the patient under general anesthesia (provided by an anesthesiologist or anesthetist). The treatments are performed in either an inpatient or outpatient setting, depending on a variety of factors.1

ECT is not typically considered the first-line of treatment. It is most often used to treat patients with treatment-resistant depression, after a failure of a number of adequate medication trials over time. However, it may result in therapeutic effect more rapidly than medications and should be considered as a possible first line treatment in life threatening catatonia (e.g. with risk of death due to severe malnutrition/starvation) or in someone who is at extremely high risk of suicide.2 Patients with severe medical or psychiatric illness often start ECT on an inpatient basis, and as they improve, might switch to outpatient treatment. Continuation and maintenance ECT are usually provided on an outpatient basis.

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The mechanism of action for ECT remains unknown. However, many studies have shown a variety of changes in the central nervous system that might play a significant role in its therapeutic effect, including ECT prompting the release of neurotransmitters, and ECT causing the hypothalamus or pituitary gland to release hormones such as thyroid stimulating hormone and endorphins.2

ECT has been found to be an effective and safe mode of treatment for a number of behavioral health disorders/conditions, and is practiced widely in the United States.1 However, the treatment continues to have some stigma attached because of misperceptions about its use, a lack familiarity with the current treatment procedure and the current level of risk of adverse effects.2

There are few contra-indications or relative contra-indications to the treatment, so a pre-treatment medical review is required before initiating treatment.

Risks of ECT are primarily those associated with anesthesia. The mortality rate (about 2 to 4 deaths per 100,000 treatments) is mostly related to cardiopulmonary events, but the mortality rate is less than that reported for normal childbirth, and is associated with the anesthesia risks.3,4

Current ECT techniques use anesthesia and brief-pulse electrical stimuli that “virtually eliminate” the past risk of fractures and minimize the risk of developing transient cognitive dysfunction effects. Not all patients who receive ECT will obtain Cognitive dysfunction / memory loss from the treatment; however, when it occurs, it can present during or after the course of ECT. The memory effects from ECT can manifest as an acute confusional state, as anterograde amnesia or as retrograde amnesia.

The acute confusional state is considered a result of both the seizure and the anesthesia. It usually resolves 10-30 minutes after the procedure.5

Anterograde amnesia is a decreased ability to retain newly acquired information. It can occur during a course of ECT and usually resolves within 2 weeks after completing the course.6

Retrograde amnesia involves forgetting recent memories, forgetting events that occur during the course of ECT and for a period of weeks or months prior to the ECT. Patients tend to retain knowledge about themselves but might forget public knowledge or information about world events. This retrograde amnesia tends to recover more slowly.7,8

ECT is most commonly used to treat severe or treatment-resistant depression. ECT has also been shown to be effective for bipolar mood disorders (depression, mania or mixed states), schizoaffective disorder, schizophrenia and catatonia.2

ECT has been found to be particularly effective in treating patients with depression with prominent suicidal ideation or patients with psychotic depression. Response rates have been found to range from 50-80% for patients with treatment-resistant depression, and maintenance medication management or maintenance ECT may significantly decrease the relapse rate.9,10

For patients with bipolar disorder, ECT has been used for treatment of severe and psychotic depression, especially if refractory to medication management.11,12

For patients with schizophrenia or schizoaffective disorders, ECT may be considered when a rapid global improvement with reduction in symptoms is needed.13 ECT might also be used in the treatment of catatonia.14

ECT may be warranted for patients who are in an acutely life-threatening situation (e.g. high risk for suicide attempt, unremitting self-injury, catatonia, starvation, intractable manic excitement, or neuroleptic malignant syndrome). ECT might also be indicated when patients have a coexisting medical condition, where ECT is considered a safer therapeutic alternative than behavioral medication management (e.g. pregnant or elderly patients), and for patients who have previously responded well to ECT or who are unwilling or unable to take medications.1,2,15,16,17

For patients who have obtained a positive therapeutic response with ECT, but who are unable to sustain the response with post-ECT behavioral health medication management, ECT as maintenance treatment may be considered, and is generally administered with decreased frequency (e.g. weekly, biweekly, monthly), and might be provided as long-term maintenance treatment, when discontinuation or further reduction in the treatments is likely to lead to a relapse.1,18

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Evidence and Source Documents

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
90870	Electroconvulsive therapy (includes necessary monitoring)

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Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	06/05/2018

[MPC] Medical Policy Committee

Revision History	Description

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06/05/2018	MPC approved to adopt MCG* B-802-T for ECT

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Clinical Review Criteria
Neurofeedback (EEG Biofeedback) and Neuropsychiatric EEG-Based Assessment Aid (NEBA) – ADHD

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Criteria

For Medicare Members

Source	Policy
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "Attention Deficit Hyperactivity Disorder (ADHD)"** for medical necessity determinations. Use the Non-Medicare Criteria below.

For Non-Medicare Members

Service	Criteria used
Neurofeedback for ADHD (biofeedback) Neuropsychiatric EEG-Based Assessment Aid (NEBA)	See MCG* A-0330: *Biofeedback Inconclusive or Non-Supportive Evidence* For attention-deficit hyperactivity disorder in children, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefits vs. harm; additional research is recommended. For adolescents, there is insufficient evidence in the published medical literature to show that this service/therapy provides better outcomes than current standard services/therapy. There was no literature reported for adults with attention-deficit hyperactivity disorder at the time of the review. *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Attention Deficit Hyperactivity Disorder (ADHD) is a common chronic neurobehavioral condition affecting approximately 5% of children worldwide. A child with ADHD may present as: 1) predominantly hyperactive, 2) predominantly inattentive, or 3) both hyperactive and inattentive. ADHD is often accompanied by impaired social

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adjustment, academic problems, and lower adaptive functioning in major life activities which may persist to adolescence and adulthood (Benner-Davis 2007, Gevensleben 2009, Lansbergen 2011).

Medication, particularly psychostimulants, is the primary treatment for ADHD. Psychostimulants work quickly, improve attention, and reduce hyperactivity and impulsitivity in about 70% of all children. However, their effect on academic achievement, family relation, and social skills is small. There are also some concerns regarding their side effects, and their long-term benefits have not been established. Behavioral therapy has been shown to reduce ADHD symptoms, but may not be sufficiently effective especially in terms of generalization and long-term effects (Leins 2007, Gevensleben 2009, Lansbergen 2011).

In searching for additional or alternative treatments for children with ADHD, neurofeedback (NF) emerged as a promising option. NF is a type of biofeedback that uses electroencephalography (EEG) to provide a signal that can be used by a person to receive feedback about brain activity. It is based on the rationale that there is a relationship between surface EEG and the underlying thalamocortical mechanism responsible for its rhythms and frequency modulations. Lubar was the first to report on EEG and behavioral changes in a hyperkinetic child. He explained that ADHD children differ from others in that their brain waves tend to be of larger amplitude. Specifically, the EEG shows excess theta activity along with lower amounts of beta activity. This pattern of brain wave activity usually indicates a sleep or daydreaming state, rather than an alert and focused state. The goal of EEG biofeedback training is to alter these abnormal brain waves by decreasing theta waves, while simultaneously increasing beta waves (i.e. theta suppression/beta enhancement). This would potentially help the child acquire self-control over certain brain activity patterns, derive self-regulation strategies, and apply the gained self-regulation skills in daily life (Lubar 1976, Lubar 1991, Bakhshayesh 2011).

In EEG biofeedback training, the therapist explains to the child the connection between what is happening in his/her cortex and what is recorded on the EEG and helps him/her learn how to gain control over the brain activity patterns. The EEG biofeedback equipment is connected to the individual with sensors that are placed on the scalp and ears. Once connected, the brainwave activity can be observed on a computer monitor. Individuals are then taught to play computerized games using their brainwave activity. Changes in the individual's brainwave activity are then fed back to the individual through visual and/or auditory information by the computer. During a typical 45-minute session, the child is seated in front of a computer, electrodes are connected to his head, and then a therapist starts up a videogame or movie on the child's screen and monitors his brain waves on another screen. The child then locks his eyes on the action, concentrating on sending the kind of brain waves that will keep a virtual airplane flying, or perhaps a favorite movie rolling. If his attention wanders or he begins to fidget, the plane slows or the movie screen darkens, and the therapist encourages him to regain focus using techniques such as slow, deep breathing. Children may also practice maintaining learned brainwave states when engaged in school- or work-related tasks (Gevensleben 2009).
In the last three decades many studies compared brain activity using electro-encephalography (EEG) among children with ADHD versus the brain activity of normal controls in an attempt to study the underlying neurophysiology of ADHD; and to investigate subtypes of the disorder and their response to treatment. The EEG frequency bands of most interest in ADHD research are the theta, beta, and alpha bands either alone or in relation to one another such as the theta/beta power or amplitude ratio. Alpha band activity is typically observed during rest when the eyes are closed and is negatively associated with central nervous system arousal. Beta band activity on the contrary, generally accompanies mental activity and concentration. Cortical theta is observed frequently in young children, but in older children and adults, it tends to appear during meditative, drowsy, or sleeping states. Researchers suggest that most children with ADHD display EEG differences in their brain electrical activity as compared to normal children, particularly with respect to their increased frontocentral theta activity primarily during the resting state. This indicates decreased cortical activity that may be associated with underarousal. A theta /beta ratio (TBR) due to increased theta is reported by many investigators as a consistent characteristic of ADHD. Some groups recommend using the TBR during eyes-opened or eye-closed resting condition as an add-on for the diagnosis and monitoring of ADHD. However, it is reported that the true functional significance of this measure is still unknown, and an elevated theta activity may be a nonspecific marker of cortical dysfunction common to other disorders such as epilepsy, bipolar disorder, and polysubstance abuse (Arns 2013, Liechti 2013, Loo 2012).

A number of studies examined the accuracy and diagnostic value of the theta power and TBR in discriminating normal children from children with learning disorders, ADD, and ADHD. In 2005, Boutros and colleagues performed a review and meta-analysis to estimate the strength and effect size of increased theta activity in ADHD patients. Based on their findings they concluded that the increased EEG theta activity in ADHD is promising and should be further developed as a diagnostic test for ADHD. Around the same time another group of investigators (Snyder and Hall, 2006) also conducted a meta-analysis to investigate the theta and beta powers and their ration (TBR) and concluded that the pooled results support the finding that an increase in the theta/beta ratio is a commonly observed trait in ADHD
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relative to normal controls. They however, cautioned that theta/beta ratio trait may arise with other conditions, and that a prospective study covering differential diagnosis would be required to determine generalizability to clinical applications (Arns 2013, Boutros 2005, Loo 2012 Snyder 2006).

Based on this EEG technology, the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System (NEBA Health, Augusta, GA) was developed and recently received Food and Drug Administration (FDA), in July 2013, to help assess ADHD in children and adolescents 6-17 years of age. It is not to be used as a stand-alone diagnostic test, but as a conjunctive tool for diagnosing ADHD. NEBA is a non-invasive test that calculates the ratio of theta and beta waves frequencies in 15-20 minutes (FDA and NEBA websites accessed January 15, 2014).

According to the FDA, the use of the device together with the complete medical and psychological examination, can help confirm an ADHD diagnosis or a clinician's decision that further diagnostic testing should focus on ADHD or other medical or behavioral conditions that lead to symptoms similar to ADHD. The FDA reviewed the NEBA System through a de novo classification process, a regulatory pathway for some low- to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device (FDA website accessed January 15, 2014).

Medical Technology Assessment Committee (MTAC)

Neurofeedback for ADHD

10/17/2011: MTAC REVIEW

Evidence Conclusion: A number of small randomized and nonrandomized controlled trials included in Arns and colleagues' meta-analysis (evidence table 1) and the pooled results of available data indicate that NF may have some beneficial effects on a number of ADHD measures. However, when compared with stimulant therapy, NF did not prove to have an equivalent or superior effect on ADHD core symptoms. None of the studies monitored potential adverse effects of NF. The small study sizes, their short duration, lack of a valid control group, mixed and multiple interventions used, lack of double-blinding, additional time spent with the therapists for NF, as well as other study methodological limitations make it hard to determine the efficacy of the neurofeedback used alone or in addition to other interventions for the treatment of children with ADHD. Gevensleben and colleagues' trial (evidence table 2) conducted by a group of researchers in a university hospital in Germany, compared NF training to computerized attention skills training. This may be considered as a more valid comparison as it controls for therapist time and attention training. The primary endpoint was improvement in attention and reduced hyperactivity as rated by the parents. No measures of children's academic functioning or classroom performance were collected. The results of the trial showed that symptoms improved in both groups; however, the score of the primary outcome measure (parents' rating of FBB-HKS [a German rating scale]) was significantly higher in children in the NF group. The trial was randomized and controlled, but was not blinded, and the NF training program was developed by the study group. After the training period 18% of the children were started on a medication. Six months follow-up data, available for only two thirds of the participants, showed that the behavioral improvements were maintained at 6 months, but the difference between the two interventions did not reach a statistically significant level. The investigators attributed the lack of significant difference to insufficient statistical power due to the smaller number of children with follow-up data. They authors concluded that NF training may help some children, but more research is needed to replicate the findings and identify which children with ADHD are more likely to benefit from NF training. Well conducted randomized trials with a sham neurofeedback control, double-blinding, and long-term follow-up are needed to establish the efficacy and safety of neurofeedback in improving the core symptoms of ADHD.

Articles: The search revealed one meta-analysis on the efficacy of neurofeedback treatment in ADHD and a number of RCTs that were included in the meta-analysis. Three small RCTs published after the meta-analysis, as well as a report on 6 months follow-up of an earlier RCT were also identified. The meta-analysis as well as the largest trial, which had a more valid design and longer follow-up, were selected for critical appraisal. Arns M, de Ridder S, Strehl U, et al. Efficacy of neurofeedback treatment in ADHD: the effects on inattention, impulsivity and hyperactivity; a meta-analysis. Clin EEG Neurosci 2009; 40:180-189. See Evidence Table. Gevensleben H, Holl B, Albrecht B, et al. Is neurofeedback an efficacious treatment for ADHD? A randomized controlled trial. J Child Psychol Psychiatry. 2009; 50:780-789. See Evidence Table. Gevensleben H, Holl B, Albrecht B, et al. Neurofeedback training in children with ADHD: 6-month follow-up of a randomized controlled trial. Eur Child Adolesc Psychiatry 2010; 19:715-724. See Evidence Table.

The use of Neurofeedback for ADHD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/20/2016: MTAC REVIEW

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Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD)

Evidence Conclusion: EEG-NF versus placebo, sham: EEG neurofeedback (EEG-NF) treatments in children with ADHD: an updated meta-analysis of randomized controlled trials: (Micoulaud-Franchi et al., 2014) (Evidence table 1) On parent assessment (probably unblinded assessment), the overall ADHD scores (-0.49 [-0.74, -0.24], p < 0.001) as well as the inattention and hyperactivity/impulsivity scores were significantly improved (-0.46 [-0.76, -0.15], p = 0.003); -0.34 [-0.59, -0.09], p = 0.007) in patients receiving EEG NF compared to controls. On teacher assessment (probably blinded assessment), only the inattention score was significantly improved (Effect size of -0.30 [-0.58, -0.03] with p=0.03). Based on the findings, EEG-NF may improve core ADHD symptoms. However, the major limitation lies in the heterogeneity of EEG-NF protocols across individual studies. Other limitations include: 1) the small number of studies, 2) small size of individuals RCTs, 3) the exclusion of relevant RCTs in the meta-analysis, 4) the lack of blinded parent assessment and 5) the lack of evaluation of study quality. These result in low quality of evidence. Due to the aforementioned limitations, result should be interpreted with caution. A randomized placebo-controlled trial of electroencephalographic (EEG) neurofeedback in children with attention-deficit/hyperactivity disorder (van Dongen-Boomsma et al., 2013) (Evidence table 2) In both groups, and based on investigator assessment, ADHD symptoms decreased over time (F= 26.56, p < .001) to a similar degree. According to teacher assessment, significant improvement of symptoms over time (F= 13.54, p = .001) was reported, without a difference between groups (F= 0.45, p = .509). On the CGI-I scale, symptoms did not worsen. On CGAS, score increased similarly in both groups (F= 1.96, p = .169).
On PSERS, the total number of adverse events decreased significantly over time (F= 6.30, p = .016) and decreased similarly in the two groups (F= 0.10, p = .754). The SDQ assessment showed that sleep problems decreased significantly over time (F= 5.42, p = .025) in both groups. Overall, no differences in improvements between the groups were reported. However, several limitations are worth noted: 1) the small sample size limiting statistical power; 2) the therapist was not blinded; 3) the use of medications by some participants could have biased the outcomes of NF; 4) no follow-up data was available to assess the short or long term effects of NF; 5) generalizability might have been compromised since the sample is composed of white children. Studies with larger sample size and long follow-up are warranted to confirm these findings. Neurofeedback versus stimulant Medication: Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Meisel et al., 2014) (Evidence table 3) Regarding pre-post comparison, ADHD symptoms and functional impairment improved in general in both groups. Academic performance was only improved (except for math and oral expression) in NF group. Concerning pre-follow-up comparisons, similar results were observed. NF group-maintained symptoms achievement at 2 & 6 months after treatment completion. Inattention improved more than hyperactivity/impulsivity across evaluators, time & treatment. The major limitations are the small sample size and lack of longer follow-ups. In addition, patients were not blinded, and allocation concealment was not discussed. The risk of bias is therefore high. However, no major differences in symptom improvement were observed. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Orem & Hestad, 2013) (Evidence table 4) After treatment, there was a significant difference between the two groups with improvement observed in the medication groups. There were significant differences after treatment between the groups on inattention, Visual Continuous Performance Test (VCPT) & reaction time measures on patient assessment. All were in favor of the medication groups. Similar findings were observed on teacher assessment. In addition, higher positive changes were observed with the medication groups. The results indicate that medication led to better symptoms control on both parent and teacher assessment, particularly on inattention, VCPT & reaction time measures and that NF did not produce positive changes. However, this pilot study has several limitations: 1) generalizability of the findings may have been compromised because of the non-use of standard protocols, 2) small sample size 3) blinding was not discussed, 4) 59% of patients had learning disabilities making harder to achieve a positive outcome. Overall, the risk of bias is high, and results should be interpreted with caution. A randomized controlled trial of combined EEG feedback and methylphenidate therapy for the treatment of ADHD (Li et al., 2013) (Evidence table 5) In terms of Core symptoms and behavioral problems, significant improvement was noted for combination group compared to the control group. For social function assessments, the combination group performance was significantly better than that of the control group after 40 sessions of treatment (p <0.001). Regarding brain function assessment, the dominant probability of 8 Hz wave decreased significantly in the combination group. Adverse events correlate with methylphenidate dosage. The authors conclude that the combination of neurofeedback and methylphenidate is effective in improving the symptoms of ADHD in children. They also demonstrated that this combination is superior in enhancing core symptoms, behavioral issues, and brain function. However, limitations reside in small sample size limiting statistical power; the lack of long-term follow-up. One of the authors had financial tie with the Janssen Pharmaceutical. Therefore, results should be interpreted with caution.
Additional study: A placebo-controlled neurofeedback study (Arnold et al., 2012) did not demonstrate superiority of NF on ADHD core symptoms.
Conclusion:

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- The body of evidence is of low quality.
- Variations in the characteristics of EEG-NF protocols, the use of medications while receiving NF treatment, the small sample size, the lack of blinding in a number of studies and the short follow-up periods may have biased the findings.
- Neurofeedback may improve the core symptoms of ADHD in children but did not demonstrate superiority or was not equivalent to pharmacological therapy in reducing ADHD symptoms in children.
- There is insufficient evidence to determine whether Neurofeedback in combination with methylphenidate is effective in reducing the core symptoms of ADHD in children.

Articles: The literature revealed a number of articles, but the following articles were selected for critical appraisal: EEG neurofeedback treatments in children with ADHD: an updated meta-analysis of randomized controlled trials (Micoulaud-Franchi et al., 2014) See Evidence table 1. A randomized placebo-controlled trial of electroencephalographic (EEG) neurofeedback in children with attention-deficit/hyperactivity disorder (van Dongen-Boomsma, Vollebregt, Slaats-Willemse, & Buitelaar, 2013) See Evidence table 2. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Meisel, Servera, Garcia-Banda, Cardo, & Moreno, 2014) See Evidence table 3. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Ogrim & Hestad, 2013) See Evidence table 4. A randomised controlled trial of combined EEG feedback and methylphenidate therapy for the treatment of ADHD (Li, Yang, Zhuo, & Wang, 2013) See Evidence table 5.

The use of Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Neuropsychiatric EEG-Based Assessment Aid (NEBA)

02/10/2014: MTAC REVIEW

Evidence Conclusion: There is no published evidence to date to determine the safety, accuracy, or clinical utility of NEBA system in discriminating between children with or without ADHD. The FDA approval was based on a clinical study of 275 children and adolescents with attention and/or behavioral concerns. The study was conducted by the manufacturer of the NEBA system and has not been published in a peer reviewed journal to date. The observational studies on the correlation between the theta/beta ratios (TBR) had their limitations, and their results were inconclusive. In addition (according to Loo, 2012) there are wide variation in EEG instrumentation that can make it very hard to compare or generalize results of studies using different EEG hardware and software.

Articles: The literature search did not reveal any published study on the NEBA system; it only identified several observational studies that investigated brain activity using EEG in children with ADHD compared with normal controls, as well as three meta-analyses that pooled the results of a number of these studies.

The use of NEBA does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
Dx Codes	**Description**
F90.0-F90.9	Attention-deficit hyperactivity disorder

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/01/2011	11/01/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	10/03/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/20/2016	Added Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD) MTAC review
08/10/2016	Merged NEBA criteria into same document
09/06/2016	Added KPWA policy for Medicare members
10/03/2017	MPC approved to adopt MCG A-0330 summary of findings as criteria language

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Elective Surgical Procedures (Level of Care)

- Cardiac Catheterization
- Pacemaker

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Hospital Outpatient Regulations and Notices
National Coverage Determinations (NCD)	Cardiac Catheterization Performed in other than a Hospital Setting 20.25 Cardiac Pacemakers 20.8
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	Billing and Coding: Percutaneous Coronary Interventions A57479
Kaiser Permanente Medical	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Elective Surgical Procedures*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

When requesting Inpatient Level of Care for certain *elective* surgical procedures (not those typically done in an ambulatory surgery center), the request will be reviewed for coverage in the most appropriate, safe, and cost-effective level of care. A member's clinical presentation may be appropriate for an alternate level of care such as a hospital-based outpatient setting.

Examples include but are not limited to Pacemaker Placement or Cardiac Catheterization.

If requesting this these services, for inpatient level of care, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Attending provider must provide documentation in the prior authorization request that supports the need to have an overnight stay of greater than 2 midnights.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

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Surgery may safely be performed in various settings. Some of the common settings used are an inpatient hospital or medical center, an off-campus outpatient hospital or medical center, or an on campus outpatient hospital. Costs for surgical procedures may vary among these different settings. To encourage the use of the most safe and appropriate, cost effective sites of service for certain medically necessary outpatient surgical procedures, prior authorization is required for the site of service for the surgical procedures listed below.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific contract and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Cardiac Catheterization Codes

CPT® or HCPCS Codes	Description
0523T	Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (List separately in addition to code for primary procedure)
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure)
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed

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93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed
93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (List separately in addition to code for primary procedure)
93505	Endomyocardial biopsy
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (List separately in addition to code for primary procedure)
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed (List separately in addition to code for primary procedure)
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (List separately in addition to code for primary procedure)
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (List separately in addition to code for primary procedure)
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure)

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93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (List separately in addition to code for primary procedure)
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (List separately in addition to code for primary procedure)
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections
93598	Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects (List separately in addition to code for primary procedure)

Pacemaker Codes

CPT® or HCPCS Codes	Description
0695T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of implant or replacement
0696T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of follow-up interrogation or programming device evaluation
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33210	Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
33212	Insertion of pacemaker pulse generator only; with existing single lead
33213	Insertion of pacemaker pulse generator only; with existing dual leads
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator
33221	Insertion of pacemaker pulse generator only; with existing multiple leads
33223	Relocation of skin pocket for implantable defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)

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33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
33227	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
33229	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33233	Removal of permanent pacemaker pulse generator only
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
33270-leadless	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed **Requires separate medical necessity review*
33271-leadless	Insertion of subcutaneous implantable defibrillator electrode **Requires separate medical necessity review*
33274-leadless	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275-leadless	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
11/1/2022	11/01/2022 [MPC]	11/02/2022

[MPC] Medical Policy Committee

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Revision History	Description
11/01/2022	MPC approved the new Elective Surgical Procedures (Level of Care) criteria. Cardiac Catherization/Pacemaker is the first approved elective procedure to be done on an outpatient basis.

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Clinical Review Criteria
Electrical Stimulation and Devices

- Electrical Stimulation for the Treatment of Dysphagia
- Functional Neuromuscular Stimulation Unit (FNS or ENS)
- Galvanic Stimulation Device
- Gastric Electrical Stimulation (Enterra)
- H-wave Stimulation Device
- Microcurrent Stimulation Device (MENS)
- NESS Stimulators for Foot Drop and Paralyzed Hands
- Neuromuscular Electrical Stimulation Unit (NMES)
- Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis
- Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
- ReBuilder System
- Transcutaneous Electrical Nerve Stimulation (TENS) Unit
- WalkAide System for Patients with Foot Drop
- Peripheral Nerve Stimulation

A Separate Criteria Document Exists for the Following Devices:

Central Nervous System Electrical Nerve Stimulator: Spinal Cord Stimulators for Pain, Deep Brain Stimulation
Electrical Stimulation for Treatment of Wounds (Wound Care Treatments)
Hypoglossal Nerve Stimulation (Treatments for Obstructive Sleep Apnea)
Osteogenic (Bone) Stimulators
Sacral Nerve Stimulator for Fecal and Urinary Incontinence
Deep Brain Stimulation
Vagus Nerve Stimulation

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Criteria
For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Electrical Nerve Stimulators 160.7 Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy 160.7.1 Neuromuscular Electrical Stimulation (NMES) (160.12) Non-Implantable Pelvic Floor Electrical Stimulator (230.8) Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13) Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2) Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27) Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2)

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Date Sent: 6/28/23
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Local Coverage Determinations (LCD)	Transcutaneous Electrical Nerve Stimulators (TENS) (L33802) Peripheral Nerve Stimulation (L37360)
Local Coverage Article	Transcutaneous Electrical Nerve Stimulators (TENS) (A52520)

For Non-Medicare Members

Device	Criteria
TENS unit	Kaiser Permanente has elected to use the MCG* (KP-0241) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider or specialist to include any medications that were tried for pain relief • This service is dependent upon other measures of pain relief having been tried
NMES Unit – Neuromuscular Electrical Stimulation	Must meet **ALL of the following:** 1) Has durable medical equipment benefit 2) Treatment of muscle atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves and other neurological reasons for disuse atrophy
FES unit – Functional Electrical Stimulation (e.g. Parastep I System)	Must meet **ALL of the following:** 1. Has durable medical equipment benefit 2. Spinal cord injury patients to achieve walking and not reverse or retard muscle atrophy with all of the following characteristics: a) Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerves); b) Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently; c) Persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction; d) Persons that possess high motivation, commitment and cognitive ability to use such device for walking; e) Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes; f) Persons that can demonstrate hand and finger function to manipulate controls; g) Persons with at least 6-month post-recovery spinal cord injury and restorative surgery; h) Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and i) Persons who have demonstrated a willingness to use the device long-term. j) Persons without one of the following conditions: i) Cardiac pacemaker; ii) Severe scoliosis or severe osteoporosis; iii) Skin disease or cancer at area of stimulation; iv) Irreversible contracture; v) Autonomic dysreflexia;
Gastric Electrical Stimulation for the Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)	Kaiser Permanente has elected to use the FDA Humanitarian Device Exemption approved indications for Diabetic Gastroparesis: • Chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years
Gastric Electrical Stimulation for the Treatment of Gastroparesis	Kaiser Permanente has elected to use the MCG* Gastric Stimulation, Electrical (A-0395) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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Device	Criteria
(other than diabetic gastroparesis)	**If requesting this service, please send the following documentation to support medical necessity:** • Last 2 years of gastroenterology notes • Most recent clinical note from requesting provider
Electrical Stimulation for the Treatment of Dysphagia	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Galvanic Stimulation Device	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
H-wave Stimulation Device	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Microcurrent Stimulation Device (MENS)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
NESS Stimulators for Foot Drop and Paralyzed Hands	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
ReBuilder System Threshold electrical stimulation	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
WalkAide System for Patients with Foot Drop	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Peripheral Nerve Stimulator (i.e., StimRouter, Stimwave, Nalu)	Peripheral nerve stimulation is not covered for any indication at this time. Under evidence review. All requests must be reviewed by the Medical Director.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Electrical Stimulation for the Treatment of Dysphagia
Gastric Electrical Stimulation (Enterra)

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Hypoglossal Nerve Stimulation
NESS Stimulators for Foot Drop and Paralyzed Hands
Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis
Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
ReBuilder System
WalkAide System for Patients with Foot Drop

Background

A transcutaneous electrical nerve stimulator (TENS) is a device that utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins.

These are not the same as neuromuscular electrical stimulators (NMES), which are used to directly stimulate muscles and are used to prevent disuse atrophy (not address pain).

The transcutaneous electrical nerve stimulator is a well-established technique with limited effect and efficacy for the control of chronic painful disorders. Patients with chronic pain are best treated with a multi-disciplinary approach that includes increasing their activity. A TENS unit may be useful for a few weeks to assist a patient in becoming more active. It is not recommended for acute pain management as medication is much more effective and is safe for short-term management. It may be used occasionally to assist with pain control in patients with acute pain.

Medical Technology Assessment Committee (MTAC)

Transcutaneous Electrical Nerve Stimulation (TENS)

06/30/1998: MTAC REVIEW

Evidence Conclusion: Jarzem et al., Transcutaneous Electrical Nerve Stimulation for Patients with Chronic Backpain, presented at the annual meeting of the American Academy of Orthopedic Surgeons, San Francisco, 1997. 350 patients with chronic back pain, randomized into 4 groups; (1) daily treatment with conventional TENS; (2) treatment with nu-wave form TENS; (3) treatment with acupuncture TENS; (4) and treatment with sham TENS. In addition, all underwent an identical exercise program by a single therapist, blinded. 26 patients dropped out. All patients improved over time, but there were no significant differences among treatment groups.

Electrical Stimulation for the Treatment of Dysphagia

BACKGROUND

Dysphagia is the subjective sensation of difficulty or abnormality of swallowing. The term is derived from the Greek dys for bad or disorder, and phago for eat. Swallowing is a complex sensory-motor behavior that involves more than 25 pairs of muscles, 6 cranial nerves, and 2 cervical nerve roots to transport saliva, ingested solids, and fluids from the oral cavity to the stomach. It consists of three sequential, physiologically interconnected phases: oral preparatory and propulsive phase, pharyngeal phase, and esophageal phase. Dysphagia occurs when there is a problem with any part of this swallowing process. It can affect any age group, and may result from congenital abnormalities, stroke, head injury, neoplasms, and/or other medical conditions. Its incidence is higher in the elderly, in patients who have had strokes, and in patients who are admitted to acute care hospitals or chronic care facilities. Some may have trouble swallowing food, liquids, or saliva, and others are completely unable to swallow. Dysphagia can be a serious health threat due to the risk of aspiration pneumonia, bronchospasm, airway obstruction, pulmonary fibrosis, malnutrition, dehydration, and death (Leelamanit 2002, Blumenfeld 2006, Shaw 2007, Bulow 2008, Humbert 2012, Tan 2013). Functional dysphagia therapy aims at reducing the risk of aspiration and improving the physiology of the impaired swallowing mechanism to restore function. The traditional therapy incorporates diet modification, position adjustment, speech therapy, and exercise to alter the muscle structure and function. Percutaneous endoscopic gastronomy tubes are often used in the management of dysphagia. Thermal tactile stimulation by the application of cold to the anterior faucal arch is also being used with some success. Existing treatments for dysphagia are usually unable to restore the complete swallow function among patients with the most severe disorders (Freed, 2001, Miller 2013, Tan 2013). Transcutaneous electrical stimulation (ES) that involves the application of electric current across the skin to stimulate nerve or muscle tissue during a functional task is commonly used in physical and rehabilitation therapy. It is used to strengthen muscles after surgery, prevent disuse atrophy of denervated muscles, decrease spasticity, and accelerate wound healing. There are several variants of electrical stimulation therapy. Transcutaneous electrical nerve stimulation (TENS) is mainly used in an attempt to alleviate neuropathic or chronic musculoskeletal pains. This can be used on atrophied or denervated muscles but does not cause muscle contraction. Functional electrical stimulation (FES) is the application of electrical current to excitable tissue to supplement or replace function that is lost in neurologically impaired individuals e.g. after spinal cord injury.

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Neuromuscular electrical stimulation (NMES) therapy is used on innervated muscles to recruit motor units and increase muscle strength. It selectively targets healthy innervated muscle fibers but does not always stimulate atrophied or denervated muscle. NMES may be considered as a FES in situations when a muscle contraction is facilitated during a functional task (Peckham 2005, Carnaby-Mann 2007, Tan 2013). Over the last 2-3 decades, NMES therapy has been proposed as a treatment option for pharyngeal dysphagia to initiate or re-establish the act of swallowing. The therapy involves the application of electric stimulation through a pair of surface electrodes located on the neck. These are usually placed in one of two configurations: one electrode above the lesser horn of the hyoid bone and the other roughly 4 cm below it, or both electrodes above the lesser hyoid bones bilaterally. Electric pulses are then delivered continuously at 80Hz for duration of 300 µs and intensity ranging from 2.5 to 25 mA depending on the patient's tolerance. The therapy is usually given for 60-minutes session every day, 5 days a week until swallowing has been restored or until the patient cannot tolerate it (Steele 2007). NMES has received great interest and raised much controversy since it was introduced. Over 9,000 speech pathologists in the US have been trained to use the technology. However, the underlying neurophysiologic basis for using the procedure that involves surface electrode placement on the external lateral neck is poorly defined. Challenge in designing a neuromuscular stimulation device for swallowing include selecting which muscles to target in the swallowing sequence, designing a device that triggers a chain of successive muscle excitations and inhibitions similar to normal swallowing process. Some scientists have argued that the current intensity delivered by NMES at the submental region is greatest at the skin surface and diminishes with depth through the platysma underlying the skin and subcutaneous fat. The deeper muscles which would pull the hyoid bone up and toward the mandible, and those that elevate the larynx to the hyoid bone, are much less likely to be activated by surface stimulation (Ludlow 2007, Steele 2007). Potential risks of NMES include arrhythmia, hypotension, laryngospasm, burns, glottic closure, and interference with pacemakers. The therapy is contraindicated in patients with pacemakers, superficial metal implants or orthotics, skin breakdown, cancer, history or cardiac disorders, seizures, impaired peripheral conduction system, pregnancy, significant reflux due to use of a feeding tube, or dysphagia due to drug toxicity (Leelamanit 2002, Blumenfeld 2006, Huckabee 2007).
Two NMES devices, the Freed Bioelectric Dysphagia Treatment Device and the Chattanooga VitalStimTM system, were cleared by the FDA for marketing in June 2001 and December 2002 respectively. Both are equivalent external electrical stimulation devices intended for re-education of the throat muscles, necessary for pharyngeal contraction, for the treatment of dysphagia from any etiology other than mechanical causes requiring surgery. The therapy treatment sessions last for 60 minutes and are most commonly administered by a speech and language pathologist. The FDA approval came with a warning that: 1.The long-term effects of chronic electric stimulation are unknown, 2. Stimulation should not be applied over the carotid sinus nerves, 3. Improper placement of the electrodes or improper use of recommended frequency, intensity or pulse, may cause laryngeal or pharyngeal spasm which may close the airway or cause difficulty in breathing.

04/14/2004: MTAC REVIEW
Electrical Stimulation for the Treatment of Dysphagia
Evidence Conclusion: The study reviewed provides insufficient evidence on the use of electrical stimulation in patients with dysphagia. It had potential selection and observation bias. The investigators compared electrical stimulation to tactile stimulation in a controlled study where patients were not randomized, but alternately assigned to electric stimulation using the Freed Bioelectric Dysphagia Treatment Device, or thermal tactile stimulation. Overall, the results of the study show that both treatment groups improved, but the final swallow scores were higher among the electrical stimulation group. The study has potential selection and observation biases and does not provide sufficient data on the long-term effectiveness of the treatment.
Articles: The search yielded 11 articles on electrical stimulation for the treatment of dysphagia. There was a longitudinal study with a control group, on electrical stimulation for swallowing disorders caused by stroke (Freed et al 2001), and another on effects of electrostimulation on salivary function of Sjogren's syndrome patients (Talal 1992). In the latter study, treatment aimed at increasing the production of saliva by an electrostimulation device placed on the tongue, which is different from the transcutaneous electric stimulating of the pharyngeal muscles. The search also revealed one case series with 23 patients, four small case reports, and four review articles. A larger study with 892 patients was submitted to the FDA but has not been published in a peer reviewed medical journal to date. *An evidence table was created for the following study:* Freed ML, Freed L, Chatburn RL et al. Electrical stimulation for swallowing disorders caused by stroke. Respir Care 2001;46:466-474. See Evidence Table

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/04/08: MTAC REVIEW
Electrical Stimulation for the Treatment of Dysphagia

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Evidence Conclusion: VitalStim was reviewed earlier by MTAC in April 2004. The best evidence at the time was the Freed et al (2001) nonrandomized controlled trial that compared electrical stimulation to tactile stimulation for the treatment of 110 patients with swallowing disorders caused by stroke. The study had its limitations and biases and did not provide sufficient evidence on the safety and effectiveness of neuromuscular electrical stimulation in treating dysphagia.
Articles: There is still a lack of published literature on the use of NMES for swallowing. The best published evidence to date is a very small (N=25) recent RCT with several limitations and a meta-analysis that included one small controlled trial (Freed, et al 2001), a retrospective study with a control group, and small case series. The results of the published controlled studies and case series are conflicting. Several case series with non-blinded subjective measures reported some improvement in swallowing. This positive effect was however not observed when more objective outcomes were used and blindly measured. The only published randomized controlled trial showed no significant differences between NMES and traditional swallowing therapy in treating patients with swallowing difficulties due to stroke. The trial was too small, unblinded, had insufficient statistical power, and no long-term follow-up. These limitations together with other methodological flaws do not allow making conclusions on the efficacy and safety of the therapy. In conclusion, there is insufficient published evidence to determine: 1. Whether patients treated with VitalStim will show more improvement in the oral and pharyngeal phases of swallowing compared to the traditional therapies used in the management of dysphagia. 2. If patients treated with VitalStim would have fewer dietary consistency restrictions compared to those receiving traditional means for dysphagia management, or 3. If patients treated with VitalStim would progress more rapidly from nonoral to oral nutrition compared to those receiving traditional means for dysphagia management.
The search yielded just over 30 articles on electrical stimulation for the treatment of dysphagia. Many were reviews and opinion pieces. There was one meta-analysis of non-randomized controlled studies and case series studies, a more recent small randomized controlled trial, and a number of case series on the effect of NMES therapy on improving swallowing. The literature search did not reveal any study on the effect of therapy on dietary restrictions, or progress from nonoral to oral nutrition. The meta-analysis and the RCT were selected for critical appraisal. Carnaby-Mann GD, Crary MA. Examining the evidence on neuromuscular electric stimulation for swallowing. A meta-analysis. Arch Otolaryngol Head Neck Surg.2007;133:564-571. See Evidence Table Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. Dysphagia April 2008. See Evidence Table Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. Dysphagia April 2008. See Evidence Table

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/16/2014: MTAC REVIEW
Electrical Stimulation for the Treatment of Dysphagia
Evidence Conclusion: NMES was reviewed earlier by MTAC in 2004 and 2008 and did not pass the evaluation criteria due to the lack of evidence on its safety and efficacy in the management of dysphagia. The best published evidence at the time was the Freed et al (2001) nonrandomized controlled trial that compared electrical stimulation to tactile stimulation for the treatment of 110 patients with swallowing disorders caused by stroke, a very small RCT with 25 patients (Bulow 2008) and a meta-analysis of small nonrandomized studies comprising 225 patients. More recently a number of randomized or quasi randomized RCTs were conducted to assess the efficacy of NMES in patients with dysphagia due to variable etiologies. The studies were small in size, had short follow-up durations, and varied widely in the patient selection, electrode positioning, stimulation protocols, combination with other therapies, and outcome measures. The results of the published trials as well as a meta-analysis of 7 trials are conflicting (evidence tables 1&2). Baijens, et al (2013) found no additional clinical benefit when submental NMES used in addition to the traditional dysphagia therapy in patients with dysphagia secondary to Parkinson's disease. Kushner, et al (2013) reported significantly better outcomes with NMES combined with traditional therapy vs. traditional therapy alone for patients with dysphagia following stroke. On the other hand Tan and colleagues' 2013 meta-analysis of RCTs suggest that NMES may be more effective than traditional therapy in patients with dysphagia due to different etiologies, except for post-stroke dysphagia. The conflicting results of the published studies, different stimulation protocols used, various underlying pathological conditions, and short follow-up durations, makes it hard to determine whether NMES provides additional therapeutic benefit for patients with dysphagia.
Articles: The literature search for studies on NMES published after the last 2008 MTAC review, revealed over 50 articles. There were two meta-analyses, 6 small randomized controlled trials, and a number of observational small studies related to the current review. One of the two meta-analyses (Geeganage et al, 2012) assessed feeding and swallowing treatment strategies including NMES in stroke patients and the other (Tan et al, 2013) evaluated NMES in patients with dysphagia caused by non-stroke conditions. The published RCTs identified by the search examined the effect of NMES on treating dysphagia due to stroke, Parkinson's disease, or cancer. The following
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meta-analysis and the RCTs were selected for critical appraisal. Baijens LW, Speyer R, Passos VL, et al. Surface electrical stimulation in dysphagic Parkinson patients: a randomized clinical trial. Laryngoscope. 2013;123:E38-44. See Evidence Table Heijnen BJ, Speyer R, Baijens LW, et al. Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: effects on quality of life. Dysphagia. 2012; 27:336-345. See Evidence Table Lim KB1, Lee HJ, Lim SS, et al. Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomized controlled trial. J Rehabil Med. 2009;41:174-178. See Evidence Table Long YB, Wu XP. A randomized controlled trail of combination therapy of neuromuscular electrical stimulation and balloon dilatation in the treatment of radiation-induced dysphagia in nasopharyngeal carcinoma patients. Disabil Rehabil. 2013;35:450-454 See Evidence Table Permsirivanich W, Tipchatyotin S, Wongchai M, et al. Comparing the effects of rehabilitation swallowing therapy vs. neuromuscular electrical stimulation therapy among stroke patients with persistent pharyngeal dysphagia: a randomized controlled study. J Med Assoc Thai. 2009;92:259-265. See Evidence Table Ryu JS, Kang JY, Park JY, et al. The effect of electrical stimulation therapy on dysphagia following treatment for head and neck cancer. Oral Oncol. 2009;45:665-668. See Evidence Table Tan C, Liu Y, Li W, et al. Transcutaneous neuromuscular electrical stimulation can improve swallowing function in patients with dysphagia caused by non-stroke diseases: a meta-analysis. J Oral Rehabil. 2013; 40:472-480. See Evidence Table Xia W1, Zheng C, Lei Q, Tang Z, et al. Treatment of post-stroke dysphagia by VitalStim therapy coupled with conventional swallowing training. J Huazhong Univ Sci Technolog Med Sci. 2011;31:73-76. See Evidence Table.

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)

BACKGROUND

Gastroparesis (GP) is a gastric motility disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. The most common etiologies of GP are diabetes mellitus, post-surgical often as the result of damage to the vagal nerve, and idiopathic. Other causes include Parkinson's disease, collagen vascular disorder, and any disease process that interferes with the neuromuscular function of the stomach. The characteristic symptoms of gastroparesis include early satiety, nausea, vomiting, bloating, and abdominal pain. These symptoms are typically driven by meal intake but can also be present continually at varying degrees of intensity. A severe gastroparesis can result in impaired quality of life, recurrent hospitalizations, malnutrition, and even death (Velanovich 2008, McCollum 2011). The standard medical management of gastroparesis involves dietary modification, glycemic control, and the use of antiemetic therapy combined with prokinetic agents such as metoclopramide and erythromycin. These therapies are generally effective for the symptomatic relief in the majority of patients with GP. However, some patients do not respond to, or cannot tolerate drug treatment, and may require palliative endoscopic or surgical therapies. Surgical options include feeding jejunostomy tubes, decompressing gastrotomy tubes, pyloroplasty, and gastrectomy as a last resort (McKenna 2008, Velanovich 2008, McCallum 2010). In the last decade, high frequency gastric electrical stimulation (GES) emerged as a potential treatment option for patients with medically refractory gastroparesis. The therapy involves delivering low-energy electrical stimuli in the muscularis propria of the stomach at a frequency significantly higher than the normal gastric slow wave frequency. This is different from gastric pacing that delivers high energy stimuli at a frequency slightly above the intrinsic slow wave activity. The Enterra® Therapy System (Medtronic, Minneapolis, MN), a stimulation device delivering high-frequency GES, was granted Humanitarian Device Exemption by the US Food and Drug Administration in 2000 for patient with chronic drug refractory nausea and vomiting secondary to gastroparesis of diabetes mellitus or idiopathic in origin (O'Grady 2009, Chu 2012). The Enterra® system consists of three main elements: a pair of leads, a pulse generator, and a programming system. The leads and pulse generator are implanted surgically via laparotomy or laparoscopically. The two leads are surgically implanted about 1 cm apart in the muscle wall of the greater curvature of the stomach, approximately 10 cm from the pylorus. They are anchored in place then connected to a pulse generator placed in a subcutaneous pocket created in the abdominal wall generally in the superior quadrant of the abdomen. The pulse generator is controlled by an external programmer that allows for interrogation and programming of stimulation via a radio-telemetry link. The battery life of the pulse generator is 5-10 years depending on the neurostimulator setting. It is sealed in the generator and thus the device must be replaced when the battery is depleted. The leads can be left in place and reused with the new pulse generator. The Enterra system produces intermittent bursts of high-frequency (~14 cycles per second) short duration pulses (~ 330 μs) that are three to four times faster than the native gastric slow wave frequency (Chu 2012, Guerci 2012, Soffer 2012). GES therapy is not without complications; researchers reported that 7-10% of the patients treated with the Enterra® system experience an adverse event mainly infection of the subcutaneous pocket. Other events include erosion of the abdominal wall by the device, leads dislodgment or penetration through the gastric wall, or tangling of wires in the generator pocket and formation of adhesions (Soffer 2012). This technology was approved by the FDA as a humanitarian device

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based on data from one study consisting of 33 patients that was not published in the peer-reviewed literature at the time.

02/14/2001: MTAC REVIEW
Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)
Articles: There are currently no peer-reviewed articles on this technology. Therefore, it is not possible for the MTAC committee to review the Gastric Electrical Stimulation Enterra™ Therapy System at this time.
No published evidence found.

The use of Gastric Electrical Stimulation Enterra Therapy System in the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* as there was no published evidence to review.

02/11/2013: MTAC REVIEW
Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)
Evidence Conclusion: There is insufficient published evidence to determine that gastric electrical stimulation (GES) may improve refractory nausea and vomiting symptoms in patients with gastroparesis secondary to diabetes mellitus. There is also insufficient evidence to determine that GES improves gastric emptying, or that it is superior to other therapies for the treatment of GP. The three published RCTs on GES had their limitations, had negative results, and could not rule out the placebo effect of the therapy. There was no, or very short washout periods between the ON/OFF modes of the experimental phases of the trials, no comparisons were made between GES and other therapies, medical therapy was tried for only one month in some cases, and the prokinetic/antiemetic agents and other therapies were not discontinued during the study periods. The Worldwide Anti-Vomiting and Electrical Stimulation Study (WAVESS) conducted by Abell and colleagues, 2003 (Evidence table 1) was the first published RCT that evaluated the efficacy of the implanted GES system for highly symptomatic patients with drug refractory nausea and vomiting secondary to gastroparesis of diabetes or idiopathic etiology. This trial together with two other observational studies were the basis for the US Food and Drug Administration Humanitarian Device Exemption approval of Enterra® Therapy System for patient with chronic drug refractory nausea and vomiting secondary to gastroparesis of diabetes mellitus or idiopathic origin. The study was a very small RCT with limitations. It was powered to enroll 80 subjects but could only recruit 33, and was changed from a RCT to an observational study after 2 months of randomization. After implantation of the device, patients were randomized to an ON or OFF stimulation of the device for one month, after which, they were crossed-over to the alternative ON/OFF mode without a washout period. All patients were kept on the prokinetic, antiemetic and other therapies they were using for the duration of the randomized and observational phases of the study. Overall, the results of the trial showed a significant decrease in the weekly vomiting frequency for all the patients combined, but not for the diabetic or idiopathic subgroups. It is to be noted that the published outcome data are different from the data presented to the FDA where no significant differences were found in the mean or median vomiting episodes between the ON and OFF modes. The total Symptom Scores (TSS) did not improve significantly during the RCT phase but showed significant improvement in the open-label phase. Side effects included infection, pacer migration, and stomach wall perforation. Another crossover RCT conducted by McCallum and colleagues, 2010 (evidence table 2) also had its methodological limitations and did not allow examining the placebo effect of GES. All study participants underwent GES for 1.5 months before randomization. There was no washout period after the initial GES or between the ON and OFF modes in the experimental randomized phases. The results of the study showed no significant difference in the (weekly vomiting frequency) WVF or other symptoms between the ON versus OFF periods but showed a significant improvement in WVF in the first 6-week unblinded period after implantation vs. baseline, which could have been carried over to the randomized phase, especially with a lack of washout period. There was a high rate of adverse events, many of which were serious, and three patients requires surgical intervention for infection requiring removal of the device, lead dislodgement, or device migration. At one year after the implant, when all patients had the device switched on, the WFV remained lower than baseline. One meta-analysis (Grady, 2009) combined the results of the first RCT (Abell 2003) together with 12 case series with no control groups, and a second meta-analysis (Chu 2012) pooled the results of two RCTs (Abell 2003, and McCallum 2010) together with 8 case series with no controls. The pooled results showed significant improvement in gastroparesis symptoms. The authors of the two meta-analyses indicated that the results of the analyses should be interpreted with caution due to the limitations and design of the studies included. The three most important complications reported were infection in the subcutaneous pocket affecting, electrodes detachment or displacement, and pulse generator migration, all of which require surgical intervention. Due to the unpredictable response of patients to GES, Abell and colleagues, 2011 (evidence table 3) investigated the effects of temporary electrical gastric stimulation therapy on gastroparesis symptoms to assess the response after a few days of therapy as a predictor of response to long-term therapy with GES. The trial included 55 patients among whom only 13 had diabetes mellitus as the cause of

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GP. The study was a crossover RCT with only one day washout period between the two sessions in which the device was alternately turned ON and OFF. In the first 3 days after implantation of the electrodes (session 1) both groups experienced a significant improvement in vomiting, nausea, and all symptom scores, irrespective of stimulation, which may indicate a placebo effect. In conclusion, larger studies with a parallel group design, sufficient power, and long-term follow-up are needed to more accurately determine the efficacy and safety of gastric stimulation therapy for gastroparesis of diabetes mellitus or idiopathic etiology.
Articles: The literature search revealed over 100 articles on gastric electrical stimulation in patients with gastroparesis. The majority were review articles, articles on technical aspects of the therapy, or observational studies and case series with no comparison groups. The search identified three randomized controlled trials and two meta-analyses that pooled the results of case series together with the randomized controlled trial. The three RCTs were selected for critical appraisal. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterol. 2003; 125:421-428. See Evidence Table McCallum RW, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol. 2010; 8:947-954. See Evidence Table Abell TL, Johnson WD, Kedar A, et al. A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis: Gastrointest Endosc. 2011; 74:496-503. See Evidence Table

The use of Gastric Electric Stimulation for the Treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

NESS Stimulators for Foot Drop and Paralyzed Hands

BACKGROUND

Foot drop is a motor deficiency caused by partial or total paralysis of the muscles innervated by the peroneal nerve. It is not a disease but a symptom of an underlying problem. It is often caused by an injury to the peroneal nerve but can also be associated with a variety of conditions such as stroke, dorsiflexor injuries, neuropathies, drug toxicities, or diabetes. The problem may be temporary or permanent depending on the cause. Foot drop is characterized by the lack of voluntary control of ankle dorsiflexion, and subtalar eversion. Patients with foot drop are unable to walk on their heel, flex their ankle, or walk with the normal heel-toe pattern. They usually exhibit an exaggerated or high-steeping walk called steppage gait or foot drop gait in order to compensate for toe drop. This unnatural walking motion may result in subsequent damage to the hip, back or knee (Voigt 2000). Management of patients with foot drop varies and is dependent on the underlying cause. Some patients may be fitted with of ankle-foot orthoses (AFO) brace, which typically limit ankle plantarflexion to enhance foot clearance during swing. Patients may also undergo physical therapy for gait training. Surgery may be an option when the cause of foot drop is muscular or neurologic. Electrical stimulation was first proposed as a treatment for foot drop by Liberson in 1961. Liberson referred to the treatment as “functional electrotherapy” because its purpose was to replace a functional movement that was lost after injury or illness. There has been extensive development of functional stimulation devices since the early 1960s. The first devices were hard-wired surface stimulators, followed by hard-wired implanted electrical stimulators, and then microprocessor-based surface and implanted systems. In the 1990s, artificial and “natural” sensors were developed as a replacement for the foot-switch. More recently, testing has been done on a device in which both the sensor and stimulator are implanted (Lyons et al. 2002). The WalkAide system is an external neuromuscular functional stimulator. It contains a control unit attached to a flexible cuff that contains two electrodes. The unit is placed on the leg below the knee, near the head of the fibula. According to FDA materials, WalkAide stimulates the common peroneal nerve which innervates the muscles that cause dorsiflexion of the ankle. This stimulation is intended to produce a more natural and stable walking stride. It is indicated for individuals with foot drop due to central nervous system conditions including cerebral palsy, multiple sclerosis, traumatic brain injury, and cerebrovascular accident. It is contraindicated for patients with traumatic accidents to the leg, complications of back, hip or knee surgery, sciatica, peripheral neuropathy, spinal stenosis, post-polio syndrome and Guillain-Barre syndrome. In addition, patients with pacemakers or who experience seizures should not use WalkAide (FDA materials; Innovative Neurotronics website). The Innovative Neurotronics WalkAide System for foot drop was approved by the FDA in August 2005 to address the lack of ankle dorsiflexion in patients who have experienced damage to upper motor neurons or pathways to the spinal cord. The NESS L300 is another electrical stimulation system that received FDA clearance (in 2006) to provide ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease. It has the same intended use and same principal of operation as the WalkAide. The main technological difference however between the two systems, is the RF wireless communications between the components of NESS L300 versus the wired communication in the WalkAide system. NESS L300 is a neuroprothesis device that consists of four main parts 1. A lower leg orthosis containing electrodes and a controlled stimulation unit, 2. A heel sensor 3. A control unit that is carried in the pocket, mounted on the waist, or on a neck strap, and 4. PDA to be used by the clinician to configurate the control unit with functional parameters as appropriate for every patient. The system is intended to provide ankle dorsiflexion in individuals with foot drop following an upper motor neuron injury or disease. During

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the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot. According to the manufacturer it may also facilitate muscle reduction, prevent/retard disuse atrophy, maintain or increase joint range of motion and increase local blood flow (FDA materials; Ness 300 website). NESS H200 or Bioness is another new muscle stimulation device developed Bioness Inc. to restore function to paralyzed muscles. It is a brace like apparatus, equipped with electrodes to stimulate and activate muscles that have been affected by stroke, injury, multiple sclerosis or cerebral palsy. The H 200is worn on the forearm and hand and holds the hand in a functional position. According to the manufacturer, the functional electrical stimulation is used to move affected areas through repetitive exercises which would strengthen the muscles, reduce spasticity, improve blood flow, and increase range of movement. A microprocessor allows the therapist to program the device with a sequence of exercises customized to each patient. The system may be also used in the home setting (Bioness Inc. web page). Stroke is one of the leading causes of disability and impairment in the United States. It is reported that only 12-18% stroke survivors will regain complete functional recovery of the upper extremity, and that about 30% to 66% of those with paretic arms will still have an impaired upper limb function after six months with routine rehabilitation. Arm dysfunction impairs the daily activities of the individual as writing, dressing, bathing, self-care, and in turn reduces the functional independence, occupational performance, and quality of life (de Kroon 2002, Meilink 2008, and Kwakkel 2008). Loss of upper extremity function following stroke is a major rehabilitation challenge. Occupational and physical therapies which are commonly used in the rehabilitation of stroke patients have not always been satisfactory in improving the reaching, grasping, holding, or releasing functions of the paralyzed limb. Investigators are now focusing on therapies that will lead to regaining and improving upper extremity functional activity rather than only minimizing the impairment (Alon 2008). Electrical stimulation (ES) has been studied and used clinically for about 40 years in different neurological conditions such as cerebrovascular accidents, multiple sclerosis, cerebral palsy, and other events. Its use for the upper limb is getting increased attention as a therapeutic modality in poststroke rehabilitation. It provides continuous low voltage stimuli which enable repetitive exercise to the neuromuscular system. ES has two modalities: 1. Therapeutic electrical stimulation (TES) which applies higher frequency (36 Hz) with the aim of activating the reduced muscle strength and preventing or lowering the pain and spasticity of the muscles, and 2. Functional electrical stimulation (FES) which applies lower frequency ES (18 HZ) in order to improve activity during the stimuli. TES includes neuromuscular electrical stimulation (NMES), EMG-triggered electrical stimulation, positional feedback stimulation training (PFST), and transcutaneous electrical nerve stimulation (TENS). These have different indications, mechanisms of action, and are applied by multiple devices with a range of possibilities for the adjustment of stimulation parameter (Berner 2004, Kroon 2002). FES on the other hand, is the application of neuromuscular electrical stimulation concurrently with the training of task specific or functional activity i.e. provoking muscle contraction in order to assist the performance of functional activities during stimulation. In the last decades, several research groups have been working on the development of FES systems for the upper extremity, and currently multiple devices aiming at restoring the upper limb function are commercially available (Snoek 2000, Alon 2008). The NESS H200, formerly known as “The Handmaster”, (NESS Ltd Ra’anana, Israel) is a portable, non-invasive, hybrid wrist/hand orthosis and electrical stimulation device that is designed to be used in hemiplegic as well as C5 tetraplegic patients. It provides an instrument for both the treatment at the level of impairment (neuromuscular and articular properties) and disability (functional handgrip with stabilized wrist). The system contains an external control unit connected by a cable to a below the elbow splint. The splint contains a body with front spiral end and a wing which pivots about the body and can be opened by lifting a release handle. Five surface electrodes are attached to the splint and correspond with the motor points in finger and thumb muscles. The control unit allows the user to select from among three exercise modes and three functional modes. The exercise modes provide stimulation to the targeted finger and thumb extensor and flexor muscles. The functional mode provides sequential key grip or palmer grasp and release patterns. The spiral design of the system allows wrist stabilization in a functional position of 10 -20o of extension. The system is also designed to permit reproducible accurate electrode positioning by the patient. Once fitted into the orthosis, the electrodes remain in position for all subsequent applications and allow consistent replication of the grasp, hold and release hand functions. The patient is provided with a progressive home exercise program and is required to follow a conditioning paradigm using the system’s exercise modes. Training periods start at 10 minutes twice daily and gradually increase to 45 minutes 2 times a day (Hara 2008, Snoek 2000). The NESS system and the Handmaster device received FDA clearance in September 2002, and August 2003 respectively, to be used to maintain or increase the range of motion, reduce muscle spasm, prevent retardation of disuse atrophy, muscle reduction, increase local blood circulation, and provide hand active range of motion and function in patients suffering from upper limb paralysis due to C5 spinal cord injury, or hemiplegia due to stroke.

12/03/2007: MTAC REVIEW

NESS Stimulators for Foot Drop and Paralyzed Hands

Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the Ness L300 system for patients with foot drop. There is insufficient published evidence to determine the efficacy and safety of the Ness H200 system for the restoration of hand movements.

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Articles: The search did not reveal any published studies, on Bioness, NESS L300, or NESS H200. Information about the devices was obtained from the FDA and/or the manufacturer's Web sites.

The use of the NESS L300 or NESS H200 in the treatment of foot drop or paralyzed hands does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/06/2008: MTAC REVIEW
NESS Stimulators for Foot Drop and Paralyzed Hands
Evidence Conclusion: The two published RCTs (Alon 2007, and Alon 2008) were conducted by the same group of investigators in the same center, using the same eligibility criteria, procedures, and outcome measures. One of the studies (Alon 2007) included patients with mild/moderate paresis (Fugl- Meyer score 11-40), and the other (Alon 2008) included patients with severe motor loss of the upper extremity (Fugl-Meyer score 2-10). The two trials compared the standard physical and occupational therapies plus FES using NESS H200 versus the standard physical and occupational therapies alone. The trials were small, unblinded, and had no extended follow-up after the end therapy. Their overall results showed some improvement in movement and function in the patients randomized to the NESS H200. The observed differences vs. standard therapy were statistically significant in patients with mild/moderate paresis but not in those with severe motor loss (Alon 2008). The lack of statistical power in the latter study, as well as open-label design, short duration, and absence of follow-up do not allow making any definitive conclusion regarding the effectiveness of the therapy or the persistence of the improvements observed in patients with severe motor impairment. Ring and colleagues' trial (2005) were a comparative study with blinded assessment of outcomes, but had the disadvantage of inappropriate randomization, small number of patients, and absence of follow-up after the six weeks of therapy. The authors categorized the participants into those with or without active voluntary motion of the fingers and wrist at baseline. Patients were assigned to receive rehabilitation with or without NESS Handmaster. The overall results of the trial showed significant improvement in spasticity, motion, and function in all participants receiving the NESS Handmaster device vs. those who did not receive the device. The observed differences were statistically significant for all variables studies for patients who had active partial range of movement at baseline. For those with no active voluntary motion in the fingers and wrist at baseline, decrease in finger spasticity was the only statistically significant improvement observed.
Conclusion: There is poor evidence to determine that the use of NESS H200 may improve upper extremity function in patients with mild or moderate paresis/paralysis with similar eligibility criteria as those in the trials, compared to standard physical and occupational therapies. There is insufficient evidence to determine whether the benefits observed would persist after therapy is ended. There is insufficient published evidence to determine that the use of NESS H200 would improve function in patients with severe motor loss in the upper extremity. There is insufficient published evidence to determine if the use of NESS H 200 would lead to a faster motor and functional recovery vs. standard therapy alone. There is fair evidence that NESS H200 is safe to use among patients with upper limb impairment due to stroke, and who has eligibility criteria similar to those of the published studies.
The search revealed a large number of published articles on the use of FES in general, but very limited publications on use the use NESS H200 (NESS Handmaster) for patients with cervical spinal cord injury or stroke. The majority of studies on NESS H200 were case reports or case series with less than 30 patients. There were two small (N=15, and N= 26) randomized controlled trials and one quasi-randomized study, that compared the outcomes of FES using NESS H200 or NESS Handmaster devices in addition to the standard rehabilitation vs. standard rehabilitation alone in stroke survivors with impaired upper extremity. All three were critically appraised.
Articles: Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation (FES) may modify the poor prognosis of stroke survivors with severe motor loss of the upper extremity. Am J Rehabil Med 2008;87:627-636 See Evidence Table Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: A pilot study. Neurorehabil Neural Repair 2007;21:207-215 See Evidence Table Ring H, and Nechama Rosenthal. Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. J Rehabil Med 2005;37:32-36 See Evidence Table

The use of the NESS H200 in the treatment of paralyzed hands does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System
BACKGROUND
The Vertis percutaneous neuromodulation therapy (PNT) system, manufactured by Vertis Neuroscience, is a minimally invasive, nonsurgical therapy. It is based on the premise that chronic back pain is caused by increased sensitization of the nerve cells that transmit pain signals. The Vertis PNT system delivers electrical stimulation to the deep tissues near the spine to alter the "hypersensitivity" of nerve pathways that cause persistent pain. Treatment consists of a series of outpatient treatment sessions performed in a clinic setting. It is intended for use

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by a physician or other clinician (e.g. physical therapist), not for patient use. The device includes three major components: Control unit - A software driven, five-channel, AC powered nerve stimulator which generates the electrical stimulus, Sterile, needle electrodes, A cable that connects the needles to the control unit. The FDA approved Verdis PNT in September 2001 for the following indications: Symptomatic relief and management of chronic or intractable low back pain and/or as an adjunctive treatment in the management of post-surgical low back pain and post-traumatic low back pain.

10/09/2002: MTAC REVIEW
Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System
Evidence Conclusion: There is insufficient evidence to determine the effect of percutaneous neuromodulation therapy on back pain.
Articles: There were no published articles evaluating the effect of PNT on back pain. Two articles that were submitted for publication were identified on the manufacturer's website. The manufacturer indicated that the articles are not yet published.

The use of percutaneous neuromodulation therapy in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
BACKGROUND
There are three main types of arthritis that can affect the knee joint: osteoarthritis, rheumatoid arthritis and post-traumatic arthritis. Osteoarthritis, the most common type, is generally a slowly progressing degenerative disease that involves the gradual wearing away of the joint cartilage. Symptoms include pain and swelling. Pain often increases after activities such as walking and stair climbing and is the principal symptom for which patients with osteoarthritis seek medical attention. The main goal of treatment is pain control, although maintaining and/or improving joint function are also goals. A stepwise approach to management of osteoarthritis of the knee is generally recommended. Initial conservative measures include weight reduction, exercise, and the use of supportive devices. Medications, including anti-inflammatories and corticosteroids, can be used to supplement the conservative approaches. For patients who fail medical management, surgical treatments are available. Pulsed electrical stimulation is a potential non-invasive alternative to surgery for patients who do not respond to medical treatment. The BioniCare Stimulator has been approved by the FDA as an adjunctive treatment for osteoarthritis of the knee. It is a portable battery-operated device that delivers a low frequency (100 Hz) electrical signal to the knee via skin electrodes. Other types of electrical stimulation including electro-acupuncture, transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES) with the Respond Select device have also been used to treat osteoarthritic knee pain.

08/01/2005: MTAC REVIEW
Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
Evidence Conclusion: There was one randomized controlled trial on BioniCare for treating osteoarthritis (Zizic et al. 1995). The authors reported that the active treatment group had significantly better outcomes than the placebo group two weeks after completing a 4-week treatment period. However, the statistical analysis may have been biased. The authors used a one-sided p-value at $p<0.05$. If they had used the commonly accepted method of dividing the p-value in half for a one-sided p-value (in this case $p<0.025$), two of the three primary efficacy variables would not have been significant. Another limitation of the study is that, although the authors reported statistically significant differences, the clinical significance is unclear. There was approximately a 10% difference in the change from baseline in patient perception of pain and patient perception of function (approximately 30% change in the treatment group and 20% change in the placebo group for each outcome variable).
Articles: The single RCT was published in 1995 and has not been replicated. In addition, no studies were identified that compared BioniCare to other treatments such as medication or TENS. Patients in the Zizic study were not required to have failed other treatments. One empirical study on the BioniCare system was identified (Zizic, 1995). This was a placebo-controlled randomized controlled trial and was critically appraised. No studies were identified that compared BioniCare to other treatments such as exercise or medication, or to different forms of electrical stimulation such as TENS. *The Zizic study was critically appraised:* Zizic TM, Hoffman KC, Holt PA et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. *J Rheumatol* 1995; 22: 1757-1761. See Evidence Table

The use of Pulsed electrical stimulation in the treatment of osteoarthritis of the knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

ReBuilder System
BACKGROUND

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Peripheral neuropathy is a disorder of the peripheral nervous system characterized by impaired function of sensory, motor and/or autonomic nerves. It results from damage to the cell body, nerve fiber, or to the surrounding myelin sheath of peripheral nerves. Manifestations include pain, numbness, tingling, extreme sensitivity to touch, lack of coordination, muscle weakness or paralysis, and bowel or bladder problems. Treatment relies on addressing the underlying cause and various treatments for pain. ReBuilder is a handheld, battery-powered nerve stimulator that delivers an electrical impulse, similar to a normal nerve signal, to specific regions of the body to alleviate pain, burning, tingling, and numbness from a variety of conditions. The ReBuilder is an FDA class II, neurologic therapeutic medical device that first received FDA 510(k) approval in 1987 for marketing as a TENS unit for pain relief. In 1989, the FDA cleared ReBuilder for other indications. The FDA approval is for the symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain relief, relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle reeducation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and maintaining or increasing range of motions. The FDA has written warning letters to manufacturer of ReBuilder against marketing the device for any off-label indications, including peripheral neuropathy.

12/19/2011: MTAC REVIEW
ReBuilder System
Evidence Conclusion: The literature studies did not identify any studies that evaluated the ReBuilder System for any indication. The search did identify a 2011 technology assessment from Kaiser Permanente. Their literature search also did not identify any studies that evaluated the safety or efficacy of the ReBuilder System (Kaiser 2011). Conclusion: There is insufficient evidence to determine the safety or efficacy of the ReBuilder System for the treatment of chronic intractable pain for any condition.
Articles: The literature studies did not identify any studies that evaluated the ReBuilder System for any indication. The search did identify a 2011 technology assessment from Kaiser Permanente. Their literature search also did not identify any studies that evaluated the safety or efficacy of the ReBuilder System (Kaiser 2011). See Evidence Table.

The use of ReBuilder System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

WalkAide System for Patients with Foot Drop
BACKGROUND
Foot drop is defined as a significant weakness in the muscles involved in flexing the ankle and toes (dorsiflexion). The specific muscles affected include the tibialis anterior, extensor hallucis longus and extensor digitorum longus. These muscles allow the toes to swing upward during the beginning of a walking stride and the planting of the heel towards the end of the stride. In patients with foot drop, the foot droops or drags along the ground during the swing phase. The condition is also called steppage gait because patients often raise their thigh excessively high to compensate for toe drop, and they appear as though they are walking up stairs. The unnatural walking motion may result in subsequent damage to the hip, back or knee. Foot drop is associated with a number of conditions such as peripheral nerve injuries, stroke, diabetes, neuropathies and drug toxicity. The causes can be divided into three categories, which may overlap: nerve damage, muscle damage, and/or a skeletal or anatomic abnormality. The conventional treatment for foot drop is the use of ankle-foot orthoses (AFO). These typically limit ankle plantar flexion to enhance foot clearance during swing. Disadvantages of AFOs are that they can be uncomfortable and limiting to wear. Surgery is sometimes beneficial when the cause of foot drop is muscular or neurologic. Electrical stimulation was first proposed as a treatment for foot drop by Liberson in 1961. Liberson referred to the treatment as “functional electrotherapy” because its purpose was to replace a functional movement that was lost after injury or illness. There has been extensive development of functional stimulation devices since the early 1960s. The first devices were hard-wired surface stimulators, followed by hard-wired implanted electrical stimulators, and then microprocessor-based surface and implanted systems. In the 1990s, artificial and “natural” sensors were developed as a replacement for the foot-switch. More recently, testing has been done on a device in which both the sensor and stimulator are implanted (Lyons et al. 2002). The WalkAide system is an external neuromuscular functional stimulator. The system contains a control unit attached to a flexible cuff that contains two electrodes. The unit is placed on the leg below the knee, near the head of the fibula. According to FDA materials, WalkAide stimulates the common peroneal nerve which innervates the muscles that cause dorsiflexion of the ankle. This stimulation is intended to produce a more natural and stable walking stride. WalkAide is indicated for individuals with foot drop due to central nervous system conditions including cerebral palsy, multiple sclerosis, traumatic brain injury and cerebrovascular accident. It is contraindicated for patients with traumatic accidents to the leg, complications of back, hip or knee surgery, sciatica, peripheral neuropathy, spinal stenosis, post-polio syndrome and Guillain-Barre syndrome. In addition, patients with pacemakers or who experience seizures should not use WalkAide (FDA materials; Innovative Neurotronics Web site). The Innovative Neurotronics WalkAide System for foot drop was approved by the FDA in August 2005 to address the lack of

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ankle dorsiflexion in patients who have experienced damage to upper motor neurons or pathways to the spinal cord.

10/02/2006: MTAC REVIEW
WalkAide System for Patients with Foot Drop
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the Innovative Neurotronics WalkAide System for patients with foot drop. A randomized controlled trial comparing WalkAide to ankle-foot orthoses is underway. The only empirical study identified was a case study, reporting on one patient. The patient used a bionic nerve (BION) implant and a portable BIONic foot drop stimulator that the authors called a "WalkAide2". It is not clear whether this is the same technology as the Innovative Neurotronics WalkAide system.
Articles: There are no published randomized or non-randomized controlled studies. According to ClinicalTrials.gov and the Innovative Neurotronics website, an RCT is underway comparing the Innovative Neurotronics WalkAide System to an ankle-foot orthosis (AFO) in patients with cerebrovascular accident. No data from this study are available at this time.

The use of the WalkAide system in the treatment of foot drop does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

TENS--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two-lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

NMES/FES--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

Gastric Neurostimulation--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open

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64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Other Electrical Stimulation--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT/HCPC Codes	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64580	Incision for implantation of neurostimulator electrode array; neuromuscular
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Peripheral Nerve Stimulator- i.e., StimRouter--

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare – Considered Not Medically Necessary **_All requests must be reviewed by the Medical Director_

CPT® Codes	Description
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)

Electrical Stimulation for the Treatment of Dysphagia
Galvanic Stimulation Device
H-wave Stimulation Device
Microcurrent Stimulation Device (MENS)
Percutaneous Neuromodulation Therapy (PNT) for Back Pain
Vertis PNT System

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ReBuilder System Threshold Electrical Stimulation--

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee--

Considered Not Medically Necessary:

HCPC Codes	Description
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
06/30/1998	02/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 01/03/2012[MDCRPC], 08/07/2012[MDCRPC], 03/05/2013[MDCRPC], 04/02/2013[MDCRPC], 01/07/2014[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/14/2016	Added NCD 160.7.1
06/02/2015	TENS: MPC approved recommendation of adopting the MCG hybrid criteria
09/28/2017	Added Gastric Neurostimulation codes
06/28/2018	Removed G0283
07/12/2018	Corrected the FES and NMES criteria
10/03/2018	Added LCD L37360 Peripheral Nerve Stimulator
06/24/2020	Added HCPC code C1823 (ESD)
09/01/2020	Removed HCPC codes A4570, C1823, E0766, E0769, G0281 and G0282. Removed CPT codes 63650, 63655, 63685, 64550, 64565, 95971, 95972, 95973, 95974, 95975, 95976, 95977, 95978 and 95979. Added HCPC code E0762. Removed Hypoglossal Nerve Stimulation indications – noted on *Sleep Apnea Treatments* criteria.

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KAISER PERMANENTE®

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Clinical Review Criteria
Electromagnetic Navigation Bronchoscopy (ENB)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Electromagnetic Navigation Bronchoscopy (ENB)*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Biopsy of peripheral lesions

When used with endobronchial ultrasound, electromagnetic navigation bronchoscopy is considered medically necessary.

Fiducial marker placement via electromagnetic navigation bronchoscopy is not considered medically necessary, as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Flexible bronchoscopy (FB) is a minimally invasive procedure that is used for the diagnosis and treatment of lung cancer. Research suggests that the sensitivity of FB is approximately 88% for diagnosing central lesions and 78% for diagnosing peripheral lesions (most commonly defined as lesions that are not visible beyond the visual segmental bronchi). However, the sensitivity of FB is dependent on lesion size. FB does not perform as well for smaller peripheral lesions. It has been estimated that for peripheral lesions less than 2 cm in diameter the sensitivity of FB is approximately 34% (Rivera 2007).

Electromagnetic navigation bronchoscopy (ENB) is a relatively new bronchoscopic tool that combines CT-generated virtual bronchoscopy and electromagnetic tracking of a steerable probe to allow physicians to perform biopsy of peripheral lesion that are not accessible through conventional bronchoscopy. It has also been suggested that mediastinal lymph nodes can be biopsied using ENB. Other uses of ENB include implantation of

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fiducial markers for radiotherapy, implantation of brachytherapy seeds or catheters, and dye marker placement for surgical resection.

Several ENB systems have received FDA approval. ENB using the superDimensions I Logic™ System (superDimensions, Inc. Minneapolis, MN) is performed in three phases – planning, registration, and navigation and biopsy (Bechara 2011, Schwartz 2010).

1. Planning: A three-dimensional image of the patient's lungs with anatomical landmarks is constructed using previously taken CT scans and proprietary software.
2. Registration: The steerable navigation catheter is inserted through the bronchoscope. The three-dimensional image with anatomical landmarks created in the planning phase is viewed and correlated with the actual image from the video bronchoscope. The position of each landmark is marked using a foot pedal.
3. Navigation and biopsy: The steerable catheter is used to navigate to the lesion. The location of the catheter's tip is displayed on the CT images. Once the catheter reaches the target, it is locked in place, and the working guide is retracted. Once the catheter is in place, any endoscopic tool can be inserted through the channel. This includes transbronchial forceps to biopsy the lesion or guide wire for the placement of fiducial markers.

Medical Technology Assessment Committee (MTAC)

Electromagnetic Navigation Bronchoscopy

08/20/2012: MTAC REVIEW

Evidence Conclusion: **Diagnostic yield** A recent RCT that included 118 subjects with evidence of peripheral lung lesions or solitary primary nodules on CT evaluated the diagnostic yield of endobronchial ultrasound (EBUS), electromagnetic navigation bronchoscopy (ENB), and combined EBUS/ENB. Results from this study suggest that combined EBUS/ENB improves diagnostic yield compared to either method alone. The pneumothorax rate was 5% in the EBUS and ENB alone groups and 8% in the combined group. There was no significant difference in pneumothorax rate between the three groups (Eberhardt 2007).

Diagnostic yield (Eberhardt 2007)		
EBUS	**ENB**	**Combined**
69%	59%	88%

A recent meta-analysis also evaluated the diagnostic yield of different guided bronchoscopy methods. Results from this meta-analysis suggest that the diagnostic yield of ENB is approximately 67%. Results from this meta-analysis should be interpreted with caution as the majority of the studies included in the meta-analysis were small case series (Wang Memoli 2012). Since the meta-analysis two additional case-series were identified. The first case-series included 112 subjects and evaluated the diagnostic yield of ENB combined with rapid on-site cytopathologic evaluation (ROSE). Overall, the diagnostic yield in this study was 84%. In lesions less than 2 cm, the diagnostic yield was 75.6% and 89.6% in lesions greater than 2 cm. There were two cases (1.8%) of pneumothorax (Lamprecht 2012). The second case-series included 101 subjects and also evaluated the diagnostic yield of ENB combined with ROSE. The diagnostic yield from this study was 85%. There were 6 cases (5.8%) of pneumothorax (Pearlstein 2012). **Fiducial marker placement** A small observational study evaluated the transcutaneous placement of fiducial markers using either CT or fluoroscopic guidance (N=15) or transbronchial placement using ENB (N=8) in patient with small, early-stage, non-small cell lung cancer. Pneumothorax occurred in 8 patients (53%) who underwent transcutaneous placement and no patients who underwent transbronchial placement. The fiducial markers did not show substantial migration during the course of treatment for either method (Kupelian 2007). Conclusion: Diagnostic yield: Results from a RCT, a meta-analysis of mainly small case-series, and two case-series suggests that the overall diagnostic yield of ENB is approximately 59 to 85%.
Safety: The pneumothorax rate in the studies ranged from 1.8 to 8%.
Fiducial marker placement: There is insufficient evidence to determine the safety and clinical utility of ENB for the placement of fiducial markers.
Articles: Several small observational studies, a randomized controlled trial (RCT), and a meta-analysis were identified that evaluated the use of ENB for diagnosing lung cancer. The meta-analysis and the RCT were selected for review. A few small observational studies were identified that evaluated fiducial marker placement using ENB. The number of patients receiving ENB for the placement ranged from 1 to 12. Due to the small sample size none of these studies were selected for review. A summary of the results from one of the more recent studies is presented below. The following articles were selected for review: Eberhardt R, Anantham D, Ernst A, Feller-Kopman D, Herth F. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized

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controlled trial. Am J Respir Crit Care Med. 2007;176:36-41. See Evidence Table. Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-Analysis of Guided Bronchoscopy for the Evaluation of the Pulmonary Nodule. Chest. 2011. See Evidence Table.

The use of ENB for diagnosis does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of ENB for fiducial marker placement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

CPT Codes	Description
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with computer-assisted, image-guided navigation (list separately in addition to code for primary procedure)

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	02/06/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/26/2020	Added “Kaiser Permanente Medical Policy” statement under Medicare section
02/06/2023	Added CPT code 31627 to criteria page

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KAISER PERMANENTE®

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Clinical Review Criteria
Superficial Radiation Therapy (Electronic Brachytherapy for Non-Melanoma Skin Cancer)

- "Xoft" Skin Treatments

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Noridian retired LCD Brachytherapy: Non-intracoronary (L34065). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Nonmelanoma skin cancer (NMSC) is the most common malignancy in the Caucasian population and its incidence continues to rise. It is estimated that more than two million Americans are affected by NMSC each year. Basal cell carcinoma (BCC) represents approximately 75% of NMSCs and squamous cell carcinoma (SCC) 25%. These cancers have a low mortality rate and are rarely life threatening but can be disfiguring when not diagnosed and treated in a timely manner. They also have a significant impact on the health care delivery system (Alam 2011, Bhatnagar 2010 & 2013).

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Treatment options for NMSC include surgery, radiation therapy, chemotherapy, and photodynamic therapy. Surgery is considered the gold standard therapy; it provides the highest cure rates and has satisfactory cosmetic results. Surgical techniques include excision, curettage with electrodessication, and Mohs micrographic surgery. The choice of procedure depends on the histologic type, size, and location of the lesion. Some patients, however, are not suitable candidates for surgery because of their age, health condition, or potential disfigurement due to the location or type of cancer. Radiation therapy has been used for selected skin cancers, typically reserved as a second-line therapy for patients with surgical contraindications or as adjuvant therapy for high-risk lesions. It may also be a good alternative to surgery for lesions located in areas where surgery may be more difficult, lead to disfigurement, or affect structural function e.g. eyelid, ear, or nose. Radiation therapy techniques used for NMSC include superficial x-rays, orthovoltage x-rays and megavoltage photons, electron beam irradiation, and high-dose rate (HDR) brachytherapy with surface applicators or surface molds. HDR brachytherapy works via a precise, radioactive seed that delivers high dose radiation within specialized catheters to a targeted area within a shielded room. It is also commonly used for breast, lung, prostate and gynecologic cancers (Bhatnagar 2010 & 2013, Frakulli 2015, Linos 2015, Safigholi 2015).

Electronic brachytherapy (EBT) is a form of HDR brachytherapy that brings an electronic brachytherapy source in close proximity to the cancerous site. EBT has the potential benefit of providing shorter and more convenient form of radiotherapy without the use of radioactive isotopes, linear accelerators, or dedicated treatment vault, and with minimal shielding requirements due to the low energy used. Currently there are three different EBT systems available for clinical application: Axxent by Xoft Inc. (Fremont, CA), the Intrabeam Photon Radiosurgery Device by Carl Zeiss Surgical (Oberkochen, Germany), and the Esteya by Elekta (Esteya EBS, Elekta AB-Nucletron, Stockholm, Sweden). The main component in these systems is a miniature X-ray tube that produces bremsstrahlung (electromagnetic) radiation using electron energies ranging from 20-70keV. Treatment of skin cancers by these systems is performed using conical applicators developed by the manufacturers and provided in different sizes (1cm, 2 cm, 3.5 cm, and 5 cm) Bhatnagar 2013, Safigholi 2015).

Medical Technology Assessment Committee (MTAC)

Electronic Brachytherapy for Non-Melanoma Skin Cancer

04/21/2014: MTAC REVIEW

Evidence Conclusion: The published study on EBT for the treatment of NMSC that was identified by the literature search was a small case series with no control or comparison group (evidence table 1). A total of 122 patients with 171 NMSC lesions (from July 2009 to April 2012) received EBT to a dose of 40 Gy in eight fractions, delivered twice weekly. Patients were assessed for acute and late toxicities, cosmesis, and local control. In 2010 Bhatnagar and Loper retrospectively reported on the short-term (median 4.1 months) results of 37 patients (44 lesions); and in 2013, Bhatnagar published the outcomes of 42 patients (46 lesions) with one or more-year follow-up data. The author reported that all lesions resolved with treatment, with no recurrences. The early side effects of the therapy were rash dermatitis (83% of the lesions) and pruritus (18%). Late adverse events included grade 1 hypopigmentation in 10% of the lesions, rash dermatitis (6.5%), as well as alopecia, and dry desquamation that occurred at lower rates (2.2%) each. One-year cosmetic evaluation was performed for 42 of the 46 lesions; 39 (92.9%) were graded as excellent, and 3/42 (7.1%) were good. Two-year outcome data for 22 lesions in 21 patients (Bhatnagar 2012) showed that cosmesis was excellent for 20 evaluable lesions, and good for 1.
Based on these results the authors concluded that EBT provides a convenient nonsurgical option for NMSC patients. The study was a case series with its limitations and potential biases. EBT was not compared any other surgical procedure or radiation therapy; it had a short follow-up duration, and the authors did not discuss how patients were selected for the procedure, and whether there were any dropouts.
Bhatnagar A, the principal investigator of the study received a research grant from the industry sponsoring the study. Conclusion: There is insufficient published evidence to determine the safety and efficacy of EBT for the treatment of NMSC. There is an ongoing clinical trial “Electronic Brachytherapy for the Treatment of NMSC” (NLM Identifier NCT01016899) with the objective of recording the recurrence in patients treated for nonmelanoma (basal cell and squamous cell carcinomas) skin cancer using the Xoft Axxent Electronic Brachytherapy System. The trial will also evaluate the cosmetic outcomes and skin toxicities related to the treatment.
Articles: The literature search for EBT for the treatment of NMSC identified only one study on the use of electronic brachytherapy for the treatment of NMSC. The initial results were reported in 2010 (Bhatnagar A, and Loper A, 2010) and 1-year results were published in 2013 (Bhatnagar A 2013). Bhatnagar A. Nonmelanoma skin cancer treated with electronic brachytherapy: results at 1 year. Brachytherapy. 2013; 12(2):134-140. See **Evidence Table.** Bhatnagar A, Loper A. The initial experience of electronic brachytherapy for the treatment of non-melanoma skin cancer. Radiat Oncol. 2010; 5:87. doi: 10.1186/1748-717X-5-87 See **Evidence Table.**

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The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/21/2016: MTAC REVIEW
Electronic Brachytherapy (EBT) for the treatment of non-melanoma skin cancer (NMSC)
Evidence Conclusion: There is insufficient published evidence to determine whether the safety and efficacy outcomes of electronic brachytherapy for NMSC are as good or superior to the outcomes of alternative treatment options. There are no published randomized or non-randomized controlled trials that compared EBT to an alternative therapy for the treatment of NMSC. The available published evidence consists of case series that used different systems for the delivery of HDR. The largest series (Bhatnagar 2010 & 2013) that used one of the three commercially available devices (the Axxent system, Xoft Inc. Sunnyvale, CA) was reviewed by MTAC earlier in 2014, and did not provide sufficient evidence on the long-term efficacy or safety of the procedure.
The more recent case series identified by the search were small retrospective series with no comparison groups, and do not provide additional evidence to support the use of EBT for NMSC. In a recently published article, Linos and colleagues (2015), expressed their concern regarding the increase in the use of EBT for skin cancer. The authors analyzed Medicare claims data and found that EBT use for skin cancer is increasing rapidly in the Medicare population. They indicated this may be attributable to marketing by the manufacturers, and that there is insufficient long-term data on the efficacy and safety of the therapy to cover the period during which recurrence and radiation sequelae would be expected (Linos, 2015).
Articles: The updated literature search for the use of electronic brachytherapy in the treatment of NMSC did not identify any controlled trial that compared the therapy with an alternative mode of treatment. The search only identified a number of small retrospective case series and a systematic review of the observational studies reporting on the outcomes of low-dose or high-dose brachytherapy used for the treatment of NMSC of the eyelid (Frakulli 2015).

The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Per NCCN Guidelines Version 1.2017 Basal Cell Skin Cancer. P. 11
"There is insufficient long-term efficacy and safety data to support the routine use of electronic surface brachytherapy."

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Superficial Radiation Therapy for Treatment of Nonmelanoma Skin Cancer. Lansdale, PA: Hayes, Inc.; 3/2018

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/06/2014	05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

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MPC Medical Policy Committee

Revision History	Description of Change
04/05/2016	Added MTAC review
04/25/2017	Added NCCN Guideline
04/17/2018	Added Hayes Guideline
08/04/2020	Removed deactivated CPT code 0182Tand CPT code 77401

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Clinical Review Criteria
Electroretinography

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Electroretinography" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this test provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Liutkevičienė et al., 2012:
During electroretinography (ERG), a total retinal response to light stimulus is recorded. ERG is comprised by a and b-waves which are generated by the outer segments of photoreceptors and Muller cells respectively. B-wave represents activities in the inner retinal layers. Several stimulations and registration techniques help record potentials of various retinal structures: early receptor potential, ERP; standard electroretinogram of full field by ISCEV (International Society for Clinical Electrophysiology of Vision); photopic negative response, PhNR; pattern (alternating contrast) ERG, pERG; multifocal ERG (mfERG).

Dettoraki et al., 2016:
Multifocal electroretinography (mfERG)
Multifocal electroretinography (mfERG) is an objective evaluation of visual function. It is noninvasive and assesses retinal diseases. During mfERG, several areas of the retina are stimulated but each response is recorded independently. mfERG measures the electrophysiological activity of the retina. Under the influence of light, retinal responses are recorded, permitting diagnosis of retinal abnormality.

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The stimulation of the retina is done by hexagonal elements alternating between black and white. Similar to full-field ERG, a corneal electrode records electrical response of the retina which consists of waveforms. The waveforms include three responses: an initial negative response (N1), a positive response (P1) and a second negative response (N2). These responses represent the function of the external layer of the retina (photoreceptors and bipolar cells). The location of the stimulus and anatomical areas correspond to the fovea, parafovea, perifovea, and periphery. mfERG can show the amplitudes of the signal.

Many factors can alter the waveforms. These include unstable electrode contact, poor fixation, continuous blinking, and errors in refraction.

mfERG detects abnormalities of the macula, peri-macular area and the mid peripheral zone of the retina which are not always seen on fundoscopy, such as chloroquine (CQ) or hydroxychloroquine (HCQ) toxicity, siderosis, anorexia nervosa, tilted disk syndrome and keratoconus. mfERG can assess drug- induced retinal toxicity. In addition, mfERG can detect central lesion in all macular diseases (age-related macular degeneration, central serous chorioretinopathy, vitelliform maculopathy, macular hole, juvenile retinoschisis and other diseases). Further, mfERG can estimate the degree of central lesion in early stages of Stargardt's maculopathy and toxic maculopathy. The combination of mfERG and visual evoked potentials (VEPs) is beneficial in the differential diagnosis of retinal and optic nerve diseases.

Another type of mfERG is wide-field (WF)-mfERG that targets peripheral areas of the retina. The testing field of WF-mfERG is 90 degree versus 45 degree for conventional mfERG. WF-mfERG is useful in detecting abnormality of retina in retinitis pigmentosa, retinal vein occlusion, birdshot chorioretinitis and vigabatrin toxicity.

Retinal toxicity
Although not frequent, drug-induced ocular toxicity must be detected early to avoid permanent vision loss. There are several medications that can cause ocular toxicity. The most frequent affecting the retina include chloroquine (CQ) and hydroxychloroquine (HCQ), vigabatrin (VGB), deferoxamine, ethambutol, interferon-α, tamoxifen, digoxin, sildenafil, canthaxanthin, amiodarone and nefazodone. Evaluation of retinal toxicity is founded on medical history and ophthalmic examination. However, other investigations including mfERG, optical coherence tomography (OCT), fundus autofluorescence (FAF), perimetry, and fundus angiography are also valuable. The sensitivity and specificity of these tests are not clear. Symptoms of CQ or HCQ retinopathy include blurred vision, photophobia, scotomas, and difficulty reading. The fundus is described as "bull's eye maculopathy".

Whatham 2013:
Full-field ERG stimulates the central and peripheral visual fields with flashlight. Pupils are dilated and response to the stimulation is assessed under dark-adapted and light-adapted conditions. The International Society for Clinical Electrophysiology of Vision (ISCEV) recommends a minimum of 20 minutes dark adaptation to produce a dark adapted (scotopic) state of sensitivity and a minimum of 10 minutes adaptation to a background luminance of 30 cd/m2 to produce a light-adapted (photopic) state of visual sensitivity. Full-filled ERG detects a range of retinal dysfunction, such as rod-cone dystrophy. Full- field ERGs are normal in focal retinal diseases including age-related macular degeneration and Stargardt's disease.

https://eyewiki.org/Electroretinogram:
The pattern ERG (PERG) uses the same stimuli, pattern-reversal stimuli, that is used in visual evoked potential (VEP). PERG records retinal ganglion cell activity and may detect optic neuropathies.
One difference between full-field ERG and mfERG is that in full-field ERG, the recording is a massed potential from the whole retina. Multifocal ERGs can map small scotomas in the central 40+ degrees of visual field (Creel, 2019). Full-field ERGs are used to record the global health of the retina, such as in retinitis pigmentosa (Creel, 2019).

Medical Technology Assessment Committee (MTAC)

Electroretinography (ERG)
7/13/2020: MTAC REVIEW

Evidence Conclusion:
HCQ-induced retinopathy: A systematic review and meta-analysis of studies with high risk of bias shows that mfERG has a high sensitivity and variable specificity. In addition, accuracy of mfERG improves with older age, increased HCQ dose, and longer duration of treatment. mfERG may detect retinal toxicity earlier than other tests.

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Metallic foreign bodies: There is insufficient evidence to assess ERG and retinal toxicity from metallic foreign bodies. The literature is comprised of case reports and case series. However, the trend from available evidence shows that ERG detected abnormalities in patients with intraocular metallic foreign bodies prior to surgery with improvement after removal of the foreign bodies.
Retinitis pigmentosa: Several studies show decreased amplitude of ERG and delayed implicit time in patients with retinitis pigmentosa. This suggests that ERG detects abnormalities in this population. Clinical validity was not reported and comparison with electro-oculogram or visual evoked potential (VEP) was rare. However, there is correlation between mfERG and corresponding mfVEP. Further, ERG may be useful in allowing long-term follow-up of disease progression in retinitis pigmentosa. mfERG may add to the diagnostic information of several patients with retinitis pigmentosa. ERG may distinguish between HCQ-induced retinal toxicity and retinitis pigmentosa. The evidence is comprised of case series and case reports with small sample sizes.
Cone-Rod dystrophy: Studies assessing clinical validity were not identified. The evidence is comprised of case reports or case series or retrospective study showing that ERG may detect cone-rode dystrophy and be useful to monitor disease progression.
Leber's congenital amaurosis, congenital stationary night blindness, achromatopsia: The evidence is insufficient to assess the accuracy of ERG in these diseases.

Articles: See Evidence Table

The use of Electroretinography (ERG) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary- experimental, investigational or unproven:

CPT® Codes	Description
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)
0509T	Electroretinography (ERG) with interpretation and report, pattern (PERG)

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Date Created	Date Reviewed	Date Last Revised
09/01/2020	09/01/2020 MPC, 09/07/2021 MPC, 09/06/2022MPC	09/01/2020

MPC Medical Policy Committee

Revision History	Description
09/01/2020	MPC approved to endorse a non-coverage policy for electroretinography. Requires 60-day notice, effective date 02/01/2021.

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Clinical Review Criteria
Enteral Formula

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Enteral Nutrition (L38955)
Local Coverage Articles	Enteral Nutrition (A58833)

For Non-Medicare Members

The criteria are for formulas only. The pumps and associated equipment are considered durable medical equipment and are covered as part of the durable medical equipment benefit.

Elemental formulas are composed of amino acids, fats, sugars, vitamins, and minerals and lack whole or partial protein. An example of an elemental formula is Vivonex. Most formulas are not elemental as they contain complete proteins and complex carbohydrates, examples of which are Ensure or ProSobee.

To qualify for enteral nutritional formula, elemental formula (either replacement or supplemental) or non-elemental formula, the member must meet **ONE of the following**, either I, II or III:

I. To qualify for Nutritional Replacement Therapy, using an *elemental* formula, members must meet **ONE of the following:**
   A. Members must have at least **ONE of the following** diagnoses:
      1. Crohn's Disease
      2. Inflammatory Bowel Disease
      3. Short Bowel Syndrome
      4. Eosinophilic gastrointestinal associated disorders
   B. The member must also meet **ALL of the following**:
      1. Formula is intended for home use
      2. The member is managed by a Gastroenterologist
      3. The member has been evaluated and will be followed by a Registered Dietitian
      4. Elemental total nutritional replacement represents 80 - 100% of diet or 80% or greater of the daily dietary requirements
      5. Alternative approaches, other than use of an elemental formula, have not resulted in adequate nutrition and control of symptoms.
      6. Member must meet **ALL of the following:**
         a. Able to tolerate oral supplementation
         b. If unable to tolerate oral supplementation, member must meet **ALL of the following**:
            - The member or caregiver must demonstrate the ability to place a nasogastric tube or manage a surgically placed feeding tube.
            - The member or caregiver must also be able to demonstrate the ability to regulate flow either via gravity drip or pump.

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II. To qualify for Nutritional Supplementation Therapy using an *elemental* formula, members must meet **All of the following:**
   A. Members must have at least **ONE of the following** diagnoses:
      1. Crohn's Disease
      2. Inflammatory Bowel Disease
      3. Short Bowel Syndrome
      4. Cystic Fibrosis involving the intestine
      5. Eosinophilic gastrointestinal associated disorders
   B. Members must also meet **ALL of the following**:
      1. Intended for home use
      2. Growth failure/retardation or cachexia has been documented
      3. The member is managed by a Gastroenterologist
      4. The member has been evaluated and will be followed by a Registered Dietitian
      5. Other therapies, such as medication, have not resulted in adequate nutrition/weight gain
   C. Member must meet **ONE of the following:**
      1. Able to tolerate oral supplementation
      2. If unable to tolerate oral supplementation, member must meet **ALL of the following**:
         a. The member or caregiver must demonstrate the ability to place a nasogastric tube or manage a surgically placed feeding tube.
         b. The member or caregiver must also be able to demonstrate the ability to regulate flow either via gravity drip or pump.

III. Oral nutrition or supplements using *non-elemental* formula may be considered medically necessary when used for the treatment of inborn errors of metabolism. Member must meet **ALL of the following**:
   A. Must have **ONE of the following** diagnosis:
      1. Phenylketonuria [PKU]
      2. Maple syrup urine disease (MSUD)
      3. Homocystinuria,
      4. Histidinemia
      5. Tyrosinemia
      6. Glycogen Storage Type II Syndrome (GSD II or Pompe disease)
   B. Formula is intended for home use (not for use in the hospital or nursing facility)

IV. *Non-elemental formula* is covered for members who require tube feeding under the following conditions:
   a) Non-function or disease of the structures that normally permit food to reach the small bowel. The condition could either be anatomic (obstruction due to head and neck cancer, reconstructive surgery, etc.) or a motility disorder (e.g., severe dysphagia following a stroke, congenital defects, etc.) **AND**
   b) Requires tube feeding to maintain weight and strength commensurate with the patient's overall health status **AND**
   c) The patient's condition is anticipated to be long term in duration, typically at least 3 months (90 days).

*Elemental formula can be delivered by tube only if indications in I or II above are met

The following are not covered:
- Intra-peritoneal nutrition is considered experimental and investigational.

*Diagnosis Codes that are covered for Eosinophilic Gastrointestinal Associated Diseases
ICD-10
K20.0 Eosinophilic esophagitis
K52.81 Eosinophilic gastritis or gastroenteritis
K52.82 Eosinophilic colitis

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist (PCP, GI specialist)
- Last 6 months of radiology notes if applicable

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Background

Until 1996, the only Kaiser Permanente plans that had coverage for enteral therapy were the Medicare plans. In 1996 an appeals case caused Kaiser Permanente to reevaluate the potential inclusion of enteral therapy for all groups. The reevaluation, which included a special work group and the Benefits Committee, concluded that the use of elemental enteral therapy for ineffective GI absorption that represented a major portion of the consumer's calorie intake, should be covered up to the level of replacement of regular cost of food (80% of charges).

This coverage was to be added in 1997 to all plans under dietary formula where enteral nutrition therapy benefit is not in place. Since only subsets of specific consumers are eligible for this coverage, criteria were developed for consistent review of requests.

In 1998, Kaiser Permanente received a request to consider coverage for Glycogen Storage Type II Syndrome supplemental formula. After review of the case and literature, the decision was made to add the disease to the criteria for coverage.

In July 1998 Kaiser Permanente received an update of the Healthy Options criteria for coverage of enteral feedings. In October 2005 the MMA program updated the coverage criteria that are applicable to Healthy Options. Kaiser Permanente criteria were adjusted to reflect the new changes.

Evidence and Source Documents

03/1998

Articles: Definitions: Inflammatory Bowel Disease includes Crohn's Disease of small intestine or colon, Ulcerative Colitis, and overlap syndromes (Non-Specific IBD, Segmental Colitis) An Elemental Diet contains oligo-peptides as the major protein source. Vivonex (lower fat- 2.5%) and Vital HN (higher fat- 8%) are typical elemental diets. Non-elemental diets contain intact proteins from a defined source (such as milk protein, meat or egg)

Growth Retardation/ Failure requires: A pediatric patient (defined as age<18 years, and epiphyses not fused on radiography) and a height per age <5th percentile, or a decrease in growth velocity of >= 2cm/year, or bone age> 2 SD below chronologic age Nutritional Replacement Therapy requires >90% (and preferable 100%) of the caloric intake be provided by the elemental formula Nutritional Supplementation Therapy requires that >50% of the caloric intake is provided by the elemental formula. The use of elemental enteral nutrition in inflammatory bowel disease has progressed from strictly nutritional to therapeutic. Although the mechanism is not fully understood, disease activity and intestinal permeability decrease in patients "fed" with elemental diets, as compared to regular diet or TPN. The therapeutic role is best documented in the management of Crohn's Disease [especially of the small intestine]. The role of this therapy in Ulcerative Pancolitis, Ulcerative Colitis limited to the left colon, nonspecific IBD, and Segmental Colitis is not supported by these data. Nutritional Therapy (whether Replacement or Supplement) is used only in conjunction with other drug therapy (including 5-ASA compounds, corticosteroids, immunosuppressives and antibiotics) not in lieu of these other therapies. The consideration of surgery as primary therapy must be considered in patients with significant strictures complicating nutrition.

References:

Griffiths et al "Meta-analysis of Enteral Nutrition as a Primary Treatment of Active Crohn's Disease" Gastro 108, 1995

Meta-analysis of enteral nutrition vs. steroids as primary therapy; findings were that steroids were more effective. Also compared composition of diets and found no clear data [not significant power] supporting elemental over polymeric.

Teahon et al "Alterations in Nutritional Status and Disease Activity during Treatment of Crohn's Disease with Elemental Diet" Scand J Gastro 30, 1995

Replacement of diet with Vivonex or similar for 5-week period, 1850-3700 kcal/d. Required significant malnutrition at entry into study. Improvement in inflammatory activity preceded nutritional improvement in most cases.

Fernandez-Banares et al "How Effective is Enteral Nutrition in Inducing Clinical Remission in Active Crohn's Disease? A meta-analysis of the Randomized Clinical Trials" JPEN 19, 1995

Applicable Codes

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Date Sent: 6/28/23
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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Elemental formula

HCPC Codes	Description
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Formula for inborn errors of metabolism

HCPC Codes	Description
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Non-elemental formula

HCPC Codes	Description
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Other specialized formulas

Not routinely covered; the medical record must document why the specific formula is medically necessary

***Not covered by Medicare**

HCPC Codes	Description
B4102*	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103*	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit *(i.e., diabetic, renal, post-surgical, ketogenic)*
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit

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	**almost always taken with another formula unless eating orally and requiring one specific nutrient*

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Date Created	Date Reviewed	Date Last Revised
7/11/1984	1/5/2010 MDCRPC, 11/2/2010 MDCRPC, 9/6/2011MDCRPC, 7/3/2012MDCRPC, 5/07/2013MDCRPC,2/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/02/2019MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC	08/13/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
8/31/2016	Added LCD for Enteral Therapy
12/06/2016	Added Intraperitoneal Nutrition (IPN) to the non-covered list
05/31/2018	Removed the Microsoft link
03/02/2021	MPC approved to amend the current criteria to include indications for non-elemental formula for patients receiving nutrition via tube feeding. Requires 60-day notice, effective date 08/01/2021.
08/13/2021	Added clarifying timeframe to define long term in IV.c. as typically at least 3 months (90 days).

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Clinical Review Criteria
EOS imaging system in children and adolescents with scoliosis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "EOS imaging system in children and adolescents with scoliosis"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Scoliosis

Scoliosis is a deformity of the spine that affects 2 to 4% of adolescents (Reamy & Slakey, 2001; Roach, 1999; Smith, Sciubba, & Samdani, 2008) and can result in cardiopulmonary compromise. It is defined as a lateral curvature of the spine more than 10 degrees with vertebral rotation (Reamy & Slakey, 2001; Roach, 1999; Smith et al., 2008). Males and females are affected equally but evolution of the curve is more frequent in females than males (Miller, 1999). It can be classified as neuromuscular, congenital, or idiopathic which is the most common form of scoliosis (Reamy & Slakey, 2001; Smith, Sciubba, & Samdani, 2008). Idiopathic scoliosis can be categorized as infantile (0 to 3 years), juvenile (4 to 9 years), and adolescent (≥ 10 years); the most common form of idiopathic scoliosis is adolescent idiopathic sclerosis (Reamy & Slakey, 2001; Roach, 1999; Smith et al., 2008).

Scoliosis requires frequent radiographic examination to assess the curve, identify underlying etiology, and help in treatment decision (Yvert et al., 2015). Standard imaging technologies including x-ray film, computed radiography (CR) and digital radiography (DR) have been used for diagnosis and monitoring. Nevertheless, there is growing concern on radiation-based harm on the long-term among children who undergo repeated x-rays (Bone & Hsieh,

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2000; Doody et al., 2000). New imaging system, EOS, has been the center of attention with the promise of reducing radiation dose and ensuring higher quality image.

EOS imaging system (From https://www.eos-imaging.com/us/professionals/eos/eos and Wade et al., 2013; McKenna et al., 2012)
EOS is an X-ray imaging that utilizes slot-scanning technology and is manufactured by EOS imaging (formerly Biospace Med, Paris, France) (Wade et al., 2013). It is a bi-planar technology that is based on two perpendicular fan beams of X-rays and proprietary detectors that travel vertically while scanning the patient. EOS can take posteroanterior (PA) and lateral images concurrently. EOS generates three-dimension images and assessment of individual vertebral rotation can be done. It generates, not only, 2D images similar to conventional imaging techniques, but also produces 3D images that are reconstructed through sterEOS software using the posteroanterior and lateral images, and a 3D statistical spine model. It also permits the rotation of a scoliotic curve with accuracy. EOS system provides low dose stereo-radiographic images. Micro dose option for pediatric follow up exams provides lesser radiation exposure. It is believed that the quality of image is high and therefore improves diagnostics.

EOS is indicated in conditions where frequent x-rays can cause harm due to radiation effect. These diseases include scoliosis (Gummerson & Millner, 2010), the main indication, sagittal deformities (kyphosis), and lower limbs deformities.

EOS is performed while the patient is in an upright, weight-bearing (standing, seated or squatting) position, and can take the entire body or a segment. The physician may choose the adequate position for the exam on the EOS radiolucent chair. The patient stays inside the EOS booth, and then an x-ray of the whole body is taken in less than 20 seconds for an adult and less than 15 seconds for a child. It is believed that EOS eliminates the need for multiple images.

Medical Technology Assessment Committee (MTAC)

Date: 07/09/2018 MTAC REVIEW

EOS imaging system in children and adolescents with scoliosis

Evidence Conclusion:

EOS accuracy

There is a lack of studies comparing the accuracy of EOS to that of standard imaging techniques.

Reproducibility & reliability of EOS 3D spine reconstruction

Rehm et al., 2017

A retrospective study (Rehm et al., 2017) evaluated the inter reader reproducibility and reliability of EOS imaging full spine reconstruction in patients with adolescent idiopathic scoliosis (AIS).
Seventy-three consecutive patients (31 men, 42 women) with moderate AIS (mean Cobb angle was 18.2° (range, 9.8°-49.9°)) had their whole spine examined with EOS imaging (AP and lateral). Mean age was 17 years (range 9-58 years). Two readers performed 3D reconstructions of the spine with sterEOS software.
Findings:

- Radiation exposure: Mean of total absorbed dose was 593.4 µGy ± 212.3
- Mean scan-time: Mean scan-time was 9.5 seconds ±1.7
- Reconstruction time: varied significantly between the readers (14.6 min vs 15.2mn P<0.0001)
- Inter-reader reproducibility and reliability of every single vertebra rotation from T1-L5: was good to very good for frontal and lateral rotation measurement but limited for axial rotation.
- Interclass correlation (ICC) was > 0.80 for all vertebral rotations but for axial rotation it was between 0.51 to 0.88. ICC was ≥0.85 for kyphosis, lordosis, pelvic incidence, sacral slope, pelvic tilt.

Main limitations: Results were limited to patients with moderate scoliosis (mean Cobb angle was 18.2° (range, 9.8°-49.9°)); the study design was retrospective with inherent bias of observational study.
Conclusion: 3D reconstruction of the spine with EOS imaging was reproducible and reliable. Inter-reader reproducibility and reliability of every single vertebra rotation was good but limited for the axial rotation.

Vidal et al., 2013

A reproducibility study (Vidal, Ilharreborde, Azoulay, Sebag, & Mazda, 2013) assessed the reliability of radiographic measurement in adolescent idiopathic scoliosis using EOS system. Seventy-five patients were recruited. Mean age was 12 years, patients had Lenke type 1 or 2 AIS; patients were divided in three groups: AIS group, operated AIS, and control. The authors reported great intra and interobserver reliability in sagittal curvatures, pelvic variables and global sagittal balance. Correlation coefficient was at least 0.85 for each

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examiner and among the examiners. The main limitation was the lack of comparison with conventional radiographs.

Ilharreborde et al., 2016 (EOS micro dose protocol for the radiological follow-up of adolescent idiopathic scoliosis)
A prospective study evaluated the reliability of EOS x-ray micro dose protocol. The authors included 32 patients who were followed for AIS. All patients underwent EOS x-ray with micro dose protocol and 3D reconstructions were performed. Intrarater and interrater reproducibility were assessed. The authors reported that intraoperator repeatability was better than inter-operator reproducibility for all clinical measurements. Interclass correlation (ICC) was >0.91 for all parameters.

Effectiveness – Radiation dose, image quality, patient health outcomes

EOS vs x-ray film or computed radiography

Wade et al., 2013
A systematic review (Wade et al., 2013) assessed the clinical effectiveness of EOS imaging system in children with scoliosis and other orthopedic conditions. A total of three observational studies were included. Inclusion criteria encompassed studies that compared EOS with X-ray film, computed radiography or digital radiography in patients with any orthopedic condition. Studies that reported any outcome were also included. Primary outcome was patient health outcomes; and secondary outcomes were radiation dose and quality of image. The risk of bias of individual studies was overall high.
Study characteristics included: sample size varied from 49 to 140 patients; patients were children and adolescents undergoing follow-up for scoliosis or required spine radiographs for the diagnosis of scoliosis or for follow-up; mean age was 14.7 – 14.8 years (SD 4.8); comparison was done between EOS/earlier version with x-ray film in two studies and with computed radiograph (CR) in one study.
Outcomes:

Patient health outcomes: were not reported
Image quality: comparable or better with EOS; no significance was reported
Radiation dose: was lower with EOS for all comparators (please refer to table below)

Radiation dose results	Mean ESD (mGy); EOS vs film; (Kalifa et al., 1998)	Mean ESD (mGy) second study; EOS vs film	Mean ESD (mGy); EOS vs CR; (Deschenes et al., 2010)
Spine PA	EOS 0.07, film 0.92	EOS 0.23, film 1.2	
Spine lateral	EOS 0.13, film 1.96	EOS 0.37, film 2.3	
Spine AP	EOS 0.08, film 0.93		
Pelvis	EOS 0.06, film 1.13		
Centre of back			EOS 0.18, CR 1.04
Proximal lateral point			EOS 0.27, CR 2.38
Outer side of proximal breast			EOS 0.11, CR 0.83
Proximal anterosuperior iliac spine			EOS 0.16, CR 1.47
Proximal iliac crest			EOS 0.30, CR 2.47
Distal iliac crest			EOS 0.11, CR 0.73
Nape of neck			EOS 0.20, CR 0.59

CR, Computed Radiography; ESD, Entrance Surface Dose;

Conclusion: there was limited data on the clinical effectiveness of EOS. EOS imaging appeared to be comparable or better than x-ray film or computed radiography in children with scoliosis in term of image quality. In addition, radiation dose appeared to be lower for EOS than x-ray or computed radiography. Also, there was no suggestion that the use of EOS enhanced management of scoliosis (from the nature and quality of the image). The long-term benefits from low dose of radiation were also unknown.
Quality assessment: the overall risk of bias was high; due to study design, risk of bias, and precision issues, the quality of evidence from the systematic review was considered low. Eight criteria of AMSTAR were met.

McKenna et al., 2012
This systematic review (McKenna et al., 2012) included the same studies already analyzed in the above systematic review (Wade et al., 2013). Therefore, the conclusion is the same.

Dietrich et al., 2013

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A study (Dietrich, Pfirrmann, Schwab, Pankalla, & Buck, 2013) aimed at comparing the radiation dose, workflow, patient comfort of EOS x-ray system and digital radiography. Data of forty-seven consecutive AP and lateral spine radiographs of standard digital radiography were compared to 134 AP and lateral spine radiographs using EOS x-ray system. Outcomes are presented in the following table:

	DR (Digital Radiograph)	EOS x-ray	P-value
DAP (Dose Area Product)	392.2±231.7 cGy*cm2	158.4±103.8 cGy*cm2	**P<0.001**
Mean examination time	449 ±122 s	248 ±77 s	**P<0.001**
Patients' comfort (noise during examination)	1.4	1.8	**P<0.01**

Table show results for spine radiographs

Limitations: Limitation included: dose area product (DAP) measurement is not the most accurate technique for measuring radiation dose; bias due to baseline confounding, bias in selection of participants into study and measurement bias were not clear; bias due to departures from intended interventions was low; missing data bias and bias in selection of the reported result were low.
Conclusion: Compared to digital radiograph, EOS x-ray system reduces radiation dose and increases noise during examination.
Yvert et al., 2015
A prospective study (see evidence table 1) reported that EOS x-ray may have better or similar image quality than digital radiography with a dynamic flat detector. In addition, no significant difference was reported between the two systems in term of radiation dose.
Hirsch et al., 2016
A prospective study (Hirsch, Ilharreborde, & Mazda, 2016) of 50 patients compared the irradiation dose and reducibility of the cobb angle on bending EOS x-ray and standard x-ray.
Irradiation dose: was five times lower with EOS bending imaging than standard bending x-ray.
Reducibility of Cobb angle: No significant difference was reported.
Patients in this study underwent preoperative assessment for AIS; this included standing AP and lateral EOS x-rays of the spine, standard side-bending x-rays in the supine position, and standing bending x-rays in the EOS booth.
Limitations across studies included study design, sample size, selected outcomes, high risk of bias; literature lacks evidence for clinical outcomes.

Conclusion:

- **Accuracy**
  - There is lack of studies on the test accuracy
- **Reproducibility & reliability of 3D spine reconstruction:**
  - Three observational (one retrospective, two prospective studies) studies were reviewed
  - The studies focused on reliability of spine reconstruction in patients with adolescent idiopathic scoliosis (AIS) using EOS system
  - High inter-reader reproducibility and reliability was reported for all clinical measurements including sagittal curvatures, pelvic variables and global sagittal balance
  - The main limitations resided in the study design and the small sample size
- **Effectiveness – radiation dose, image quality, patient health outcomes**
  - One systematic review and three observational studies were reviewed
  - Radiation dose and image quality were evaluated
  - Comparison was made between EOS x-ray and computed radiography or x-ray film
  - Patients were children and adolescents undergoing follow-up for scoliosis or required spine radiographs for the diagnosis of scoliosis
  - Radiation dose was lower with EOS x-ray than the comparators
  - Image quality was comparable or better with EOS
  - Patient health outcomes: lack of data preclude conclusion on patient health outcomes
  - Data on the association of dose reduction and cancer occurrence were insufficient
  - There was no suggestion that the use of EOS enhances management of scoliosis
- **Evidence**: Overall, evidence is low

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- Compared to conventional techniques, EOS system has better or similar image quality and reduces radiation dose. However, the impact of this benefits is not clear.

The use of EOS imaging system in children and adolescents with scoliosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

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Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018 MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC	08/07/2018

MPC Medical Policy Committee

Revision History	Description
08/07/2018	Added MTAC review from 7/9/18 and created document

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Clinical Review Criteria
Epidural Steroid Injections

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Epidural Steroid Injections for Pain Management (L39242)
Local Coverage Article (LCA)	Billing and Coding: Epidural Steroid Injections for Pain Management (A58995)

For Non-Medicare Members

Effective until August 1, 2023	**Does not require review**
Effective August 1, 2023	**Epidural Steroid Injections (Interlaminar, Caudal, or Transforaminal)** **<u>Initial Epidural Steroid Injections (ESI)</u>** Initial Epidural Steroid Injections (ESI) are proven and medically necessary when **ALL of the following** criteria are met: • One of the four indications below: o **Suspected Lumbar Radiculopathy/Radicular Pain:** ▪ Leg pain is > or equal to back pain present in nerve root distribution (e.g., L5, S1, etc.) **PLUS, ONE or MORE**: ▪ Positive supine straight leg raising test - radicular leg pain reproduced when the leg is extended >30°(e.g., if patient reported pain down the posterior thigh and lateral calf, expectation is a positive SLR test would reproduce that pain and not cause nonspecific pain like calf tightness or low back pain) OR ▪ Motor weakness or sensory loss in a radicular distribution (must be in a specific radicular distribution) OR ▪ EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms OR ▪ Patient's history or advanced imaging consistent with symptoms described o **Suspected Cervical Radiculopathy/Radicular pain** defined as: ▪ Pain in a *nerve root* distribution (e.g., C6, C7) OR

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	▪ Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) *OR* ▪ EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms OR ▪ Patient's history or advanced imaging consistent with symptoms described o **Suspected Thoracic Radiculopathy/Radicular Pain Defined as:** ▪ Band of numbness OR ▪ Pain or sensitivity in the thoracic dermatomal distribution OR ▪ Patient's history or advanced imaging consistent with symptoms described o **Neurogenic claudication** defined as: ▪ Bilateral or unilateral leg pain upon standing and walking that is temporarily relieved by forward flexion or sitting or lying down OR ▪ The pain of lumbar stenosis is caused by relative ischemia of the lumbar nerve roots when in an upright position • Treatment of presumed radiculopathy when there has been failure of at least a *4-week trial* of appropriate conservative management **with BOTH of the following:** o Physical Therapy* or home exercise* **AND** o Medications (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) oral or topical or acetaminophen) unless contraindicated **If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable.* • MRI or CT with or without Myelography, or EMG within the past 24-months demonstrates **ONE of the following:** o For an indication of *spinal stenosis*: Imaging consistent with moderate to severe lumbar spinal stenosis at the level to be treated for patients with a clinical diagnosis of neurogenic claudication o For an indication of r*adiculopathy*: Imaging consistent with compression or displacement of the corresponding nerve root OR EMG consistent with acute nerve impingement **AND** o No Contraindications below** **Repeat Epidural Steroid Injections (ESI)** Repeat Epidural Steroid Injections (ESI) are proven and medically necessary when **ALL of the following** criteria are met. • Pain has returned or deterioration in function has occurred • Prior injection resulted in 50% improvement in pain for two or more weeks and **at least ONE of the following:** o Increase in the level of function/physical activity (e.g., return to work) o Reduction in the use of pain medication and/or additional medical services *Additional epidural injections are ***not*** considered medically necessary if these criteria are not met. **Epidural Steroid Injection (ESI) Limitations**

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	• Maximum of four (4) ESI sessions along the spinal column per year. Definitions: o A year: the 12-month period starting from the date of service of the first approved injection • Maximum of two (2) transforaminal ESI injections in one date of service **<u>**Epidural Steroid Injection (ESI) exclusions/contraindications</u>** • Anticoagulated • Axial back pain (isolated to neck, mid-back, or low back pain) • Back pain in the setting of trauma (acute spinal fractures) • Bleeding disorders that are not reversed • Infection • Currently on antibiotics for an infection • Currently on high dose steroids • Demyelinating disease that is causing radicular symptoms • Local malignancy • Other CNS processes which predispose to transverse myelitis (case-by-case) • Uncontrolled Diabetes
Effective November 1, 2023	**Epidural Steroid Injections (Interlaminar, Caudal, or Transforaminal)** **For Non-Medicare Members** MPC approved to adopt the proposed revisions to the existing ESI criteria to include acknowledge the importance of conservative therapy. Changes include the following: **Epidural Steroid Injections (Interlaminar, Caudal, or Transforaminal)** **<u>Initial Epidural Steroid Injections (ESI)</u>** Initial Epidural Steroid Injections (ESI) are proven and medically necessary when **ALL of the following** criteria are met: • One of the five indications below: o **Suspected Lumbar Radiculopathy defined as:** ▪ Lower extremity pain is > or equal to back pain present in nerve root distribution (e.g., L5, S1, etc.) **PLUS, ONE or MORE**: ▪ Positive supine straight leg raising test - radicular leg pain reproduced when the leg is extended >30°(e.g., if patient reported pain down the posterior thigh and lateral calf, expectation is a positive SLR test would reproduce that pain and not cause nonspecific pain like calf tightness or low back pain) OR ▪ Motor weakness or sensory loss in a radicular distribution (must be in a specific radicular distribution) OR ▪ EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms OR ▪ Patient's history or advanced imaging consistent with symptoms described o **Suspected Cervical Radiculopathy/Radicular pain defined as**: ▪ Pain in a *nerve root* distribution (e.g., C6, C7) OR ▪ Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) OR ▪ EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms OR

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	▪ Patient's history or advanced imaging consistent with symptoms described o **Suspected Thoracic Radiculopathy/Radicular Pain defined as:** ▪ Band of numbness OR ▪ Pain or sensitivity in the thoracic dermatomal distribution OR ▪ Patient's history or advanced imaging consistent with symptoms described o **Lumbar Radicular Pain (at any level) defined as:** ▪ Moderate to severe pain in nerve root distribution (e.g., L5, S1, etc.) **AND** ▪ Patient's available history and prior imaging is consistent with radicular pain as the primary etiology o **Neurogenic claudication** defined as: ▪ Bilateral or unilateral leg pain upon standing and walking that is temporarily relieved by forward flexion or sitting or lying down OR ▪ The pain of lumbar stenosis is caused by relative ischemia of the lumbar nerve roots when in an upright position • Treatment of presumed radiculopathy when there has been failure of at least a *4-week trial* of appropriate conservative management **with BOTH of the following:** o Physical Therapy* or home exercise* **AND** o Medications (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) oral or topical or acetaminophen) unless contraindicated **If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable.* • MRI or CT with or without Myelography within the past 24-months demonstrates **ONE of the following:** o MRI or CT can be waived for the indication of simple lumbar radicular pain without loss of neurologic function (numbness or weakness) of less than six months duration o For an indication of *spinal stenosis*: Imaging consistent with moderate to severe lumbar spinal stenosis at the level to be treated for patients with a clinical diagnosis of neurogenic claudication o For an indication of *radiculopathy*: Imaging consistent with compression or displacement of the corresponding nerve root **OR**, if imaging does not show compression an EMG consistent with acute nerve impingement **AND** • None of the contraindications below without documentation of a medically justifiable reason for proceeding ** **<u>Repeat Epidural Steroid Injections (ESI)</u>** Repeat Epidural Steroid Injections (ESI) are proven and medically necessary when **the following** criteria are met. • Pain has returned or deterioration in function has occurred **AND** • If initial steroid injection was done empirically (without CT or MRI) and patient did not respond adequately, advanced imaging must be done prior to repeat injections **AND** • Prior injection resulted in less than 50% improvement in pain for two or more weeks and the ESI approach is being changed (intralaminar to

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	transforaminal or vice versa) or a different level is being injected (evidence of nerve root compression by CT, MRI, or EMG is required) **OR**
	• Patients condition has declined after patients' initial injection resulted in at least 50% improvement in pain for two or more weeks and **at least ONE of the following:**
	  o Increase in the level of function/physical activity (e.g., return to work)
	  o Reduction in the use of pain medication and/or additional medical services
	NOTE: Additional epidural injections are ***not*** considered medically necessary if these criteria are not met.
	
	Epidural Steroid Injection (ESI) Limitations
	• Maximum of four (4) ESI sessions along the spinal column per year.
	  Definitions:
	  o A year: the 12-month period starting from the date of service of the first approved injection
	• Maximum of two (2) transforaminal ESI injections in one date of service
	
	****Epidural Steroid Injection (ESI) exclusions/contraindications**
	• Anticoagulated
	• Axial back pain (isolated to neck, mid-back, or low back pain)
	• Back pain in the setting of acute spinal fractures
	• Bleeding disorders that are not reversed
	• Systemic bacterial or fungal Infection
	• Currently on antibiotics/antifungals for an infection
	• Currently on high dose steroids
	• Demyelinating disease that is causing radicular symptoms
	• Local malignancy
	• Other CNS processes which predispose to transverse myelitis (case-by-case)
	• Uncontrolled Diabetes

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (including PT notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Epidural steroid injections can serve as both a diagnostic and a therapeutic tool for patients with symptoms related to a disc herniation in the spine. Overall, the volume of evidence for the use of therapeutic epidural injections in the treatment of acute and chronic back pain is large. Clinical studies have shown that epidural steroid injections have provided short-term improvement and may be considered in the treatment of selected patients with radicular pain as part of an active therapy program. There is however insufficient evidence to demonstrate that epidural steroid injections are effective in the treatment of back pain in the absence of radicular symptoms.

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References

Washington State Department of Labor & Industries Spinal Injections Coverage Decision. Retrieved 01/26/2023 from https://lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/_docs/SpinalInjectionsCoverageDecision.pdf

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPCS Codes	Description
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
64479	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, single level
64480	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
64483	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, single level
64484	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)

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Date Created	Date Reviewed	Date Last Revised
03/07/2023	03/07/2023[MPC],	06/06/2023

[MPC] Medical Policy Committee

Revision History	Description
03/07/2023	MPC approved to adopt clinical criteria for Epidural Injections. Requires 60-day notice, effective date 08/01/2022.
06/06/2023	MPC approved to adopt the proposed revisions to the existing ESI criteria to include acknowledge the importance of conservative therapy. 60-day notice required, effective date 11/01/2023

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Clinical Review Criteria
External Trigeminal Nerve Stimulation (eTNS) for ADHD

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Criteria

For Medicare Members

Source)	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"External Trigeminal Nerve Stimulation (eTNS) for ADHD"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Trigeminal Nerve Stimulation, Transcutaneous: Behavioral Health Care (B-820-T) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Attention-deficit/hyperactivity disorder (ADHD) is the most common behavioral disorder in childhood. It is defined in the DSM-5 as a "P*ersistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development and negatively impacts directly on social and academic/occupational activities"*. The reported prevalence of ADHD in children varies from 2 to 18 percent depending upon the diagnostic criteria and the population

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studied. The etiology of the disorder is not fully known, but according to the experts, a combination of genetic, neurological, and environmental factors contributes to its pathogenesis and heterogeneous phenotypes (Felt 2014, Polanczyk 2015, Belanger 2018).

There are three sub-types of ADHD: 1. Predominantly inattentive type (including poor concentration, difficulty completing tasks, ease of distraction, and disorganization); 2. Predominantly hyperactive -impulsive type (e.g. restlessness, persistent fidgeting, impatience, excessive talking, difficulty waiting for turn); and 3. The combined type. Diagnosing a child with ADHD can be challenging due to the lack of specific tests, biomarkers, or symptoms in addition to the common presence of other comorbidities that may affect symptom presentation, increase the severity of the disorder and/ or lead to greater functional impairment. The DSM-5 requires the presence of a sufficient number of core symptoms and functional impairment to diagnose an individual with ADHD. This requires extensive evaluation by a health care professional and involves obtaining information from multiple sources primarily from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care; comprehensive evaluation of the child's symptoms which should include the assessment for other conditions that might coexist with ADHD such as emotional or behavioral disorders (e.g., anxiety, depressive oppositional defiant, and conduct disorders), developmental (e.g. learning and language disorders), and physical conditions (e.g. tics, and sleep apnea) (AAP Guidelines 2011, Felt 2014, Akutagava-Martin 2016, Bélanger 2018).

Treatment of ADHD varies depending on the age of the patient and the presence of comorbidities. It needs to be individualized and is often multimodal requiring the use of both behavioral and pharmacological therapies. The American Academy of Pediatrics guideline recommends behavioral therapy as a first line treatment of preschool aged children (4-5 years of age); FDA- approved medications for ADHD and/or parent- and/or teacher administered behavior therapy as a first line treatment for elementary school-aged children (6–11 years of age); and FDA-approved medications as the first line treatment for adolescents (12-18 years of age). Psychostimulants, are most effective for the treatment of core ADHD symptoms, have generally acceptable adverse effect profiles and may be considered for children aged 6 years and older. Effective behavioral therapies include parent training, classroom management, and peer interventions. Other nonpharmacological interventions such as social, organizational skills, and cognitive training; diet; and exercise should be considered for children with ADHD and other psychiatric and developmental comorbidities (Felt 2014. Feldman 2018).

It is reported that around 70% of patients with ADHD using stimulant medications respond to therapy. In some cases, however, the response may me suboptimal and requires the use of more than one drug. This, in addition to the stigma of using stimulants, its side effects, intolerance, and lack compliance among some children, have led to the investigation of and/or development of alternative non-pharmacological therapies for the potential treatment of ADHD. Among these approaches are EEG-based neurofeedback, computer-based working memory training, and neuromodulation therapy (Grigolon 2019).

Neuromodulation therapy is an evolving therapy that has been, and/or being investigated for the potential treatment of different chronic conditions including pain, spinal cord injuries, epilepsy, movement disorders, and others. It is defined as the "alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body". Existing and emerging neuromodulation treatments range from non-invasive techniques such as transcranial magnetic stimulation (TMS) to techniques involving the surgical implantation of devices to alter activity in discrete areas of the nervous system. Among these therapies are deep brain stimulation, hypoglossal nerve stimulation, spinal cord stimulation, vagus nerve stimulation, occipital nerve stimulation and trigeminal nerve stimulation (TNS) (International Neuromodulation Society website).

TNS is a non-invasive neuromodulation technique that has been recently developed for neurological and psychiatric disorders based on the hypothesis that electrical stimulation of the supraorbital branch of the trigeminal nerve modulates cortical and subcortical areas related to neuropsychiatric disorders. The trigeminal nerve carries sensory information from the skin, muscles, and skull to extensive important structures in the brain, including the nucleus solitarius, the locus coeruleus, the vagus nerve and the cerebral cortex. The nerve also sends signals to the anterior cingulate cortex, which is believed to be involved in mood, attention and decision-making (Grigolon 2019, NeuroSigma website, International Neuromodulation Society website).

In April 19, 2019, the FDA granted marketing approval, through a de novo premarket review pathway*, of the Monarch eTNS System (NeuroSigma) to be used as a non-drug option for the treatment of attention deficit hyperactivity disorder (ADHD) in children 7 to12 years of age who are not currently taking prescription ADHD medication (FDA website accessed May 9, 2019).

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The Monarch eTNS System™ (NeuroSigma, Inc., Los Angeles CA) is a small device, the size of a cell phone, powered by a 9-volt battery. It is connected through a thin wire to a small electrode patch that adheres to a patient's forehead during sleep. The system delivers mild electrical stimulation to the branches of the trigeminal nerve, which sends therapeutic signals to the parts of the brain assumed to be involved with concentration and impulse control. The child wears the patch for an average of eight hours at night and removes it in the morning. The electrical stimulation feels like a tingling sensation on the skin, and the device should be used in the home under the supervision of a caregiver during periods of sleep. The exact mechanism of eTNS is not yet known, but according to some investigators, neuroimaging studies showed that eTNS increases activity in the brain regions that are believed to be important in regulating attention, emotion and behavior. It is reported that the response to eTNS may take up to 4 weeks to become evident, and patients should consult with their health care professional after four weeks of use to assess treatment effects (FDA website).

According to the FDA, "the Monarch eTNS System should not be used in children under seven years of age, in patients with an active implantable pacemaker, with active implantable neurostimulators, or in patients with body-worn devices such as insulin pumps. The eTNS System should also not be used in the presence of radio frequency energy such as magnetic resonance imaging (MRI) as it has not been tested in an MRI machine, or cell phones, because the phone's low levels of electromagnetic energy may interrupt the therapy. The most common side effects observed with eTNS use are drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache and fatigue. No serious adverse events were associated with use of the device" (FDA website).

Medical Technology Assessment Committee (MTAC)

External Trigeminal Nerve Stimulation (eTNS) for ADHD

07/08/2019: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence to determine the comparative safety and effectiveness eTNS to stimulants and /or behavioral therapies currently used for the treatment of ADHD in children.
- There is low-moderate quality evidence from one relatively small sham-controlled randomized pilot trial that eTNS has more than a placebo short-term effect in improving the severity and frequency of ADHD symptoms examined by ADHD-RS and CGI-I in around 50% of selected children 8-12 years of age during 4 weeks of therapy.
- There is insufficient evidence to determine the sustainability of the observed effect of eTNS after discontinuation of the treatment.
- There is insufficient evidence to determine the long-term safety and efficacy of TNS in the treatment of children with ADHD.
- There is insufficient evidence to determine the optimal duration of TNS therapy i.e. whether it should be used only for 4 weeks, long-term, or periodically applied to the child.
- eTNS therapy is not without side effects; it was associated with an increase in appetite, weight gain, fatigue, headache, drowsiness and other adverse events. The authors noted that the adverse effects were not clinically significant leading to discontinuation of the treatment.
- Long-term RCTs comparing the effectiveness of eTNS to other therapies is needed to determine the equivalence or superiority of TNS to standard therapies, optimal duration of treatment, durability of the observed effect, and whether TNS would have a potential impact on child's brain development.

Articles: The literature search only identified the published pivotal randomized, sham-controlled pilot study on trigeminal nerve stimulation for ADHD (McGough, 2019) and an earlier small observational feasibility study of trigeminal nerve stimulation in youths ADHD (McGough, 2015). Both studies were conducted by the same group of principal investigators who had financial ties with the industry.

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McGough JJ, Sturm A, Cowen J, et al. Double-Blind, Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder. *J Am Acad Child Adolesc Psychiatry*. 2019 Apr; 58(4): 403-411.

McGough JJ, Loo SK, Sturm A, et al. An eight-week, open-trial, pilot feasibility study of trigeminal nerve stimulation in youth with attention-deficit/hyperactivity disorder. *Brain Stimul*. 2015 Mar-Apr; 8(2):299-304. See Evidence Table

The use of External Trigeminal Nerve Stimulation (eTNS) for ADHD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® /HCPC Codes	Description
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
Dx Codes	**Description**
F90.0-F90.9	Attention-deficit hyperactivity disorder

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
08/06/2019	08/06/2019[MPC], 08/04/2020 [MPC], 08/03/2021 [MPC], 08/02/2022[MPC]	08/03/2021

[MPC] Medical Policy Committee

Revision History	Description
08/06/2019	MPC approved to adopt non-coverage policy
08/03/2021	Added HCPC code K1016 and Dx codes F90.0-F90.9. MPC approved to adopt MCG Care Guideline B-820-T Trigeminal Nerve Stimulation, Transcutaneous: Behavioral Health Care for medical necessity reviews. Requires 60-day notice, effective date January 1, 2022.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Exoskeleton

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Exoskeleton*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or consulting specialist.

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Background

The CDC estimates that there are about 200,000 people in the United States (US) living with a spinal cord injury (SCI) (CDC 2014). Depending on the vertebral level and the degree of completeness, SCI can result in a variety of degrees of neurological deficit. Individuals with traumatic, motor-complete SCI abruptly lose the ability to stand and walk, relying on wheelchairs as a means of locomotion. Eventually, extreme inactivity causes rapid and marked alteration in body composition and can lead to additional complications such as ulcers, weakened bones, digestive disorders, and urinary tract infections (UTI). To add to this, the loss of mobility can negatively impact a patient's quality of life (QoL) and places SCI patients at higher risk for secondary medical conditions such as, diabetes and cardiovascular disease, to name a few (Spungen, Asselin et al. 2013).

A variety of techniques have been attempted to restore walking abilities with limited success. The concept of exoskeletons was first introduced in Russia in 1890, however, the first true exoskeleton was developed in the US, for military use, and consisted of an outer framework for the lower extremities powered by motors and hydraulics to deliver at least part of the energy for movement. When applied, the device was intended to enable soldiers to carry heavy objects while running or climbing stairs. Several different prototypes have been developed for the military; however, none have been able to overcome a variety of technological limitations such as power source and joint flexibility. In more recent years, the concept of an exoskeleton has been applied in the medical field to

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aid in the rehabilitation of patients with loss of motor function due to stroke or SCI (Talaty, Esquenazi et al. 2013). Currently, several devices have been developed for this indication, however, only one company, Argo Medical Technologies, Inc. (Marlborough, MA), has received clearance for marketing in the United States (US).

The ReWalk™ was designed to allow patients with paraplegia, due to SCI, to fully weight bear while standing and to ambulate over ground. In its entirety, the system includes two leg braces with motorized joints and motion sensors, a harness, and a backpack for holding the computer that controls the device as well as a battery that is estimated to last for three to four hours. The device can facilitate standing, walking, and sitting modes and operates by powering hip and knee motion allowing patients functional and independent walking with the use of lofstrand forearm crutches to maintain balance. Use of the ReWalk™ requires training in a rehabilitation setting (Zeilig, Weingarden et al. 2012).

Medical Technology Assessment Committee (MTAC)

02//09/2015: MTAC REVIEW

Exoskeleton

Evidence Conclusion: The literature search revealed only a small number of publications relating to the exoskeleton. No randomized controlled trials (RCT) comparing exoskeletons to wheelchairs were revealed. The FDA's approval relied on three observational studies that assessed the safety and tolerance of the ReWalk. In each of the studies, patients were trained to use the device in a clinical setting under the guidance of a physical therapist. Upon training completion (approximately 8 weeks), subjects underwent performance evaluations. None of the studies were carried out in a home-setting or assessed long-term performance. No studies were selected for critical appraisal due to methodological limitations such as study design and small sample size. An extensive list of ongoing studies relating to exoskeletons was revealed after searching in the National Institute of Health's clinical trials database. Conclusions: There is insufficient evidence to support the effectiveness of exoskeleton suits for ambulation compared to wheelchairs. There is insufficient evidence to support the safety of exoskeleton suits for ambulation compared to wheelchairs.

Articles: The literature search revealed only a small number of publications relating to the exoskeleton. No randomized controlled trials (RCT) comparing exoskeletons to wheelchairs were revealed. The FDA's approval relied on three observational studies that assessed the safety and tolerance of the ReWalk. In each of the studies, patients were trained to use the device in a clinical setting under the guidance of a physical therapist. Upon training completion (approximately 8 weeks), subjects underwent performance evaluations. None of the studies were carried out in a home-setting or assessed long-term performance. No studies were selected for critical appraisal due to methodological limitations such as study design and small sample size. An extensive list of ongoing studies relating to exoskeletons was revealed after searching in the National Institute of Health's clinical trials database.

The use of Exoskeleton does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

HCPCS Codes	Description
K1007	Bilateral hip, knee, ankle, foot (HKAFO) device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
03/03/2015	03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC],	03/16/2021

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	07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	

[MPC] Medical Policy Committee

Revision History	Description of Change
03/16/2021	Added new HCPCS code K1007 effective 10/1/2020

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Clinical Review Criteria

Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Dysphagia is a clinical term that refers to difficulty in swallowing. It may be caused by various pathologies including neuromuscular disorders and diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson disease, and myasthenia gravis. Other etiologies for dysphagia include stroke, traumatic brain injury, head and neck tumors, ageing, generalized weakness, and other non-neurogenic causes. Dysphagia may have a major impact on the quality of life of patients and can lead to malnutrition, dehydration, or aspiration pneumonia (Park 2016).

Dysphagia may occur at any phase of the swallowing process; in the oral phase when impaired lingual movements may lead abnormal bolus formation and manipulation; in the pharyngeal phase due weakening of the pharyngeal constrictors that are crucial for the transfer of the oral bolus from the mouth to the esophagus,

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decreased hyoid bone movement, and delayed laryngeal movements leading to pharyngeal residues and aspiration; or in the esophageal stage due to impaired upper esophageal sphincter movements.

Swallowing difficulty in ALS patients may result from weakness and/or spasticity of the muscles of deglutition, including the muscles of mastication, the tongue, lips, pharynx and larynx. In addition, weakness of the respiratory and ventilatory muscles impairs the airway protection by reducing the expiratory pressure needed to produce effective cough. In MS, the swallow coordination can be disrupted by demyelination of the corticobulbar tracts, cerebellar and/or brainstem involvement and the weakness or paresis of the muscles important for the swallow function. Research showed that disruption of the neuromuscular sequencing of pharyngeal and laryngeal events during swallow occurred in up to 90% of individuals with MS. In addition, similar to ALS, the reduced strength of the expiratory muscles not provide sufficient pressure for cough production and airway clearance. The pathophysiology of oropharyngeal dysphasia in Parkinson's disease is not clearly understood but is postulated to be due to dysfunction of the brain stem, degeneration of the substantia nigra, as well as disturbance of nondopaminergic neural networks (Van hooren 2014, Park 2016, Byeon 2016, Plowman 2016, Silverman 2017).

Management of dysphagia can be broadly divided into two approaches: 1. The remedial approach with the goal of improving swallowing function through different exercises; and 2. The compensatory approach that aims at safer swallowing e.g. by controlling the material and viscosity of the food, and the use of specific postural techniques and maneuvers during the food intake. The compensatory approaches, however, have a temporary effect and cannot induce recovery of the damaged swallow network. Investigators have thus focused on the remedial approaches that aim at restoration of function. Different new therapeutic modalities for managing swallowing in neurologic disorders have been developed and introduced to practice in the recent years, such as neuromuscular electrical stimulation, deep brain stimulation, respiratory muscle training, and others (Byeon 2016, Park 2016).

Recently expiratory muscle strength training (EMST) has emerged as a potential remedial therapy for swallowing disorders. It is an exercise program that focuses on increasing the force-generating capacity of the expiratory muscles during breathing with the aim of improving the maximum expiratory pressure, voluntary coughing effectiveness, as well as improving displacement of the hyoid during swallowing. Researchers explained that during the swallowing process suprahyoid muscle contraction in the pharynx pulls the hyoid bone in the anterior superior direction, and that sufficient movement of the hyoid bone in this direction is associated with airway protection and safe swallowing such as opening of the upper esophageal sphincter during swallowing. Neurogenic disorders may result in weakness of the suprahyoid muscles (anterior belly of the digastric, mylohyoid, and geniohyoid muscles) that are important for coughing and breathing out forcefully and swallowing. Weakness of these muscles leads to insufficient movement of the hyoid bone and in turn reduces the cough capacity and airway clearance. Activation of the suprahyoid muscles during EMST is thus believed to be effective in improving swallowing. It was initially investigated in the early 2000s by a team of researchers in Florida as a swallowing rehabilitation intervention in patients with Parkinson's disease (Pitts 2012, Laciuga 2014, Eom 2017, Moon 2017, Park 2016, Pearson 2017, Silverman 2017).

Expiratory muscle training is performed by hand-held resistive or pressure threshold devices. The resistance-based devices rely on adjusting the diameter of the airflow vent holes in the device. Reducing the dimeter of the vent holes imposes resistance requiring increases respiratory muscle force. These devices have no threshold for the user to overcome and can be ineffective for strength training if used with inadequate airflow. Pressure-threshold devices on the other hand, rely on the pressure exerted during expiration. The device has a pressure threshold relief valve that opens only when a sufficient expiratory pressure is generated by the user during a forceful expiration into the device.

EMST150 device (Aspire Products, LLC; Gainesville, Florida) is a pressure-threshold handheld calibrated device that includes a one-way, spring-loaded valve with an adjustable external dial. The valve blocks the flow of air until enough pressure is produced. Once the targeted pressure is produced, the valve opens, and air begins to flow through the device. The latter allows adjusting the pressure amount in a range between 0 and 150 cm H2O. The pressure-threshold load is based on the patient's maximum expiratory pressure (MEP) obtained through a pressure manometer. During training the pressure threshold device is adjusted incrementally to progressively increase the resistance (progressive overload). The expiratory force must be sufficient to open the spring-loaded valve and allow the air flow. The pressure released valve requires a consistent flow of air to remain open. If the expiratory force is inadequate, the valve will not open and no air will flow through the device. These mechanics may serve as a biofeedback during the use of the device. The "dose" of EMST is typically defined in terms of the number of repetitions per set, with 5 sets completed each day, for 5 days per week with the device resistance set at 75% of the patient's MEP and progressed each week (Pitts 2009, Troche 2010, Brooks 2017).

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When training ceases or the body undergoes a long period of detraining (inactivity) following a period of physical training, it loses some or all the positive gains achieved during training. This suggests that training should take place continually to maintain the benefits of an exercise program, particularly in individuals with neurodegenerative disease (https://emst150.com/faq/)

EMST is a form of therapy and is not subject to FDA regulations. The technology has not been previously reviewed by MTAC it is being reviewed based on a request form the Clinical Review Unit for decision support.

Medical Technology Assessment Committee (MTAC)

Date: 07/09/2018 MTAC REVIEW

Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders

Evidence Conclusion:

The published studies that investigated the benefit of expiratory muscle strength training in patients with dysphagia due to neurogenic disease are limited in quantity and quality. The majority examined pre-post effect of EMST among patients with swallowing disorders secondary to Parkinson's disease (PD) and were conducted by the team of investigator who developed the EMST150 device. The published RCTs that used EMST in patients with PD or other neurologic disorders compared the therapy to sham treatment and not to any other remedial or compensatory approaches to determine whether it has equivalent or superior effect to the traditional therapies used for the management of dysphagia. The trials were too small with attrition bias and examined the effect of the therapy only for the duration of expiratory training (4-5 weeks), which does not allow examining the durability of effect after discontinuation of the therapy. In addition, the published trials generally included patients in the early stages of the disease/disorder or those with mild to moderate dysphagia and may not be generalized to more severe or advanced cases who may not benefit from or tolerate the treatment.

Effects of EMST on dysphagia secondary to Parkinson's disease

Troche et al's, 2010 RCT (Evidence table 1) compared EMST versus sham treatment in 68 participants with mild to moderate dysphagia secondary to Parkinson's disease. The primary outcome was improvement in swallowing safety using penetration-aspiration score (PAS). Secondary outcomes included swallow physiology as assessed by hyoid movement and UES opening, as well as swallow quality of life and respiratory measure (maximum expiratory pressure [MEP]).

After 4 weeks of active or sham EMST training, patients in the active therapy group showed statistically significant improvement in in the PAS compared to baseline values, while those undergoing sham therapy group did not show a significant improvement. The authors calculated a NNT of 5 to gain on additional improvement and a NNT of 2 for a net benefit improvement with the use of EMST. The results also showed that EMST group had significant improvements in the upper esophageal sphincter (UES) opening, UES widest, and UES closure, but with no significant improvement in hypoid elevation duration. Both the active and sham therapy groups showed some improvement in the swallow quality of life. The adherence to therapy and adverse events were not discussed.

The study was randomized and controlled. However, it was a short-term study that compared EMST to a sham treatment and not to an alternative active therapy. In addition, the authors compared pre-post outcomes within each group and not between groups. The trial included patients with mild to moderate impairment in swallowing due to PD and its results may not be generalized to severe swallowing impairment in patients with PD, or to swallowing dysfunction due to other diseases or disorders.

A very small follow-up study (Troche, 2014) explored changes in MEP and PAS three months after the end of EMST training among 10 participants selected from the original trial and showed no statistically significant deterioration in MEP or PAS three months post completion of the EMST regimen. The authors reported that the detraining effects on swallow safety was less clear and concluded that the results of this study indicate that there is a need for the development of maintenance programs to sustain function following intensive periods of training. It is worth noting that the device used in the trial EMST150 was initially developed by the principal investigators of the trial.

In a study published by a single author (Byeon, 2017), 33 patients with dysphagia caused by Parkinson's disease were randomly assigned to receive EMST using EMST150 device (n=18) or EMST plus postural techniques (n=15). The postural techniques included chin tucking, head rotation, head tilting, bending head back and lying down straight for 30 minutes per session. The therapy was given 5 days a week for 4 weeks. The primary outcome was swallowing recovery measured by video fluoroscopic studies (VFS). The results of the trial showed a decrease in mean VSF scale score in both groups after treatment, but the decrease in the combined intervention group was significantly greater than in the EMST-only group. the study was a small RCT, with short follow-up duration, and conducted mainly among men, all of which would limit generalization of the results.

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Effects of EMST on dysphagia secondary to stroke
There were three smalls RCTs, (Park et al, 2019 [n=27] Moon et al, 2017 [n=18] and Eom et al, 2017 [N=40]) published to date, that investigated the effect of a 4-week EMST on suprahyoid muscle activity and airway aspiration in patients with oropharyngeal dysphagia secondary to acute/subacute stroke. The trials were conducted by the same team of principal investigators in university hospitals in Korea, which makes it difficult to rule out a potential overlap between the participants. All three trials had similar protocol, intervention, outcome measures, and results. To avoid introducing bias by duplication the results for the overlapping participants, the largest and most recent trial (Eom et al, 2017) was selected for critical appraisal.
Eom and colleagues' trial (2017) (Evidence table 2) randomized 33 patients >65 years of age with dysphagia due to stroke to undergo active EMST therapy using EMST150 device or to a sham therapy using a nonfunctional EMST system with no loading device. The two groups underwent training for 4 weeks (5 sets of 5 breaths 5 days a week for 4 weeks). All participants were assessed by fluoroscopic swallowing study (VFSS) before and after the intervention. The primary outcome was improvement in swallowing assessed by video fluoroscopic scale (VDS) and safety measured by in laryngeal penetration score (PAS). Only 26 (78.8%) of the participants completed the study.
The overall results of the study showed that the 2 groups improved in both the oral and pharyngeal phases of the VDS and the PAS after the 4 weeks of therapy compared to baseline. The improvements observed were significantly better in the active treatment group.
The study was randomized, controlled, and had objective outcomes. However, it was a very small trial, conducted among patients with subacute stroke and the improvement, as observed in the placebo group, may be due to the natural neurological recovery of the condition and not due to the intervention. In addition, the study period was only four months and insufficient to determine the long-term durability of the observed effects.
Effects of EMST on dysphagia secondary to multiple sclerosis

Silverman and colleagues' (2017) sham controlled RCT (Evidence table 3) examined the effect of EMST on the swallowing function and swallow-related quality of life in 42 patients with MS. 36 completed the maximum pressure expiratory (MEP) test and were randomized, and n=32 completed 5-week study. Sixteen patients underwent EMST using the EMST150 device and twenty patients underwent a sham therapy using the EMST150 device without an internal pressure threshold spring. All participants were instructed to complete 5 sets of five repetitions (total of 25 times in approximately 20 minutes /day) 5 days a week for 5 weeks. The primary outcomes were the change in MEP, penetration aspiration score (PAS), and improvement swallow quality-of-life (SWAL-QOL). MEP was obtained weekly to monitor and adjust the device, and video fluoroscopy was used to record swallow function and measure PAS.
The overall results showed improvement in MEP in the two study groups with no significant difference between them. The improvement in the sham group and lack of statistical significance between the 2 groups suggests that simple expiratory breathing alone without the positive pressure load can improve the MEP in patients with MS. The results also show that PAS improved in 40% in the EMST and 14% in the sham group. There was no significant difference between the 2 groups in the total swallow score.
The study was randomized, controlled, blinded, and had objective outcomes. However, it was a very small trial, with no power analysis, unclear method of randomization and allocation concealment, only 76% of the enrolled participants completed the trial, and there was no ITT analysis. In addition, the study period was only five weeks, does not allow examining the long-term durability of observed benefit, and the authors had financial ties with the industry.

Conclusion:
- There is no published evidence to date to determine that EMST is superior or equivalent to other remedial or compensatory approaches used to manage swallowing disorders in patients with neurogenic disease or disorders.
- There is low-quality evidence showing that EMST may improve short-term swallowing outcomes, compared to no treatment in selected patients with mild to moderate dysphagia secondary to Parkinson's disease,
- There is low-quality evidence showing that EMST may improve short-term swallowing outcomes in patients with dysphagia secondary to acute/subacute stroke, compared to no active treatment. The benefits observed in the sham therapy groups may suggest that the EMST has a placebo effect, or that dysphagia may improve as a natural recovery of the condition and not due to the intervention.
- The benefits observed in the sham therapy groups in neurogenic conditions other than stroke may also indicate a placebo effect of the EMST, or that expiratory breathing alone without the positive pressure load can improve the MEP.

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- There is insufficient evidence to determine whether the short-term benefits observed with EMST therapy compared to sham treatment would last after treatment cessation.
- Adverse outcomes were not reported in any of the trials.

The use of Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders doesn't meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

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Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018 MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC	08/07/2018

MPC Medical Policy Committee

Revision History	Description
08/07/2018	Added MTAC review from 7/9/18 and created document

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KAISER PERMANENTE®

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Clinical Review Criteria
Extracorporeal Photopheresis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Extracorporeal Photopheresis (110.4)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Extracorporeal Photopheresis for Acute and Chronic Graft vs. Host
Medical necessity review no longer required for this service.

Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)
Must meet **ALL of the following**:

A. The extracorporeal device must be FDA approved;
B. The patient has cutaneous t-cell lymphoma that has not responded to other forms of treatment;
C. The use is for palliative treatment of associated skin manifestations.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Extracorporeal photopheresis (ECP) is a treatment modality for graft-versus-host disease (GVHD) and cutaneous t-cell lymphoma (CTCL). CTCL refers to several clonal t-cell malignancies that primarily manifest as skin conditions. GVHD is a complication of allogenic stem cell transplantation.

Extracorporeal photopheresis (ECP) is one of the treatment options for refractory acute and chronic GVHD. ECP involves removing the patient's peripheral blood and separating it into leukocyte-depleted blood and leukocyte-enriched plasma. The leukocyte-depleted blood is returned to the patient. The leukocyte-enriched plasma is exposed to ultraviolet light in the presence of an extracorporeally administered photosensitizing agent, 8-methoxypsoralen (8-MOP). The cells are then re-infused into the patient and die in one-week period. During that week, they are capable of stimulating an anti-idiotypic t suppressor response. The exact mechanism of action of ECP is not known. The Therakos Photopheresis System is FDA approved as a class III medical device specifically for photopheresis (Greinix et al., 2000; Woltz et al., 2006).

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There are no agreed-upon standards for the optimal frequency and duration for ECP treatment in patients with chronic GVHD, and there is wide variability in practice. Patients may be treated two or three days a week every two to three weeks for 3 to 30 months (Woltz et al., 2006).

Extracorporeal photopheresis (ECP) is also a treatment option for CTCL. ECP involves removing a portion of the patient's blood and separating into red and white blood cells by centrifugation. The red cells are returned to the patient. The white cells are mixed with a photosensitizing agent, 8-methoxypsoralen or methoxsalen (Uvadex, Therakos), and irradiated with ultraviolet light (UVA light, 320-400 nm). When activated, the photosensitizing agent binds with the cellular DNA of the white cells and accelerates their death. The altered cells are then re-infused into the patient. The intention is that these cells will stimulate an immune response against the damaged pathogenic t cell clones. In the pivotal study upon which FDA approval was based, a case series with 37 patients by Edelson and colleagues, a greater treatment effect was seen in patients with erythrodermic CTCL (later-stage disease) compared to those with plagues or tumors. This distinction has been difficult to confirm in later case series because studies generally include patients at different stages of clinical disease and do not report findings separately by disease stage. The effectiveness of ECP for treating CTCL, particularly Sezary Syndrome, continues to be debated in the literature. Some of the controversies are whether prior treatment with systemic corticosteroids and systemic chemotherapy reduces the effectiveness of ECP and which sub-groups of patients are most likely to benefit from ECP treatment. To date, there have not been any randomized controlled trials comparing ECP to other treatments for CTCL (Apisarnthanarax et al., 2002; Russell-Jones, 2000; FDA Web site; Therakos Web site).

The FDA has approved the photopheresis device UVAR and the photosensitizing Uvadex (both by Therakos) for the palliative treatment of skin manifestations of cutaneous t-cell lymphoma that has not responded to other forms of treatment. ECP is covered by Medicare for the same indication.

Evidence and Source Documents

Extracorporeal Photopheresis for Acute and Chronic Graft vs. Host Disease
Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)

Medical Technology Assessment Committee (MTAC)

Extracorporeal Photopheresis in the Treatment of Acute and Chronic Graft Versus Host Disease

BACKGROUND

Graft-versus-host disease (GVHD) is a complication of allogenic stem cell transplantation (SCT). There are two forms of GVHD, acute and chronic. Acute GVHD occurs within the first 100 days of transplantation. In acute GVHD, the T-lymphocytes from the donor recognize tissues or cells in the recipient as foreign and produce a multi-organ (i.e. skin, liver, intestines) autoimmune-like syndrome. The T-lymphocytes use information from genetic markers known as human leukocyte antigens (HLA) to detect differences. Even when donors are matched for HLA markers, GVHD can occur because minor differences in these markers could still exist. Efforts to prevent acute GVHD include using closely matched donors, umbilical cord blood and/or post transplant immunosuppression with drugs including cyclosporine and methotrexate. Acute GVHD is commonly treated with corticosteroids which produce sustained responses in 50-80% of patients depending on the initial severity of disease. Second-line therapy includes different combinations of immunosuppressive agents. Newer treatments include infusion of mesenchymal stem cells (MSC), down-regulation of antigen-presenting cells (APC) and suicide gene transduced T cells (Bacigalupo, 2007). Chronic GVHD can occur after the first 100 days post-transplant, either in patients who experienced acute GVHD or a de novo onset. It is the main cause of late morbidity and mortality after allogenic SCT. Chronic GVHD generally involves donor T cells expanding and attacking the host's immunologic system; its pathophysiology is poorly understood compared to acute GVHD (Woltz et al., 2006; PerezSimon et al., 2006). Standard first-line treatment for chronic GVHD includes prednisone alone or in combination with a calcineurin inhibitor such as cyclosporin or tacrolimus. A recent review article (Perez-Simon et al., 2006) states that there is no generally accepted salvage treatment for patients with chronic GVHD who do not respond to prednisone. Treatments that have been used for refractory chronic GVHD include mycophenolate mofetil, anti-interleukin-2a receptor antagonists, sirolimus, pentostatin, CD20 antagonists, tumor necrosis factor-a antagonists and extracorporeal photopheresis. Other, newer treatments include anti-CD25 immunotoxin and inhibition of nuclear factor-dB. The authors of the review article recommend that chronic GVHD patients enter clinical trials for salvage treatment if at all possible. Extracorporeal photopheresis (ECP) is one of the treatment options for refractory acute and chronic GVHD. ECP involves removing the patient's peripheral blood and separating it into leukocyte-depleted blood and leukocyte-enriched plasma. The leukocyte-depleted blood is returned to the patient. The leukocyte-enriched plasma is exposed to ultraviolet light in the presence of an extracorporeally administered photosensitizing agent, 8-methoxypsoralen (8-MOP). The cells are then re-infused into the patient and die in one-week period. During that week, they are capable of stimulating an antiidiotypic T

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suppressor response. The exact mechanism of action of ECP is not known. The Therakos Photopheresis System is FDA approved as a class III medical device specifically for photopheresis (Greinix et al., 2000; Woltz et al., 2006). There is no generally agreed-upon standards for the optimal frequency and duration for ECP treatment in patients with chronic GVHD, and there is wide variability in practice. Patients may be treated two or three days a week every two to three weeks for 3 to 30 months (Woltz et al., 2006). ECP for acute and chronic graft versus host disease was first reviewed by MTAC in 2002. At that time, the empirical evidence consisted of small case series, with sample sizes varying from 3 to 23. The item failed MTAC evaluation criteria, and the Health Plan Medical Directors decision was to review requests on a case-by-case basis. A new review is being requested due to the length of time since the previous review, and recent changes made to Medicare criteria. Medicare now covers ECP for patients with chronic GVHD whose disease is refractory to standard immunosuppressive drug treatment.

06/12/2002: MTAC REVIEW
Extracorporeal Photopheresis in the Treatment of Acute and Chronic Graft Versus Host Disease
Evidence Conclusion: There is not enough evidence to permit conclusions on the effectiveness of extracorporeal photopheresis for treating acute or chronic graft-versus-host disease.
Articles: The search yielded 16 articles. There were no randomized controlled trials. Seven of the articles were reviews or editorials, two were case reports and seven were small case series (varying in size from n=3 to n=23). Due to the low grade of evidence and the small size of the studies, no evidence tables were created.

The use of extracorporeal photopheresis in the treatment of acute and chronic graft versus host disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/20/2007: MTAC REVIEW
Extracorporeal Photopheresis in the Treatment of Acute and Chronic Graft Versus Host Disease
Evidence Conclusion: The published studies that evaluated actigraphy for the assessment of insomnia were conducted on selected groups of patients and used different actigraph models, software, and scoring algorithms. Most studies were conducted in sleep laboratories where recording conditions are standardized, and the artifacts controlled. These controls would be lost when the actigraphy devices are used in the home environment, where it is intended for use. Also, the algorithms that were validated for a specific model, mode of operation, or in a selected population may by not be equally accurate when used with a different brand of device, different gender or age group. The studies reviewed compared actigraphy to PSG, but the authors did not indicate whether the investigators interpreting the results of one test were blinded to the results of the other. The overall results of the studies reviewed, indicate that compared to polysomnography, actigraphy had a high sensitivity (92-98%) but very low specificity (28-48%) in detecting insomnia. It was also found to overestimate the total sleep time and sleep efficiency. Actigraphy tends to overestimate sleep in people with insomnia when they are lying quietly as quiet wakefulness could be miscoded as sleep. Insomnia patients can remain inactive for a period of time attempting to fall asleep on the other hand actigraphy may underestimate the amount of sleep and overestimate the duration awake among those who are asleep but are restless or have large amounts of movements during sleep. The use of actigraphy for the assessment of periodic leg movements in sleep was evaluated in only a few small studies with methodological limitations. It was compared with polysomnography with bilateral anterior tibialis electromyelography (BATEMG). However, EMG and leg actigraphy are not interchangeable, and each measures a different event. One records electrical activity of a certain muscle and the other records leg acceleration. Leg activity may be due to movement artifacts produced by obstructive sleep apnea. Kemlink et al (2007) did not exclude patients with suspicious sleep apnea and did not adjust for it in the analysis. In conclusion there is insufficient evidence to determine that actigraphy would replace PSG or add to its value in the diagnosis and management of patients with sleep disorders.
Articles: No randomized or non-randomized controlled trials were identified. The empirical evidence continues to consist of case series. The largest case series on ECP for acute GVHD (n=59) and for chronic GVHD (n=71) identified in the search were critically appraised. In addition, a case series on ECP in pediatric patients with either acute or chronic GVHD (n=77) was critically appraised. There were additional smaller case series. The studies reviewed include: Greinix HT, Knobler RM, Worel N et al. The effect of intensified extracorporeal photochemotherapy on long-term survival in patients with severe acute graft versus host disease. Stem Cell Transplant 2006; 91: 405-408. See Evidence Table. Couriel DR, Hosing C, Saliba R et al. Extracorporeal photochemotherapy for the treatment of steroid resistant chronic GVHD. Blood 2006; 107: 3074-3080. See Evidence Table. Messina C, Locatelli F, Lanino e et al. Extracorporeal photochemotherapy for pediatric patients with graft versus host disease after hematopoietic stem cell transplantation. Br J Hematol 2003; 122 118-127. See Evidence Table.

The use of extracorporeal photopheresis in the treatment of acute and chronic graft versus host disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*
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Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)

BACKGROUND

Cutaneous T-cell lymphoma (CTCL) refers to several clonal T-cell malignancies that primarily manifest as skin conditions. The classical subsets of CTCL include mycosis fungoides (MF), the most common form, and Sezary Syndrome (SS). MF usually presents as chronic eczematous or psoriasiform patches or plaques whereas SS is characterized by erythroderma and leukemia. SS is sometimes viewed as an advanced form of MF. According to the CTCL disease staging system (stage IA-IVB), patients with Sevary Syndrome have stage IV disease. (Apisarnthanarax et al., 2002; Duvic et al., 2003; RussellJones et al., 2000). Therapeutic options differ according to clinical disease stage. Early patch-plaque MF (Stage 1 and IIA) is generally a benign and chronic condition and can be treated with conservative therapies such as topical corticosteroids, retinoids and mechlorethamine (nitrogen mustard). Early stage disease can also be treated with ultraviolet B (UVB) phototherapy or psoralen plus ultraviolet A photochemotherapy (PUVA). Some of the treatments used in early stage disease, such as PUVA or oral bexarotene, are also used for later stage disease but may be less effective. Historically, the most common treatment for late-stage disease (Stage IIB-IVB) is chemotherapy. No single-agent or multi-agent regimen has been shown to be clearly superior to the others. Disadvantages of systemic chemotherapeutic agents are that they have immunosuppressive effects which can lead to opportunistic infections, sepsis or death (Apisarnthanarax et al., 2002). Extracorporeal photopheresis (ECP) is another treatment option for CTCL. ECP involves removing a portion of the patient's blood and separating into red and white blood cells by centrifugation. The red cells are returned to the patient. The white cells are mixed with a photosensitizing agent, 8-methoxypsoralen or methoxsalen (Uvadex, Therakos), and irradiated with ultraviolet light (UVA light, 320-400 nm). When activated, the photosensitizing agent binds with the cellular DNA of the white cells and accelerates their death. The altered cells are then reinfused into the patient. The intention is that these cells will stimulate an immune response against the damaged pathogenic T cell clones. In the pivotal study upon which FDA approval was based, a case series with 37 patients by Edelson and colleagues, a greater treatment effect was seen in patients with erythrodermic CTCL (later-stage disease) compared to those with plagues or tumors. This distinction has been difficult to confirm in later case series because studies generally include patients at different stages of clinical disease and do not report findings separately by disease stage. The effectiveness of ECP for treating CTCL, particularly the following information was used in the development of this document and is provided as background only. Sezary Syndrome continues to be debated in the literature. Some of the controversies are whether prior treatment with systemic corticosteroids and systemic chemotherapy reduces the effectiveness of ECP and which sub-groups of patients are most likely to benefit from ECP treatment. To date, there have not been any randomized controlled trials comparing ECP to other treatments for CTCL (Apisarnthanarax et al., 2002; Russell-Jones, 2000; FDA website; Therakos website). The FDA has approved the photopheresis device UVAR and the photosensitizing Uvadex (both by Therakos) for the palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other forms of treatment. ECP is covered by Medicare for the same indication. Extracorporeal photopheresis for CTCL has not been reviewed previously by MTAC. ECP for the treatment of graft versus host disease was reviewed by MTAC in June, 2002.

06/05/2006: MTAC REVIEW

Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)

Evidence Conclusion: There are no randomized controlled trials evaluating the efficacy of extracorporeal photopheresis for treating patients with CTCL. The published literature consists of small, predominantly retrospective case series. The ECP treatment protocol was similar in the case series that were reviewed, generally consisting of treatment every 4 weeks with a tapering off by lengthening treatment intervals in patients who achieved a response. Data from case series suggests that ECP might be helpful for treating skin manifestations of CTCL, the FDA approved indication. However, there are no data on the efficacy of ECP for skin conditions compared to an alternative treatment or no treatment. In the single prospective study, 27/37 patients had a positive response to treatment, defined as at least a 25% reduction in the skin score. 24/29 patients with erythroderma had a positive response after a mean follow-up of 42 weeks (Edelson et al., 1987). A study published 5 years later on the 29 patients with erythroderma (Heald et al., 1992) found that most of the patients had at least some improvement in skin manifestations of CTCL and 6 had a complete remission. It is not possible to draw conclusions about survival after ECP treatment due to the lack of comparative data from RCTs. Predicted median survival using life-table analysis in the Heald/Edelson study was 60 months from time of diagnosis of the erythrodermic state. One of the case series (Fraser-Andrews et al. 1998) included a non-randomized comparison group of patients who did not receive ECP treatment. They did not find a statistically significant difference in median length of survival from time of SS diagnosis in the two groups (39 months in ECP-treated patients vs. 26.5 months in non-ECP treated patients, p=0.12). Other than a lack of randomization, limitations of the Fraser-Andrews study was the wide variety of other treatments patients received before, during and after ECP treatment, or instead of ECP treatment. It is difficult to attribute a response to the ECP treatment itself. The limited data on use of ECP for CTCL identified few adverse effects.

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Articles: No randomized controlled trials were identified. The empirical studies were all case series, each with a sample size of less than 50. Desirable features of case series were prospective design, larger sample size, clear eligibility criteria, longer follow-up and survival included as an outcome. Three studies included survival as an outcome in addition to treatment response, had sample sizes n>25 and had reasonably long-term follow-up; however, only one of them was prospective. These three studies were critically appraised. The prospective study reporting on patient survival was the original Edelson (1987) study, with follow-up data reported by Heald and colleagues in 1992. Excluded studies include a prospective study that included only 14 patients and a small (n=20) study that included survival as an outcome but was retrospective and did not specify eligibility criteria. *Studies reviewed include:* Heald P, Rook A, Perez M et al. Treatment of erythrodermic cutaneous T-cell lymphoma with extracorporeal photochemotherapy. J Am Acad Dermatol 1992; 27: 427-433. (Follow-up of Edelson R et al. NEJM 1987; 316: 297-303). See Evidence Table. Gottlieb SL, Wolfe JT, Fox FE et al. Treatment of cutaneous t-cell lymphoma with extracorporeal photopheresis monotherapy and in combination with recombinant interferon alfa: A 10-year experience at a single institution. J Am Acad Dermatol 1996; 35: 946-957. See Evidence Table. Fraser-Andrews E, Seed, P, Whittaker S. et al. Extracorporeal photopheresis in Sezary syndrome. Arch Dermatol 1998; 134: 1001-1005. See Evidence Table.

The use of extracorporeal photopheresis in the palliative treatment of cutaneous T-cell lymphoma lesions does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
36522	Photopheresis, extracorporeal

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Date Created	Date Reviewed	Date Last Revised
06/12/2002	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 12/03/2013[MPC] ,10/07/2014[MPC], 08/04/2015[MPC], 11/01/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	08/20/2007

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Fecal Microbial Transplant for Treatment of C. Difficile Infection

- Fecal GI Infusion
- Fecal Capsule (G3 OpenBiome)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Medical Policy Clinical Review Criteria, ***Fecal GI Infusion for the Treatment of C. Difficile Infection,*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Fecal GI Infusion	Fecal GI infusion is covered when **ALL of the following** are met: 1) Clostridium difficile infection confirmed by a positive stool test for *C.* difficile toxin 2) Has had at least two recurrences following adequate antibiotic therapy This would be defined as a symptomatic toxin-positive failure after at least one prolonged tapering course of vancomycin (generally over a 4-6-week period).
FMT capsule, G3 OpenBiome	If the above criteria are met, oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory clostridium difficile infection is covered.

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Background

Clostridium difficile (C difficile) is the leading cause of antibiotic associated diarrhea and its rates continue to rise. During the past several years, the incidence of C difficile infection (CDI) has increased to an epidemic level; it has become more severe, more refractory to standard treatment, and more likely to relapse. According to the CDC, the number of hospitalized patients with any CDI discharge diagnoses more than doubled from approximately

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139,000 to 336,600, and the number with a primary CDI diagnosis more than tripled, from 33,000 to 111,000 from 2000 to 2009. This rise in incidence and severity of the disease is possibly associated with the emergence of the hypervirulent strain (NAPI/ribotype 027). CDI is responsible for a spectrum of infections including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon, which may lead to sepsis and even death. It often occurs in patients in health-care settings where antibiotics are prescribed, and symptomatic patients are concentrated. The most common risk factor for CDI is the use of broad-spectrum antibiotics or the concomitant use of multiple and prolonged antimicrobials. Other risk factors include advanced age (65 years or older), recent organ transplantation, gastrointestinal surgery, inflammatory bowel disease, immunosuppressive drugs, presence of multiple co-morbidities, and others. Mature colonic bacterial microbiota (community of micro-organisms) in a healthy adult is generally resistant to C difficile colonization. Any factor altering the balance of intestinal microbiota leads to a selective advantage and colonization by C difficile colonization after exposure to the bacteria
The standard treatment for C difficile associated disease includes discontinuation of offending/inducing antibiotic and treatment with metronidazole or vancomycin. Most patients initially respond to this therapy, but 15-30% experience a symptomatic recurrence after discontinuation of the treatment. The risk of recurrence rises to 40% after a first recurrence and to more than 60% after two or more recurrences. The increased incidence and severity of CDI, and the high recurrence rate with conventional treatments have led researchers to explore alternative strategies and therapies with varying degrees of success. These include the use of additional courses of metronidazole and vancomycin, pulsed/tapered antibiotics, the use of new drugs as nitazoxanide and fidaxomicin, immune therapy such as IV immunoglobulin, active immunization, toxin binding, and alternative approaches as the use of probiotics (such as lactobacillus species, which is a low-virulent microorganism that could compete with C difficile for nutrients and sites of mucosal adherence), and fecal transplantation to recreate the colonic environment (Brandt 2012, Guo 2012, Kassam 2011, 2013).

Fecal transplantation (FT), also known as fecal microbiota transplantation (FMT), fecal bacteriotherapy, fecotherapy, fecal microbiota reconstitution, or human probiotics infusion, refers to the process of instilling a liquid suspension of stool from a healthy donor into the gastrointestinal (GI) tract of another person, theoretically to promote normalization of flora and restore the intestinal microbiota. It is of particular utility in recurrent or refractory C difficile infection. The exact mechanism of FMT in treating CDI is not clear but may involve the re-colonization of microbiota with missing components to generate colonization resistance or direct antagonistic activity of the normal microbiota to C difficile. There is also the possibility that the transplantation of donated flora results in an immunological response facilitating the eradication of C difficile. The re-establishment of the normal composition of the intestinal flora by the use of human fecal microbiota was first used by Ben Eiseman in 1958 for the treatment of four patients with pseudomembranous colitis. Lately, FMT has received more attention with the publication of promising results of case series. It is however, not widely accepted as a therapeutic tool due to lack of published trials with long-term outcomes and concerns regarding its safety and acceptability (Guo 2012, Matilla 2012).

There is no clear definition of CDI, its recurrence, relapse or re-infection, and there is no standardized protocol for FMT as regards the choice of donor (family member or volunteer donor), screening of donors, quantity and preparation of stools collected, form of infusion, and measurement of outcomes. There is also no consensus on the most appropriate form of delivery for the fecal microbiota. Until 1989 retention enema was the most common route for FMT; subsequently it was infused via nasogastric tube, colonoscopy and more recently self-administered enemas. The colonoscopic approach seems to be the most common and favored approach as it allows the examination of the disease extent and inoculation of the entire colon and ileum. Regardless of the delivery method, the steps of the procedure are similar and include evaluating the patient eligibility, patient consent, identification and screening of donors, preparation of the sample, and infusion of the suspension prepared. Donor stool is most often used within 8 hours of passage, but frozen samples have been thawed and used 1-8 weeks after passage. Stool is commonly suspended in saline; however, water, milk, and yogurt have also been used as diluents. The suspension is filtered through gauze pads or strainer, and then aspirated into syringes for use. The volume of stool suspension used for FMT varied between studies from less than 200 ml to 500 ml or more. Patients undergoing FMT typically remain on their CDI antimicrobials until 2-3 days prior to the procedure. Bowel preparation is performed regardless of the route. If infused via nasogastric tube, the suspension is applied after fitting the tube in place. After the infusion the tube is rinsed with saline solution and removed. If applied via colonoscopy, the colonoscope is inserted and advanced to the terminal ileum, and then working backwards the stool suspension is administered, most in the terminal ileum and ascending colon. The aftercare requires regular clinical checkups and testing the stools for C difficile. The risk of the procedure includes risks associated with application as perforation and hemorrhage, as well as the risk of microbial translocation and sepsis. FMT is relatively contraindicated in patients with severe comorbid conditions or those taking immunosuppressants, though such patients have been successfully treated with the fecal transplant (Brandt 2011, Gough 2011, Postigo 2012, Rohlke 2012, Kleger 2013, Aroniadis 2013).

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Fecal transplantation is not regulated by FDA, to date, as fecal matter is organic. According to the FDA the complex nature of FMT products presents specific scientific and regulatory challenges. The Center for Biologics Evaluation and Research (CBER), together with the National Institute of Allergy and Infectious Disease (NIAID) are holding a public workshop in May 2013, to facilitate clinical development of FMT.

Medical Technology Assessment Committee (MTAC)

Fecal GI infusion for the Treatment of C. Difficile infection

04/15/2013: MTAC REVIEW

Evidence Conclusion: There is some evidence from one small RCT that fecal transplantation has a significantly higher success rate than vancomycin in treating patients with recurrent C difficile infection. Meta-analyses of case series with no control groups also show a high cure rate of recurrent CDI with FMT. There is insufficient evidence to determine whether FMT is effective for the treatment of patients with the more virulent strain ribotype 027 C difficile. There is insufficient evidence to determine the most effective and safe modality for delivering the FMT. There is insufficient evidence to determine the long-term efficacy and safety of FMT.

Articles: The literature search for studies on fecal transplantation for the treatment of *C difficile* infection revealed one recent RCT (van Nood 2013), and four systematic reviews (Gough 2011, Guo 2012, Kassam 2013 and Sofi 2013). The latter two pooled the results of the published studies in meta-analyses. Sofi and colleague's analyses combined the results of case series and case reports, while Kassam and colleagues excluded the small case series (<10 subjects) and case reports in an attempt to minimize bias. The search also identified a review comparing nasogastric versus colonoscopic FMT (Postigo 2012), and a protocol for a Cochrane review, which is still being prepared. van Nood 2013 RCT, and the Kassam and colleagues' meta-analysis that had a more valid methodology were selected for critical appraisal: van Nood E, Vrieze A, Nieuwdorp M, et al. Duodenal infusion of donor feces for recurrent Clostridium difficile, *N Engl J Med.* 2013; 368:407-415. See Evidence Tables. Kassam Z, Lee CH, Yuan Y et al. Fecal Microbiota Transplantation for Clostridium difficile Infection: Systematic Review and Meta-Analysis. *Am J Gastroenterol* 2013; Mar 19. doi:10.1038/ajg.2013.59 See Evidence Tables.

The use fecal GI infusion for the treatment of C. difficile infection meets the *Kaiser Permanente Medical Technology Assessment Criteria*.

Oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory clostridium difficile infection

BACKGROUND

Clostridium difficile (*C difficile*) infection (CDI) is one of the most prevalent hospital acquired infections in the United States and is the leading cause of antibiotic associated diarrhea. The incidence of *C*DI has increased to an epidemic level; it has become more severe, more refractory to standard treatment, and more likely to relapse. According to the CDC, CDI was estimated to have caused almost half a million infections in the United States in 2011, and 29,000 deaths within 30 days of the initial diagnosis. It is believed that the rise in incidence and severity of the disease may be related to the emergence of the hypervirulent strain of the organism (NAP1/BI/027) that is particularly associated with higher rates of treatment failure and recurrence (Youngster 2014, Hirsch 2015, CDC webpage accessed November 2015). CDI is responsible for a spectrum of infections including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon, which may lead to sepsis and even death. It often occurs in patients in health-care settings where antibiotics are prescribed, and symptomatic patients are concentrated. The most common risk factor for CDI is the use of broad-spectrum antibiotics or the concomitant use of multiple and prolonged antimicrobials. Other risk factors include advanced age (65 years or older), recent organ transplantation, gastrointestinal surgery, inflammatory bowel disease, immunosuppressive drugs, presence of multiple co-morbidities, and others. Mature colonic bacterial microbiota (community of micro-organisms) in a healthy adult is generally resistant to colonization and overgrowth of pathogenic bacteria. Any factor altering the balance of intestinal microbiota allows pathogens such as *C difficile* to proliferate and dominate the gut ecosystem (Matilla 2012, Rohlke 2012, Sofi 2012, Brandt 2012, Kassam 2013, Hirsch 2015). The standard management of CDI includes discontinuation of offending/inducing antibiotic and treatment with metronidazole or vancomycin. Most patients initially respond to this therapy, but 15-30% experience symptomatic recurrence after discontinuation of the treatment. It is reported that antibiotics targeting CDI may eradicate the active infection, but do not restore the long-lasting dysbiosis of the microbiota, which is the major risk factor for relapse. This risk rises to 40% after a first recurrence and to more than 60% after two or more recurrences. The increased incidence and severity of CDI, and the high recurrence rate with conventional treatments have led researchers to explore alternative strategies and therapies with varying degrees of success. These include the use of additional courses of metronidazole and vancomycin, pulsed/tapered antibiotics, the use of new drugs as nitazoxanide and fidaxomicin, immune therapy such as IV immunoglobulin, active immunization, toxin binding, and alternative approaches such as use of probiotics as lactobacillus species, which is a low-virulent microorganism that could compete with *C difficile* for nutrients and sites of mucosal adherence, and fecal microbiota transplantation (Brandt

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2012, Guo 2012, Kassam 2013, Hirsch 2015). Fecal microbiota transplantation (FMT), also known as fecal transplantation (FT), fecal bacteriotherapy, fecotherapy, fecal microbiota reconstitution, or human probiotics infusion, refers to the process of transplantation of stools from a healthy individual into the gastrointestinal (GI) tract of the affected patient, theoretically to promote normalization of flora and restore the intestinal microbiota. It may be particularly useful in recurrent or refractory *C difficile* infection. The exact mechanism of FMT in treating CDI is not clear but may involve the re-colonization of microbiota with missing components to generate colonization resistance or direct antagonistic activity of the normal microbiota to *C difficile.* There is also the possibility that the transplantation of donated flora results in an immunological response facilitating the eradication *of C difficile.* The re-establishment of the normal composition of the intestinal flora by the use of human fecal microbiota was first used by Ben Eiseman in 1958 for the treatment of four patients with pseudomembranous colitis. Lately, FMT has received more attention with the publication of promising results of a small RCT and a number of case series (Guo 2012, Matilla 2012, van Nood 2013). There is no standardized protocol for FMT as regards the choice of donor (family member or volunteer donor), screening of donors, quantity and preparation of stools collected, form of infusion, and measurement of outcomes. There is also no consensus on the most appropriate form of delivery for the fecal microbiota. Traditionally FMT has been performed by transplanting a liquid suspension of feces from a related healthy donor into the gastrointestinal tract of the affected patient through nasogastric tube, endoscopy, enema, or colonoscopy. The traditional methods are time-consuming, may be technically challenging, unaesthetic, and not accepted by many patients (Brandt 2011, Gough 2011, Postigo 2012, Rohlke 2012, Kleger 2013, Aroniadis 2013). More recently, orally administered capsules containing cryopreserved fecal material have been described. The capsules are generally prepared using fecal material harvested from unrelated healthy donors fulfilling strict criteria including screening negative for HIV, hepatitis A, B, and C as well as Treponema pallidum. Fecal matter is collected under sterile conditions, combined with saline, processed, sieved, centrifuged, and mixed again with saline along with glycerol, to protect the biological material from becoming damaged when frozen. The fecal material is then dispensed into double or triple capsules and stored at -80°C (-112°F). The capsules should be kept frozen until the time of administration and ingested as quickly as possible after extraction from the freezer. Capsules may be kept at room temperature for up to 90 minutes for patient comfort and ease of swallowing. Another described method is the immediate freezing and storing of the fecal suspension or slurry in 5- or 10-ml syringes at -80°C then thawing and triple encapsulating it prior to its use. Capsules should never be refrozen and should be disposed of if not used within 90 minutes. OpenBiome (Boston, MA) a stool bank that created a fecal transplant pill (G3) recommends the intake 30 capsules, swallowed consecutively in a single session for the treatment of CDI (OpenBiome website, Youngster 2014, Hirsch 2015). FMT capsule G3 (OpenBiome) are size 00 (approximately the size of a large multivitamin) and are provided with two placebo test capsules. The patient is asked to ingest one test capsule prior to the start of treatment, under direct observation of the physician, to ensure the patient's ability to swallow. Any clinical concerns suggesting an aspiration risk is an absolute contraindication to capsule administration. Other contraindications include severe complicated CDI, dysphagia, history of gastroparesis, allergy to any of the ingredients, adverse events attributable to a previous FMT, and any condition that the treatment my pose a health risk (OpenBiome website). According to OpenBiome, FMT Capsule G3 may be used as a treatment for *C. difficile* infection not responsive to standard therapies in accordance with the FDA's guidance on the use of fecal microbiota for transplantation, and in clinical trials under an Investigational New Drug (IND) application.

12/21/2015: MTAC REVIEW

Oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory *clostridium difficile* infection

Evidence Conclusion: There is a lack of published studies on the use of oral cryopreserved FMT capsules for patients with relapsing or refractory CDI. Currently the literature on oral FMT capsules for patients with relapsing *C difficile* infection (CDI) consists of two small case series and one case report. Youngster and colleagues (2014) (evidence table 1), evaluated the safety and rate of resolution of diarrhea following the administration of cryopreserved FMT capsules in 20 patients (11-89 years of age) with refractory *C. difficile* infection. The oral capsulized FMT was prepared from stool samples gathered from healthy adult volunteers who had been comprehensively screened for infectious diseases and avoided eating common allergens for several days before donating. Each patient ingested 15 FMT capsules consecutively each day for two successive days. If their symptoms did not improve within 72 hours, they were offered a second course of treatment with fecal material from the same donor. They were followed-up for 6 months and the primary outcomes were safety and clinical resolution of diarrhea with no relapse at 8 weeks. The results of the study show that after the first 2 days of treatment, 14 of the 20 patients (70%) experienced clinical resolution of diarrhea, defined as less than 3 bowels movements /24 hours, and remained symptom free for 8 weeks. After a second course of treatment, four of the remaining patients became symptom free, resulting in an overall 90% rate of symptom resolution. No serious adverse events were reported. The study was a small observational study with no control or comparison group and relied on patient report on clinical outcomes. Patients with symptomatic improvement were not retested for *C difficile.* The authors indicated that it was a pilot feasibility study that only provides preliminary data on the safety

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and effectiveness of this the oral capsulized FMT. Hirsch et al, 2015 (Evidence table 2), conducted a chart review of 19 patients treated with orally administered FMT capsules for recurrent CDI. FMT was prepared from stools donated by healthy volunteers unrelated to the recipients. Before receiving the FMT, the patients were required to discontinue any CDI antimicrobial treatment for 24 hours and were given a proton pump inhibitor on the evening and morning prior to the therapy. After a light breakfast, they received 6-22 capsules of FMT under supervision in an outpatient setting and were instructed to sit upright and not eat for an hour after ingesting the capsules. Patients were encouraged to drink 4 oz. of fermented milk product twice daily and to consume pro-biotic nutrients for at least 3 days after the FMT. They were followed-up by phone interviews within 2 days, 3 weeks, and after 90 days to assess the response to the therapy and adverse events. Those with recurrent CDI were retreated with antimicrobial therapy and subsequently offered repeat FMT (approximately 6 weeks after the initial FMT) and followed up for an additional 90 days. The primary outcome was resolution of CDI associated diarrhea without relapse assessed at 90 days after the last FMT. 13 of the 19 patients treated (68%) responded to a single course, and four responded to the second course of therapy with a total response rate of 89%. No serious adverse events were reported. The study was a small retrospective case series with no control or comparison group and relied on patient and family report on clinical outcomes. In addition, the follow-up duration was insufficient to determine the long-term safety and effectiveness of the orally ingested FMT capsules. It is also worth noting that the authors have financial ties to Symbiotic Health Inc. Conclusion: There is insufficient evidence to determine that orally ingested FMT capsules prepared from stools provided by volunteer donors is safe and effective for the treatment of patients with CDI. There is insufficient evidence to determine that orally ingested FMT capsules prepared from stools provided by volunteer donors is safe and effective for the treatment of patients with CDI with the more virulent strain *C difficile* (NAP1/BI/027). There is insufficient evidence to determine the long-term efficacy and safety of orally ingested FMT capsules. Case series may only generate hypothesis and large RCTs with long-term follow up are studies are needed to support the observed findings and determine the optimal donor, optimal dose of FMT, long-term safety, and long-term efficacy of cryopreserved oral capsulized FMT.
Articles: The literature search revealed two small cases series (one prospective and one retrospective) and a case report on the use of oral cryopreserved FMT capsules for patients with relapsing CDI. There are no published meta-analyses or randomized controlled trials, to date, that compared the use of the oral FMT capsules to standard therapy or to other traditional methods of delivering FMT for the treatment of refractory or relapsing CDI.
The following two case series were critically appraised. Youngster I, Russell G, Pindar C, et al. Oral, capsulized, frozen fecal microbiota transplantation for relapsing Clostridium difficile infection. *JAMA*. 2014 Nov 5; 312(17):1772-1778. See Evidence Table 1. Hirsch BE, Saraiya N, Poeth K, et al. Effectiveness of fecal-derived microbiota transfer using orally administered capsules for recurrent Clostridium difficile infection. *BMC Infect Dis*. 2015 Apr 17; 15:191 See Evidence Table 2.

The use of Oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory clostridium difficile infection does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
05/13/2013	05/13/2013 MDCRPC, 01/07/2014 MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC	05/02/2017

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	05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
01/06/2016	MTAC review was discussed at MPC and approved to adopt criteria for FMT capsule, G3 OpenBiome
05/02/2017	Revised criteria language so it is specific on how to manage care after two recurrences
05/02/2017	Adopted Kaiser Permanente policy for Medicare members

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Fertility Services

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare Members

Effective until November 1, 2023

For baseline policy for all plans, click here to view the criteria. *(Internal use only)*
*Individual groups may provide additional benefits or exclusions – see current coverage agreement or contact member services for specific exceptions and limitations.

Based on Kaiser Permanente policy, a member is considered infertile if they are unable to conceive or produce conception:

- After 1 year of frequent, unprotected heterosexual sexual intercourse for members 35 and under
- After 6 months of frequent, unprotected heterosexual sexual intercourse if the female partner is over age 35 years.
- Alternately, a woman without a male partner may be considered infertile if she is unable to conceive or produce conception after at least 12 trials of medically supervised donor insemination (6 cycles for women aged 35 or older).
  - The initial 12 trials of medically supervised donor insemination (6 cycles for women aged 35 or older) to establish an infertility diagnosis, are not covered under the infertility benefit.
- A member is not considered “infertile” if they have had a voluntary sterilization (e.g. tubal ligation, vasectomy). Infertility treatment post-voluntary sterilization is not covered, even if the plan has an SI rider.

As of 1/1/2022, the following plans waived the requirement for a diagnosis of infertility but may still require prior authorization or clinical review based on individual benefits and plan riders.
Association of Washington Cities (AWC)
Boeing
City of Seattle
Meta (Facebook) – for cryopreservation only
SEIU

For *only* Kaiser Permanente Individual & Family (I&F) and Small Business Group (SBG) contracts

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In addition to base infertility/sterility services listed in the Infertility and Sterility policy, member is eligible for:

- Tubal patency/uterine irregularities- HSG (radiology)
- TSH, prolactin (lab)
- Testing for Ovarian reserve –Day 3 FSH
- Semen analysis (if member has Kaiser coverage) (lab)
- Member must use in-network lab

Effective November 1, 2023

Referrals to Reproductive Endocrinology and Infertility (REI) specialists and associated services are not covered as a base benefit and are only eligible for coverage when the member has a sterility and infertility (SI) rider or other evidence of coverage in their contract. **When a Sterility/Infertility (SI) rider is present, initial consultation with an REI specialist is covered without additional criteria review. However, tests and procedures are subject to clinical criteria (as elaborated below).**

Please note that individual riders/contracts may vary in benefit design either excluding or waiving criteria for some services. These may include, but are not limited to, fertility-promoting medications, medications for erectile dysfunction, artificial insemination, in vitro fertilization, long-term cryopreservation, surrogacy services and tubal reanastomosis. The member's rider/contract should be reviewed before making a final coverage determination and supersedes clinical review criteria.

Reproductive services are also subject to lifetime coverage limits which vary by rider/contract and service category.

Exclusions

Unless otherwise stated in the members rider/contract, the following services are not covered

- Reproductive services after voluntary sterilization of a male or female partner (e.g., tubal ligation, vasectomy), including tubal reanastomosis, vas reanastomosis, sperm extraction, artificial insemination and in vitro fertilization
- Long-term cryopreservation (i.e., apart from real-time efforts to conceive)
- Costs related to donor genetic material used for artificial insemination or invitro fertilization
- Services for the purpose of surrogacy
- Routine use of pre-implantation genetic testing (with IVF); medical necessity criteria for pre-implantation genetic testing can be found in a separate clinical criteria - see PGD criteria here

The following services are subject to clinical review criteria unless the services have been specifically excluded or the criteria has been waived in the member's rider/contract.

Definition of Infertility	The definition of infertility is used to determine eligibility for infertility workup (e.g., diagnostic laboratory or imaging studies) apart from other reproductive services enumerated below. Based on Kaiser Permanente policy, a member is considered infertile if they are unable to conceive or produce conception: • Inability to achieve conception after frequent unprotected heterosexual intercourse lasting 12 months for members under 35 years of age or 6 months for members 35 years of age and older • Inability to achieve conception after 6 cycles of artificial insemination (of which at least 3 cycles must be medically supervised) for members under 35 years of age or 3 cycles of

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	medically supervised artificial insemination for members 35 years of age and older • A member is not considered "infertile" if they have had a voluntary sterilization (e.g., tubal ligation, vasectomy) *S*ome members may be eligible for reproductive services without meeting the definition of infertility. Please refer to specific criteria listed below.*
Pharmaceutical Therapy to Promote Fertility	• Both oral and injectable medications to promote ovulation for the purpose of fertility require evidence of coverage (SI rider or contract language) and are covered under the pharmacy benefit subject to any applicable prior auth requirements. • Medications for erectile dysfunction are not covered under this policy but may or may not be covered under the pharmacy benefit subject to any applicable prior auth requirements.
Artificial insemination (AI)	AI including intravaginal, intracervical, and intrauterine insemination techniques and associated medications, laboratory, imaging, and procedure codes may be covered for the purpose of conception. This includes hysterosalpingogram that would confirm tubal patency necessary for the success of such techniques. Members are eligible for coverage when they have a SI rider that does not specifically exclude these services, have not exceeded their lifetime maximum and meet **ONE OR MORE** of the following criteria: • Natal female member without a male partner (applies to single members and same-sex female couples) • Natal female member's male partner is unable to participate in natural insemination due to a physical condition. Erectile dysfunction responsive to medical therapy is excluded even when such medication is not a covered benefit. • Inability to achieve conception after frequent unprotected heterosexual intercourse lasting 12 months for members under 35 years of age or 6 months for members 35 years of age and older • Documentation of an infectious disease that would make unprotected heterosexual intercourse unsafe according to the medical opinion of the member's treating clinician • Documentation of a heritable genetic trait in the male partner (such as an autosomal dominant trait in the male or co-occurrence of an autosomal recessive trait in both partners) would jeopardize the future health of naturally inseminated offspring according to the medical opinion of the member's treating clinician and the member intends to use donor genetic material that does not pose the same risk
In Vitro Fertilization (IVF)	IVF techniques including egg retrieval, fertilization, short-term storage, implantation and associated medications, laboratory, imaging, and procedure codes are eligible for coverage when the member has an SI rider that does not specifically exclude these services, has not exceeded their lifetime maximum and meets **ONE OR MORE** of the following criteria: • Inability to achieve conception after frequent unprotected heterosexual intercourse lasting 12 months for members under

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	35 years of age or 6 months for members 35 years of age and older • Presence of previously diagnosed male-factor infertility that is reasonably expected to prevent conception (with heterosexual intercourse or artificial insemination). Mild to moderately reduced sperm count and/or motility are not included. • Inability to achieve conception after 6 cycles of artificial insemination (of which at least 3 cycles must be medically supervised) for members under 35 years of age or 3 cycles of medically supervised artificial insemination for members 35 years of age and older • Presence of previously diagnosed female factor infertility that is reasonably expected to prevent conception with heterosexual intercourse or artificial insemination (e.g., fallopian tubes are not patent) • Member has coverage and meets criteria for Preimplantation Genetic Testing
Surgical Procedures of the Fallopian Tube(s) to Promote Fertility	Surgical therapy of the fallopian tube(s) to promote fertility may be covered when the patient has an SI rider or evidence of coverage in their contract and meets **ALL** of the following criteria: • Member meets the definition of infertility above • Imaging (HSG) confirms scarring of the fallopian tube(s) or the patient has undergone prior surgery of the fallopian tube(s) not for the purpose of voluntary sterilization (e.g. ectopic tubal pregnancy) • The member intends to become pregnant once tubal patency is re-established • The member has not had a voluntary tubal ligation for the purpose of sterilization

If requesting these services, please send the following documentation to support medical necessity:

• Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Infertility is a common problem. According to the Centers for Disease Control and Prevention (CDC), about 10 percent of U.S. women ages 15 through 44 years have difficulty getting pregnant or staying pregnant.[1]

Both women and men can have problems that cause infertility. About one-third of infertility cases can be connected to the woman. Another third of the cases of infertility can be connected to the man. In the remainder of instances, a cause can't be found.

Applicable Codes

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Creation Date	Review Date	Date Last Revised
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[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt coverage for KP I&F and SBG plans
06/04/2019	Added SEIU has no requirements regarding: age, duration of time, or gender per SEIU contract
05/05/2020	Information regarding the SI-AO rider for SIEU cryopreservation (Effective 8/1/2020) was added
01/04/2022	Added definition of infertility from KP policy document. Listed groups that are no longer requiring a diagnosis of infertility for members to access benefit as of 01/01/2022.
12/16/2022	Updated criteria to include indication for, *"A member is not considered "infertile" if they have had a voluntary sterilization."*
06/06/2023	MPC approved to adopt the proposed changes to Fertility Services criteria definition of infertility with additional indications for AI and IVF. Renamed title of criteria to "Fertility Services" (formerly Infertility Services). Requires 60-day notice, effective 11/1/2023.

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Clinical Review Criteria
Hip Surgery Procedures for Femoroacetabular Impingement Syndrome

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Hip Surgery Procedures for Femoroacetabular Impingement Syndrome***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Femoroacetabular impingement (FAI) syndrome is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint (orientation or morphology) are thought to cause friction/impingement and pain. It is theorized that FAI starts the breakdown of cartilage, leading to osteoarthritis. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in over coverage of the femoral head). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration. Surgery to correct FAI includes arthroscopy, open dislocation of the hip, and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

Medical Technology Assessment Committee (MTAC)

Femoroacetabular Impingement Syndrome

06/17/2013: MTAC REVIEW

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Evidence Conclusion: There is no new evidence that would change or add to the recommendations of the HTA review as regards the conservative or surgical treatment of femoroacetabular impingement. The results of these non-randomized observational studies as well as other published retrospective series with or without a comparison group should be interpreted with caution. Due to the nature of the study design, they are subject to selection bias, observation bias, confounding and other limitations, and only provide the lowest grade of evidence.
Articles: Larson CM, Giveans R, Stone RM, et al. Arthroscopic debridement versus refixation of the acetabular labrum associated with femoroacetabular impingement. Mean 3.5 –year follow-up. *Am J Sports Med*. 2012; 40:1015-1021. Larson and colleagues (2012) reported on outcomes of two cohorts of patients with femoroacetabular impingement who were treated with either arthroscopic debridement or refixation of the acetabular labrum in one center, but at different time periods. The mean follow-up ranged between 24 and 72 months with a mean of 42 months. The results indicate that the labral fixation was associated with better Harris Hip Scores (HHS), Short Form-12 (SF-12) and visual analog scale (VAS) for pain outcomes compared to arthroscopic focal debridement. Zingg PO, Ulbrich EJ, Buehler TC, et al. Surgical hip dislocation versus hi arthroscopy for femoroacetabular impingement. Clinical and morphological short-term results. *Arch Orthop Trauma Surg*.2013; 133:69-79. Zingg and colleagues (2013) compared surgical hip dislocation versus hip arthroscopy in 38 patients presenting with clinically FAI that was morphologically verified with plain radiographs and MRI. In 28 of the 38 participants the selection of the procedure was based on the patient's decision, and only 10 agreed to be randomly allocated to either procedure. There were statistically significant differences in the morphological pathology (in terms of acetabular coverage angle, and head-neck offset ratio) between the two groups at baseline. The primary outcome of the study was the alpha angle on a cross-table view. The results of the study showed that patients in the hip arthroscopy group had faster recovery and better short-term outcomes compared to those treated with surgical hip dislocation. However, the hip arthroscopy showed some overcorrection of the cam deformity and limited frequency of labrum refixations, which the authors indicate that they may lead to negative impact on long-term outcomes.

The use of FIS does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Per the Washington State Health Care Authority Health Technology Clinical Committee (HTCC) coverage determination following Femoroacetabular Impingement Syndrome re-review (adopted 1/17/2020):

Hip surgery for femoroacetabular impingement syndrome is not a covered benefit.

Applicable Codes

Considered not medically necessary:

CPT® Codes	Description
27299	Unlisted procedure, pelvis or hip joint
29914	Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion)
29915	Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
08/06/2013	02/04/2013[MPC], 12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/05/2022

[MPC] Medical Policy Committee

Revision History	Description
06/06/2017	Adopted KP policy for Medicare members
04/07/2020	Removed generic service code 27299 and added more specific codes 29914, 29915 and 29916

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04/29/2020	Added CPT codes 27299 and 29862 and ICD-10 codes M25.851, M25.852 and M25.859
04/26/2021	Removed CPT code 29862 and ICD-10 codes M25.851, M25.852 and M25.859
11/06/2021	Removed CPT code 29916
04/05/2022	Added the Washington Health Care Authority HTCC decision from January 2020.

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Clinical Review Criteria
Foot Care

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Routine Foot care services still require review and need to meet medical necessity as outlined in the LCD. The following ***retired*** LCD's are to be used to determine medical necessity for routine foot care reviews: LCD for Routine Foot Care (L24356) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. LCD for Symptomatic, Pathological Nail and its Treatment (L24366). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. Wound and Ulcer Care (L38904)
Local Coverage Article	None

For Non-Medicare Members

I. For the purpose of the Clinical Review Criteria foot care* is defined as:

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A. Cutting or removal of corns or calluses;
B. Trimming, cutting, clipping, or debriding of nails;
C. Other hygienic and preventative maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot;
D. Asymptomatic foot care is not typically a covered service unless certain complications are present. It is not provided more frequently than every 60 days. The criteria below identify when foot care is covered. They are divided into sections of foot care for the asymptomatic and symptomatic foot.

II. Kaiser Permanente covers foot care services as medically necessary when **EITHER** of the following criteria is met:

A. The foot care services that are associated with systemic conditions that are significant enough to result in severe circulatory insufficiency and/or areas of severe desensitization in the lower extremities, including, but not limited to, **ANY** of the following:

- Marked diabetic neuropathy documented on physical exam*
- Peripheral vascular disease*
- Marked peripheral neuropathy documented on physical exam*
- Non-traumatic partial amputation of a foot

*For neuropathies chart must record the physical findings of severe loss of sensation such that non-professional services might pose a danger to the patient. For peripheral vascular disease, the diagnosis and severity must have been confirmed by a vascular surgery evaluation.

B. In the absence of a systemic condition, treatment of mycotic nails may be covered.

- The treatment of mycotic nails for an ***ambulatory*** patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.
- The treatment of mycotic nails for a ***non-ambulatory*** patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

III. Exclusions

A. General diagnoses such as arteriosclerotic heart disease, circulatory problems, vascular disease, and venous insufficiency are not sufficient to permit coverage of routine foot care. Likewise, incapacitating injuries or illness such as rheumatoid arthritis, CVA, fractured hip and blindness which make trimming the nails difficult, ***are not*** diagnoses for which routine foot care is payable.

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Background

Asymptomatic foot care or routine foot care is usually not covered for members in the absence of localized illness, injury or symptoms involving the foot. Most Kaiser Permanente coverage contracts exclude routine foot care coverage. Kaiser Permanente developed criteria consistent with the Medicare those published by Medicare.

Foot care includes:

- Cutting or removal of corns or calluses
- Trimming, cutting, clipping, or debriding of nails
- Other hygienic and preventative maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

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- Debridement of nails is a procedure that is needed to remove excessive material (reduce thickness and length) from a dystrophic nail but not a non-dystrophic nail. In contrast, trimming of nails is a procedure that may be directed at either type of nail.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
11055	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); single lesion
11056	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); 2 to 4 lesions
11057	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); more than 4 lesions
11719	Trimming of nondystrophic nails, any number
11720	Debridement of nail(s) by any method(s); 1 to 5
11721	Debridement of nail(s) by any method(s); 6 or more
G0127	Trimming of dystrophic nails, any number
G0247	Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include the local care of superficial wounds (i.e., superficial to muscle and fascia) and at least the following, if present: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails
S0390	Routine foot care; removal and/or trimming of corns, calluses and/or nails and preventive maintenance in specific medical conditions (e.g., diabetes), per visit

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
06/27/1997	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	02/02/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/04/2015	Editorial changes were made to criteria
9/1/2015	Changed LCD hyperlink
09/08/2015	Revised LCD L36107 & L34199
06/07/2016	Revised criteria to simplify guidelines
08/06/2019	Criteria revision regarding need for confirmation and documentation from the appropriate vascular surgeon specialist. An amendment was made to II. A. 4. to read “non-traumatic partial amputation of a foot.”
02/02/2021	MPC approved to update criteria for routine foot care services and exclusions.

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Clinical Review Criteria
Galectin-3 Blood Assay Test

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Galectin-3 Blood Assay Test" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies for congestive heart failure (CHF).

The use of Galactin-3 for all other indications does not meet medical necessity because its clinical utility has not been established.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Heart failure (HF) is one of the most frequent and challenging medical disorders. It is a complex progressive disease with high morbidity and mortality. The prognosis of patients with HF is poor despite the advances made in the diagnosis, medical management, and device therapies. It is thus important to diagnose HF early and to identify the patients at higher risk of poor outcomes (Lok 2013, Browners 2014).

Accurate risk stratification of HF patients may help in the decision making for managing the disease; including individualizing the therapeutic approach and the proper use of invasive and costly therapies. However, risk prediction in acute, chronic, and new onset HF remains a challenge. Clinical parameters, such as advanced age, higher New York Heart Association (NYHA) functional class, reduced left ventricular ejection fraction (LVEF), lower body mass index, renal dysfunction, and anemia, have all been associated with poor outcomes in HF, but are not significant predictors of mortality. In recent years efforts were made to find biomarkers that might help in the risk stratification, and prognostication of acute and chronic heart failure. Brain natriuretic peptide (BNP) and its N-terminal part (NT-proBNP) have become well-established markers used in the diagnosis and management of HF patients. Both are released in response to myocyte stretch and provide useful information for HF diagnosis,

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prognosis, and response to therapy. However, natriuretic peptides only indicate ventricular loading conditions and may not reveal other important mechanisms for HF. Other novel biomarkers from different physio pathological pathways such soluble ST2, growth differentiation factor-15, highly sensitive troponins, and Galectin-3, have recently emerged and are being evaluated for their potential use in adding value to the risk stratification of HF patients. For a biomarker to be useful to a clinician, it should be available, accurate, and reliable. It also should add incremental value to the clinical variables or other established markers, provide prognostic information, have an impact on patient management, and be responsive to interventions (Carrasco-Sanchez 2014, Coburn 2014, Filipe 2014, Gruson 2014, Pouleur 2014, Schmitter 4014, Srivatsan 2014).

Galectin-3 (Gal-3) is a member of a family of proteins comprising soluble β-galactoside-binding lectins that have regulatory roles in fibrogenesis, inflammation, tissue repair, and cell proliferation. It is mainly known for its role as a mediator of tumor growth, progression, and metastases. Gal-3 is also associated with increased age, diabetes, nephropathy, and fibrotic conditions such as liver fibrosis, renal fibrosis, idiopathic lung fibrosis, and chronic pancreatitis. Recently, it has been suggested that Gal-3 may play a role in the pathophysiology of HF through promotion of inflammation, myocardial fibrosis and myocardial remodeling, which are key processes for the development and progression of HF. It was thus suggested that an increased Gal-3 level in the circulation may reflect active and excessive myocardial fibrogenesis in patients with HF and can thus be used as a marker for poor prognosis related to excessive and potential irreversible myocardial fibrosis (Lok 2010, Gullestad 2013, Carrasco-Sanchez 2013, Suarez 2014).

GAL-3 is measured in the circulation by manual or automated assays. The enzyme linked immunosorbent assay manual assay (ELISA) is the most frequently used method in the published studies. Manual assays are, however, laborious and take considerable time for sampling, handling, incubation, and washing steps. More recently, several automated assays with faster delivery of the results, have been developed and are commercially available. A number of manual and automated assays have received FDA approval for measuring circulating Gal-3. Others are still seeking approval. The ARCHITECT Galectin-3 assay, BGM Galectin -3TM are among those approved by the FDA to be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure.

Galectin-3 testing in HF patients has not been previously reviewed by MTAC. It is being reviewed for its use as a prognostic marker in patients with heart failure based on requests from contracted providers for its coverage.

Medical Technology Assessment Committee (MTAC)

Galectin-3 Blood Assay Test

02/09/2015: MTAC REVIEW

Evidence Conclusion: 1. Prognostic value of galectin-3 in patients with acute or chronic heart failure: The published studies on the prognostic value of Gal-3 in patients with HF are mainly secondary studies analyzing data from existing databases for RCTs examining the effect of drug therapy or other interventions on outcomes of patients with HF. In these studies, blood samples were obtained once at baseline and the plasma was stored for years at temperatures below 70o-80oC. Baseline plasma Gal-3 levels were then correlated with the incidence of CVD, HF, rehospitalization, and mortality during follow-up. The results were not validated in external cohorts and could be related to specific characteristics of the patients studied, or other unmeasured cofounders. There are several other issues with these kinds of analyses that would limit generalization of their results. Retrospective analyses may only suggest correlation and not causality; blood samples were obtained only once in the majority of studies, with no serial measurements of Gal-3 and thus cannot determine whether it varies by time and the effects of this variation if any, the plasma samples were frozen, and it is unknown if Gal-3 would degrade over the years. In addition, a number of these studies used arbitrary cutoff levels for Gal-3 to categorize patients into subgroups in order to test for interactions and associations. It was also questioned whether the detection of Gal-3 in the circulation accurately reflects activity in the tissues. The ideal study for evaluating the prognostic value of a novel biomarker would be a prospective study with long-term follow-up that examines the additive or incremental value of the new biomarker on top of existing established prognostic markers or clinical variables. The results should then be externally validated in other patient populations. In general, the analyses of the published studies suggest that the plasma concentration of Gal-3 is high in patients with HF. There is insufficient evidence however, to determine that the high plasma level of Gal-3 in these patients is an independent prognostic marker for poorer outcomes. The results of the published analyses are conflicting; some suggest that after adjusting for many clinical variables including NT-proBNP, elevated Gal-3 levels may be associated with higher rates of all-cause mortality, CV events and /or rehospitalization in patients with heart failure. Other analyses, on the other hand, show that after adjusting for similar or additional clinical variables including NT-proBNP, Gal-3 is not a significant independent prognostic marker for any of the outcomes studied (Table 3 shows the differences in the variables adjusted for). There were variations between the studies in their inclusion criteria, patient characteristics, cause,

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type, severity, duration, and therapies used for managing the heart failure. There were also differences in population sizes, duration of follow-up, number of covariables used in the multivariate analyses, and the cutoff for Gal-3, which was mainly arbitrarily selected. Studies that showed a significant association between Gal-3 and outcomes tended to be smaller studies that adjusted for less clinical variables in their analyses. The two largest studies HF-ACTION (Felker et al, l 2012) and CORONA (Gullestad et al, 2014) showed that Gal-3 was significantly associated with the risk of primary outcomes studies in the univariate analyses performed, but the association observed was no longer significant when series of multivariable models including NT-proBNP were performed. Chen and colleagues (2015) performed a meta-analysis of 11 studies with 8,419 participants (Evidence table 1) to assess the association between Gal-3 and adverse outcomes in HF patients. The pooled results of the analysis suggest that increased serum Gal-3 was associated with higher all-cause mortality or CV mortality after adjusting for other established factors. These results, however, have to be interpreted with caution due to several limitations. The meta-analysis pooled the results of studies including patients with acute or chronic, and with systolic or diastolic heart failure, and conducted among different patient populations. Two of the 11 studies included in the analysis were performed by the same principal authors among the same group of patients. There was significant heterogeneity between the studies as well as significant publication bias. The population sizes varied between the included studies from 240 to 1,440 patients, and the follow-up duration ranged between 1 and 8.7 years. There were also differences between the studies in the cutoff values for Gal-3 and the variables adjusted for in calculating the hazard ratios (table 3). Meijers et al's (2014) pooled analysis (Evidence table 2) of three clinical trials showed that patients with elevated Gal-3 (>17.8 ng/mL) were more likely to be re-hospitalized for HR at 30, 60, 90, and 120 days after discharge. Gal-3 was found to be an independent predictor for re-hospitalization after adjusting for age, gender, NYHA class, renal function, LVEF, and BNP. Addition of Gal-3 to the clinical risk model comprising these variables significantly improved the net risk classification of patients for postdischarge rehospitalization and fatal events at each time point. The pooled analysis had its limitations and its results should be interpreted with caution.

2. Incremental value of galectin-3: The most commonly used way to evaluate the ability of a prognostic HF biomarker in predicting an event is to assess the area under the Receiver Operator Curve (AUC) which is a balance of sensitivity and specificity of the test or tool, and to compare it with a gold standard (C-statistics). However, a small but statically significant difference between the AUC for the gold standard and biomarker studied, may be clinically irrelevant, and there is no generally agreed upon clinically improvement in the C-statistics (Januzzi 2014). Area under Receiver Operator Curve (AUC) for Gal-3, NT-proBNP, and combinations

Author/ Study	N of patients	Outcome	AUC						
			Clinical model	Ref. † model	Gal-3	NT-proBNP Or BNP	Clinical or Reference model +Gal-3	Clinical model +BNP	Gal-3 +BNP
Zhang et al, 2015	1,440	All-cause death		0.82	0.71	0.79	0.83		0.81
		CV death		0.83			0.83		
Ahmad et al 2014/ HF-ACTION	813	Pump failure	0.82		0.76	0.83	0.83	0.87	
		SCD	0.68		0.66	0.67	0.71	0.73	
De Boer et al, 2010/COACH	592	Death or HF hospitalization			0.67	0.65 (BNP)			0.69
Lok, et al, 2010/ DEAL-HF* 2013	232	All-cause mortality			0.612	0.611			
	209				0.68	0.63			0.69
Van Kimmenade 2006**	599	Mortality			0.74	0.67			

†Reference model included sex, age, DM, ischemic HD, SBP, NYHA functional class, LVEF, ARB/ACE I, B-blocker, hemoglobin, sodium, and NT-proBNP.

*Patients with high baseline levels of both markers were observed to have approximately 1.5-2-fold higher mortality rate compared to those in other categories.

** The combination of an elevated galectin-3 with NT-proBNP was a better predictor of mortality than either of the 2 markers alone.

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oCutoff values for Gal-3 were: 22.4 for in-hospital death in Zhang et al's study (sensitivity =0.69 and specificity =0.62), 13.9 ng/mL in HF-ACTION, and 18.05 ng/mL in DEAL-HF
oCutoff values for NT-proBNP were: 2,472 pg/mL in Zhang et al's study, and 852 pg/mL in HF-ACTION.
Accuracy of Gal-3 in the diagnosis of HF was studied in a small study with N= 35 patients with HF and 43 controls (Sheng et al, 2014) showing the following results:

	Sensitivity %	Specificity %	Accuracy %	PPV %	NPV %	AUC
Gal-3	94.3	65.1	78.2	68.8	93.3	0.891
NT-proBNP	77.1	90.7	84.6	87.1	83.0	0.896

At a cutoff of 17.8 ng/mL for Gal-3 and 100 pg/mL for NT-proBNP
90.7 84.6 87.1
83.0 0.896
3. Clinical utility of Galectin-3: The literature search did not identify any randomized controlled trial that examined the use of Gal-3 as a target in HF therapy, or that evaluated its impact on selecting a management strategy for patients with HF. Published studies on the disruption of galectin-3 gene to block myofibroblast activation are experimental, with the hypothesis that direct inhibition of Gal-3 may be possible by N-acetyle-seryl-aspartyl-lysyl-proline (Ac-SDKP), a naturally occurring tetrapeptide that prevents and reverses inflammation and collagen deposition in heart after hypertension or myocardial infarction (Hrynchyshyn 2013). Studies on anti-galectin-3 therapy for heart failure are ongoing. The effect of measuring the concentration of circulating Gal-3 on patient management was indirectly examined in post hoc analyses of data obtained from RCTs evaluating different therapies for HF; rosuvastatin in the CORONA study and valsartan in the Val-HeFT.
The CORONA study (Kjekshus et al, 2007) aimed at examining the beneficial effects of rosuvastatin among patients with chronic, symptomatic, systolic, ischemic heart failure. The trial randomized 5,011 patients over the age of 60 years, with chronic ischemic heart failure to receive 10 mg of rosuvastatin or placebo per day. The primary composite outcome was death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke. Secondary outcomes included death from any cause, any coronary event, death from cardiovascular causes, and the number of hospitalizations. After a median follow-up of 32.8 months the results of the trial showed that rosuvastatin did not reduce the primary outcome or the number of deaths from any cause in these older patients with systolic heart failure but reduced the number of cardiovascular hospitalizations. In a post hoc analysis of CORONA study, Gullestad and colleagues (2012) investigated whether plasma Gal-3 can identify patients with chronic HF for whom statins are effective. Of the 5,011 patients enrolled in the CORONA study, 1,462 (29%) patients had baseline plasma specimens available for measuring Gal-3. These were obtained from nonfasting blood samples obtained at baseline and stored at -80oC. There were significant baseline differences between this subset of patients and the entire CORONA participants. For this secondary analysis, the investigators categorized patients into two groups based on the median Gal-3 baseline level (19.0 ng/mL) and found that after a median follow-up of 32.8 months, patients with Gal-3 below the median level who were assigned to rosuvastatin had significantly lower primary event rate, lower total mortality, and lower rates for the composite outcome of all-cause mortality and HF hospitalization, compared to placebo. No benefits were observed for patients with Gal-3 above the median level. The authors noted that the combination of Gal-3 and NT-proBNP (at cutoff of 102.7 pmol/L) identified patients with a large benefit from rosuvastatin treatment. Val-HeFT trial (Cohn et al, 2001) was a randomized placebo-controlled trial that enrolled 5,010 patients >18 years of age with symptomatic HF to evaluate the efficacy of valsartan. Blood was sampled, and the separated plasma was stored at -70oC. The primary outcomes of Val-HeFT were all-cause mortality and the first morbid event (defined as death, sudden death with resuscitation, hospitalization for HF, or the administration of intravenous inotropic drug or vasodilator for four or more hours without hospitalization). The results of the trial showed that after a median follow-up duration of 23 months, valsartan had no effect on mortality, but reduced the first morbid event by13% and hospitalization for HF by 28%. These 3 endpoints were analyzed in the Galectin-3 substudy by Anand and colleagues (2013). This post hoc analysis of Val-HeFT trial examined whether circulating Gal-3 levels can predict the response to valsartan. Baseline samples for measuring Gal-3 were available for 1,650 patients (~30% of the participants). The overall results of this secondary analysis indicate that the use of valsartan was not associated with a beneficial effect on any outcome in this subgroup of patients with available baseline Gal-3 measurements. The authors then arbitrarily categorized patients into two groups based on the median level of Gal-3 (16.2 ng/mL) and found that valsartan treatment was associated with a significant decrease in hospitalization only among patients with Gal-3 below the median level and not for those with levels above the median. This is a posthoc analysis with several limitations and does not directly examine the impact of measuring Gal-3 levels on patient management, and/or treatment outcomes. The results of these post hoc analyses should be interpreted with caution due to several limitations. The studies did not directly examine the impact of

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Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

measuring Gal-3 levels on patient management, and/or treatment outcomes. They were secondary analyses that included less than one third of the population in each of the two trials, there were some significant baseline differences between the patients with Gal-3 measurements and the entire participants in each of the studies, Gal-3 was measured from specimens obtained at baseline and stored for years, and the results of the trials did not show any significant effect of either drug used (rosuvastatin or valsartan) on the primary outcomes studied. *Conclusions:* There is insufficient evidence from longitudinal studies with long-term follow-up and serial measurements of Gal-3 to determine that elevated circulating Gal-3 levels are independent prognostic markers for poor outcomes in patients with HF. There is insufficient evidence to determine that Gal-3 adds clinically significant incremental value to established markers and clinical variables. There is insufficient evidence to determine that circulating Gal-3 has an impact on management decisions made for patients with HF.
Articles: The literature search revealed over 200 articles on Galectin-3 and heart failure. The great majority were unrelated to the current review. There were several published studies on the prognostic value of Gal-3 in patients with heart failure. These were mainly secondary analyses of data or subsets of data collected for patients enrolled in large cohort studies or randomized controlled trials that investigated different other therapies or interventions. The search also identified a pooled analysis of the results of 3 trials (Meijers 2014), and a more recent meta-analysis (Chen et al, 2015) that pooled the results of 11 studies. The literature search did not identify any RCT that directly studied the impact of using the plasma levels Gal-3 on the management of patients with HF. The two meta-analyses were selected for critical appraisal (Evidence tables 1 & 2). The characteristics of the studies included in the larger meta-analysis as well as selected studies published in the last 5 years and not included in the meta-analyses were reviewed and summarized in Evidence Table 3. Chen A, Hou W, Zhang Y et al. Prognostic value of serum galectin-3 in patients with heart failure: a meta-analysis. Int J Cardiol 2015; 182:168-170. See Evidence Table 1. Meijers WC, Januzzi JL, de Filippi C, et al. Elevated plasma galectin-3 is associated with near-term rehospitalization in heart failure: a pooled analysis of 3 clinical trials. Am Heart J. 2014 Jun;167(6):853-60.e4.See Evidence Table 2.

The use of Galectin-3 Blood Assay Test does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
82777	Galectin-3

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
03/03/2015	03/03/2015[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	08/04/2015

[MPC] Medical Policy Committee

Revision History	Description
08/04/2015	Addendum: Insufficient Evidence for all other indications Addendum: Congestive Heart Failure (CHF) as an indication

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KAISER PERMANENTE®

Clinical Review Criteria
Gender Affirming Surgeries

Kaiser Foundation Health Plan of Washington

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Gender Dysphoria and Gender Reassignment Surgery (140.9). CMS has deferred to the local MAC for decision coverage (Noridian for Washington State. Currently Noridian has no policy as of 04/05/2022)
Local Coverage Determinations (LCD)	None
Local Coverage Article	MM9981 - Gender Dysphoria and Gender Reassignment Surgery
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Gender Affirming Surgeries***" for medical necessity determinations. Use the Non-Medicare criteria below.

Self-Funded Groups:

Coverage may vary for members of self-funded groups and may provide additional exclusions – see member's specific contract or contact member services for specific exceptions and limitations.

Self-Funded Group	Policy
For Microsoft employees	See the member's contract for specific coverage details
For Sound Health and Wellness	See ***Non-Medicare policy*** below for coverage details, **with the exception of the following exclusions**: • Facial contouring and other facial reconstructive surgeries; and • Procedures including but not limited to hairline advancement and transplantation; and • Body hair removal (*except face/neck and preop genital hair removal*); and • Voice modification including speech therapy; and • Collagen injections • Liposuction • Abdominoplasty; and • Other cosmetic procedures are not covered services under the plan *Per the Summary of Material Modifications dated March 31, 2023*
For Washington State Teamsters Trust	See the member's contract for specific coverage details
For King County employees	See the member's contract for specific coverage details. Coverage

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	criteria are based on the Standards of Care published by the World Professional Association for Transgender Health.

Effective until November 1, 2023

For Non-Medicare Members:

Members must be enrolled in the Kaiser Permanente of Washington Gender Health Case Management Program to qualify for the gender health services benefit.

All referrals must be submitted by the Gender Health Case Management team.

I. Requirements for hair removal to treat gender dysphoria
Kaiser Permanente of Washington will cover hair removal for members with documented gender dysphoria according to the criteria below. Member can have either electrolysis or laser hair removal or both. The member must work with the Kaiser Permanente of Washington Gender Health Case Manager to determine the best provider for the service and arrange for either insurance billing or member reimbursement for services.

Procedures:

Facial Hair Removal*
- 16+ with parental consent or 18+ years old
- Currently on antiandrogens (spironolactone, leuprolide) unless contraindicated OR testosterone <100 OR hx of orchiectomy

Body Hair Removal*
- 16+ with parental consent or 18+ years old
- Treatment with antiandrogens for 2-3 years unless contraindicated AND testosterone <100 OR hx of orchiectomy

**Hair removal for non-binary patients reviewed on a case-by-case basis.*

Preoperative hair removal for genital reconstructive surgery – as indicated based on surgical plan, see element V below.

Note: Patients who have not had gender reassignment surgery (gonadectomy or vaginoplasty) should continue hormone/anti-androgen therapy unless contraindicated during and after hair removal to prevent recurrence.

II. Requirements for Mastectomy (i.e., initial mastectomy, with nipple sparing or tattooing) for members assigned female at birth or non-binary members. Member must meet **ALL of the following**:
A. Age 18 years or older (Note: age requirement will not be applied to mastectomy for members assigned female at birth or non-binary members if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention)
B. Single letter of referral from a qualified mental health professional*; *and*
C. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; *and*
D. Capacity to make a fully informed decision and to consent for treatment; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question.
F. Twelve months of living in a gender role that is congruent with their gender identity (real life experience).

❖ Note that a trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy for members.

If the referring medical provider or mental health provider requests surgical intervention prior to the patient's completion of 12 months of living in desired gender, the surgeon, the primary care provider, and the qualified mental health professional must submit evidence of medical necessity and clear rationale for the proposed surgical intervention to be done early. The three providers must submit written documentation to the plan that includes:
a. A comprehensive, coordinated treatment plan with evidence that all treatment plan criteria for surgery and treatment goals have been met; and
b. Clear rationale for the variation from the 12-month period of living in desired gender; and

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c. Patient understands the treatment plan, risks and benefits of surgery prior to completing the 12-month period; and
d. The plan will determine authorization and consent to care based on medical necessity from the documentation outlined in A-F above.

III. Requirements for breast augmentation for members assigned male at birth:
A. Single letter of referral from a qualified mental health professional; and
B. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; and
C. Capacity to make a fully informed decision and to consent for treatment; and
D. Age 18 years or older (Note: age requirement will not be applied to augmentation for members assigned male at birth if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention)
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
F. Twelve months of living in a gender role that is congruent with their gender identity (real life experience) and
G. Twelve months of continuous hormone therapy as appropriate to the member's gender goals.

If the referring medical provider or mental health provider requests surgical intervention prior to the patient's completion of 12 months of hormone therapy and/or living in desired gender, the surgeon, the primary care provider, and the qualified mental health professional must submit evidence of medical necessity and clear rationale for the proposed surgical intervention to be done early. The three providers must submit written documentation to the plan that includes:
a. A comprehensive, coordinated treatment plan with evidence that all treatment plan criteria for surgery and treatment goals have been met; and
b. Clear rationale for the variation from either the 12-month period of hormone therapy and/or living for 12 months in desired gender; and
c. Patient understands the treatment plan, risks and benefits of surgery prior to completing the 12-month period; and
d. The plan will determine authorization and consent to care based on medical necessity from the documentation outlined in A-G above.

The criteria above apply for only initial augmentation mammaplasty for members assigned male at birth, any additional breast augmentation after an initial mammaplasty is considered a cosmetic procedure, and therefore, a contract exclusion.

IV. Requirements for gonadectomy (hysterectomy and oophorectomy for members assigned female at birth and orchiectomy in members assigned male at birth):
A. Two referral letters from qualified mental health professionals*, one in a purely evaluative role. (At least one letter should be an extensive report. Two separate letters or one letter with two signatures is acceptable. One referral letter can be from a Kaiser Permanente of Washington Gender Health Case Manager and the other needs to be from a qualified mental health professional*); and
B. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Age of majority (18 years or older); *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; *and*
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones – chart notes must describe the contraindications in detail)

V. Requirements for genital reconstructive surgery (including, but not limited to: vaginectomy, vulvectomy, colpocleisis, colpectomy, metoidioplasty, vaginoplasty, perineoplasty, colovaginoplasty, penectomy, clitoroplasty, labioplasty, phalloplasty, scrotoplasty, urethroplasty, testicular prosthesis (expanders and implants), penile prosthesis. hair removal in the pubic surgical area for members assigned male at birth, hair removal on the

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forearm prior to phalloplasty for members assigned female at birth, Mons Resection)

A. Two referral letters from qualified mental health professionals*, one in a purely evaluative role (At least one letter should be an extensive report. Two separate letters or one letter with two signatures is acceptable. One referral letter can be from a Kaiser Permanente of Washington Gender Health Case Manager and the other needs to be from a qualified mental health professional*); and
B. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; and
C. Capacity to make a fully informed decision and to consent for treatment; and
D. Age 18 years and older; and
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones); and
G. Twelve months of living in a gender role that is congruent with their gender identity (real life experience)

VI. Eligibility for: layrngochrondroplasty for members assigned male at birth is based on meeting **ALL of the following** criteria:

A. Member is at least 18 years old
B. Member has been diagnosed with persistent, well documented gender dysphoria.
C. Member has the capacity to make fully informed decisions and to consent to treatment.
D. If significant medical or mental health concerns are present, they are reasonably well controlled.
E. Member has a current referral letter for laryngochrondroplasty surgery or other gender reassignment surgery from a qualified mental health professional who has independently assessed the patient. This assessment must be current within the past 12 months. For providers working within a multidisciplinary specialty team, the assessment and recommendation can be documented in the patient's chart. The referral is expected to cover the following recommended content:
   a. The client's general identifying characteristics.
   b. Results of the client's psychosocial assessment, including any diagnoses.
   c. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date.
   d. An explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the patient's request for surgery.
   e. A statement about the fact that the patient has the capacity to provide informed consent.
   f. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.
F. Member has had a mental health evaluation and a medical evaluation and has been deemed to have no medical or psychological contraindications for surgery.

VII. Requirements for gender affirming voice modification surgery

A. Pitch lowering surgery (eg Type III thyroplasty) is considered medically necessary if the voice fails to deepen below speaking F0 150Hz after 1.5 years of consistent masculinization hormone therapy

OR

B. Pitch elevation surgery is considered medically necessary when speaking $F_0 < 150$ Hz

AND

C. ALL of the following are met**:**
   a. Age 18 years of age or older
   b. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria
   c. Capacity to make a fully informed decision and to consent for treatment
   d. Single letter of referral from a qualified mental health professional in support of the requested procedure(s)*
   e. Established with a Speech Language Pathologist (SLP) with experience working with Transgender patients for voice therapy and has engaged with voice therapy techniques with consistent follow-up, documented as attendance at ≥ 75% of sessions for at least 6 months
   f. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 above 150 Hz (feminizing) or speaking F0 below 150Hz (masculinizing)
   g. Member agrees to follow-up post-operatively with their surgeon and voice therapist/SLP on a regular

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cadence (1 week, 1 month, 3 months, 6 months, 1 year, 2 years, etc.)

h. Patient has none of the following contraindications:
   1. No active laryngeal pathology, except for muscle tension
   2. No medical diagnoses that would impair wound healing
   3. No medical diagnoses that would seriously impair breathing or swallowing
   4. No planned upcoming surgeries within 2 months after pitch modification surgery
   5. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question.

VIII. Requirements for gender affirming facial surgery– member must meet **ALL** of the following:

A. Member is at least 18 years old
B. Member has been diagnosed with persistent, well documented gender dysphoria
C. Member has the capacity to make fully informed decisions and to consent to treatment
D. If significant medical or mental health concerns are present, they are reasonably well controlled
E. Member is undergoing or has undergone other treatments to transition gender
F. Member has a current referral letter for gender-affirming procedure(s) from a qualified mental health professional who has independently assessed the patient within the past 12 months. For providers working within a multidisciplinary specialty team, the assessment and recommendation can be documented in the patient's chart. The referral letter is expected to cover the following content:
   a. The client's general identifying characteristics.
   b. Results of the client's psychosocial assessment, including any diagnoses.
   c. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date.
   d. A statement about the fact that the patient has the capacity to provide informed consent.
   e. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

With regard to requested gender affirming facial surgery– must meet **ALL** of the following:

A. For each requested procedure, documentation from an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery) that the member experiences dysphoria specifically associated with that facial element is required (e.g., documentation of dysphoria related to a stereotypically masculine nose for a requested rhinoplasty); **AND**
B. The goal of each procedure is to alter or reshape the facial feature to an appearance that is within the range of normal for the member's identified gender, as determined by an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery)

Procedures for gender affirming facial surgery may include (but are not limited to): mandible contouring, brow lift, and forehead reduction, among others. See below for a list of common procedures* which may or may not be covered for a particular patient.

Procedures intended solely to reduce the appearance of aging that will not result in significant improvement of the condition being treated are considered not medically necessary.

*Procedures considered for gender affirming facial surgery when medical necessity criteria in the applicable policy statement listed above are met – this list represents common procedures; others will be reviewed on a case-by-case basis:

Typically covered:

- Brow lift
- Hairline advancement
- Lip lift
- Mandible contouring
- Forehead reduction and contouring

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Sometimes covered:

- Rhinoplasty

Typically not covered:

- Blepharoplasty
- Lip augmentation
- Cheek implants
- Facelift

IX. The following procedures are **not covered** as a part of this benefit:

- Abdominoplasty
- Calf implants
- Collagen injections
- Cryopreservation of fertilized embryos
- Drugs for hair loss or growth
- Facials
- Hair implant
- Liposuction
- Mastopexy
- Neck tightening
- Pectoral implants
- Removal of redundant skin
- Reversal of prior genital surgery or reversal of surgery to revise secondary sex characteristics
- Sperm preservation in advance of hormone treatment or gender surgery
- Ultrasonic Assisted Lymphatic Massage
- All other cosmetic procedures that do not meet medical necessity

* Characteristics of a Qualified Mental Health Professional:

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; and
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; and
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria;
4. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; and
5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

Effective November 1, 2023

For Non-Medicare Members:

Members must be enrolled in the Kaiser Permanente of Washington Gender Health Case Management Program to qualify for the gender health services benefit. **To be considered in network all *initial* referrals for gender affirming services including surgical consults (excluding GAHT and/or blockers) must be submitted by the Gender Health Case Management team *(Not applicable for options patients utilizing out of network benefit. Out of network provider to place referral and request authorization from the health plan).***

I. Requirements for hair removal to treat gender dysphoria

Kaiser Permanente of Washington will cover hair removal for members with documented gender dysphoria according to the criteria below with a goal of hair removal to align with identified gender. Member can have either electrolysis or laser hair removal or both. The member must work with the Kaiser Permanente of Washington Gender Health Case Manager to ensure prior authorization is obtained for the service and arrange for either insurance billing or member reimbursement for services.

Procedures:

Facial Hair Removal*

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- 16+ with parental consent or 18+ years old **AND**
- Six months of maximally tolerated Gender Affirming Hormone Therapy (GAHT) (including but not limited to antiandrogens such as spironolactone; T blockers such as leuprolide; and hormones such as: estrogen) appropriate to their desired gender, unless medically contraindicated (e.g., GAHT may be contraindicated when not consistent with members gender identity such as non-binary) **OR**
- In testicular bodied patients, testosterone <100 **OR**
- History of orchiectomy

NOTE: Hair removal is not covered for members using exogenous testosterone, as hair growth is expected

Body Hair Removal*

- 16+ with parental consent or 18+ years old **AND**
- Taking Gender Affirming Hormone Therapy (GAHT) (including but not limited to antiandrogens such as spironolactone; T blockers such as leuprolide; and hormones such as: estrogen) appropriate to their desired gender, for 2-3 years unless medically contraindicated (e.g., GAHT may be contraindicated when not consistent with members gender identity such as non-binary) **AND**
- In testicular bodied patients, testosterone <100 **OR**
- History of orchiectomy

NOTE: Hair removal is not covered for members using exogenous testosterone, as hair growth is expected

Preoperative hair removal for genital reconstructive surgery – as indicated based on surgical plan, see element IV below.

Note: Patients who have not had gender reassignment surgery (gonadectomy or vaginoplasty) should continue hormone/anti-androgen therapy unless contraindicated during and after hair removal to prevent recurrence.

II. **Requirements for Mastectomy** (i.e., initial mastectomy, with nipple sparing or tattooing) for members assigned female at birth. Member must meet **ALL of the following**:

A. Age 18 years or older (Note: age requirement will not be applied to mastectomy for members assigned female at birth if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention)

B. Single letter of referral from a qualified mental health professional** within the past 18 months; and the letter should include:

i. Gender incongruence is marked and sustained;

ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;

iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;

iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

C. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question.

D. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated). **Note:** a trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy for members.

E. Patient has already undergone social transition*** or has a plan to do so after surgery

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III. **Requirements for breast augmentation** for members assigned male at birth:

A. Age 18 years or older

B. Single letter of referral from a qualified mental health professional** within the last 18 months; and this letter should include:

i. Gender incongruence is marked and sustained;

ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;

iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;

iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

C. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and

D. Patient has already undergone social transition*** or has a plan to do so after surgery and

E. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated)

The criteria above apply for only initial augmentation mammaplasty for members assigned male at birth, any additional breast augmentation after an initial mammaplasty is considered a cosmetic procedure, and therefore, a contract exclusion.

IV. **Requirements for gonadectomy (hysterectomy, oophorectomy or orchiectomy) and genital reconstructive surgery** (including, but not limited to: vaginectomy, vulvectomy, colpocleisis, colpectomy, metoidioplasty, vaginoplasty, perineoplasty, colovaginoplasty, penectomy, clitoroplasty, labioplasty, phalloplasty, scrotoplasty, urethroplasty, testicular prosthesis (expanders and implants), penile prosthesis, hair removal in the pubic surgical area for members assigned male at birth, hair removal on the forearm prior to phalloplasty for members assigned female at birth, mons resection:

A. Age 18 years and older; and

B. One referral letter from a qualified mental health professional** within the last 18 months; and this letter should include:

i. Gender incongruence is marked and sustained;

ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;

iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;

iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

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C. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
D. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated); and
E. Twelve months of living in a gender role that is congruent with their gender identity (real life experience) Patient has undergone social transition*** and has been living in gender congruent identity for at least twelve months

V. Requirements for gender affirming voice modification surgery

A. Requirements for gender affirming voice modification surgery
B. Pitch lowering surgery (e.g., Type III thyroplasty) is considered medically necessary if the voice fails to deepen below speaking F0 150Hz after 1.5 years of consistent masculinization hormone therapy

OR

C. Pitch elevation surgery is considered medically necessary when speaking $F_0 < 150$ Hz

AND

D. ALL of the following are met**:**
   a. Age 18 years of age or older
   b. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
   c. Patient has already undergone social transition*** or has a plan to do so after surgery
   d. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated)
   e. Single letter of referral from a qualified mental health professional** in support of the requested procedure(s) in the last 18 months; and the letter should include:
      i. Gender incongruence is marked and sustained;
      ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
      iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
      iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
      v. Other possible causes of apparent gender incongruence have been identified and excluded;
      vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
   f. Established with a Speech Language Pathologist (SLP) with experience working with Transgender patients for voice therapy and has engaged with voice therapy techniques with consistent follow-up, documented as attendance at ≥ 75% of sessions for at least 6 months
   g. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 above 150 Hz (feminizing) or speaking F0 below 150Hz (masculinizing)
   h. Member agrees to follow-up post-operatively with their surgeon and voice therapist/SLP on a regular cadence (1 week, 1 month, 3 months, 6 months, 1 year, 2 years, etc.)
   i. Patient has none of the following contraindications:
      i. No active laryngeal pathology, except for muscle tension
      ii. No medical diagnoses that would impair wound healing
      iii. No medical diagnoses that would seriously impair breathing or swallowing
      iv. No planned upcoming surgeries within 2 months after pitch modification surgery

VI. **Requirements for gender affirming facial surgery**– member must meet **ALL** of the following:

A. Member is at least 18 years old; and
B. One referral letter from a qualified mental health professional** in the last 18 months; and this letter should include:
   i. Gender incongruence is marked and sustained
   ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
   iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
   iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

C. Member is undergoing or has undergone other treatments to transition gender

With regard to requested gender affirming facial surgery– must meet **ALL** of the following:

A. For each requested procedure, documentation from an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery) that the member experiences dysphoria specifically associated with that facial element is required (e.g., documentation of dysphoria related to a stereotypically masculine nose for a requested rhinoplasty); **AND**

B. The goal of each procedure is to alter or reshape the facial feature to an appearance that is within the range of normal for the member's identified gender, as determined by an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery)

Procedures for gender affirming facial surgery may include (but are not limited to): mandible contouring, brow lift, and forehead reduction, layrngochrondroplasty among others. See below for a list of common procedures* which may or may not be covered for a particular patient.

Procedures intended solely to reduce the appearance of aging that will not result in significant improvement of the condition being treated are considered not medically necessary.

*Procedures considered for gender affirming facial surgery when medical necessity criteria in the applicable policy statement listed above are met – this list represents common procedures; others will be reviewed on a case-by-case basis:

Typically covered:

- Brow lift
- Hairline advancement
- Lip lift
- Mandible contouring
- Forehead reduction and contouring
- Tracheal Shave

Sometimes covered:

- Rhinoplasty

Typically not covered:

- Blepharoplasty
- Lip augmentation
- Cheek implants
- Facelift

VIII. The following procedures are **not covered** as a part of this benefit:

- Abdominoplasty
- Calf implants
- Collagen injections
- Cryopreservation of fertilized embryos
- Drugs for hair loss or growth
- Facials
- Hair implant
- Liposuction
- Mastopexy
- Neck tightening
- Pectoral implants

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- Removal of redundant skin
- Reversal of prior genital surgery or reversal of surgery to revise secondary sex characteristics
- Sperm preservation in advance of hormone treatment or gender surgery
- Ultrasonic Assisted Lymphatic Massage
- All other cosmetic procedures that do not meet medical necessity

**Characteristics of a Qualified Mental Health Professional for:

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; and
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; and
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria;
4. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; and
5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

***Social Transition: (e.g., name change, pronoun change, communication of affirmed gender identity to others) in place or judged by clinician to be unnecessary (e.g., nonbinary gender identity). This requirement is based on evidence of mental health benefits from social transition and lack of evidence to support gender affirming surgical therapy in the absence of social transition. Coverage may still be considered after additional mental health evaluation and/or explanation of not pursuing social transition.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gender Dysphoria refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth. Gender dysphoria is only experienced by some gender-nonconforming people.

Transgender individuals usually present to the medical profession with a sophisticated understanding of their identity, and a desired course of treatment, including hormone therapy and potentially gender-realignment surgery. The therapeutic approach to gender dysphoria consists of three elements: hormones, real life experience and, finally, surgery for some patients.

The use of hormone therapy and surgery for gender transition/affirmation is based on many years of experience treating transgender people. Research on hormone therapy is providing us with more and more information on the safety and efficacy of hormone therapy, but all of the long-term consequences and effects of hormone therapy may not be fully understood. Therefore, a careful diagnosis, differential diagnosis, and exploration of identity is absolutely vital to the patient's best interest and the patient provider relationship. A vital part of the long-term diagnostic therapy is the so-called real-life experience, in which the patient lives as a member of the desired gender continually and in all social spheres in order to accumulate necessary experience.

Hormone therapy and gender-realignment surgery are superficial changes in comparison to the major psychological adjustments necessary in affirming gender identity. One aspect of treatment should concentrate on the psychological adjustment, with hormone therapy and gender-realignment surgery being viewed as confirmatory procedures dependent on adequate psychological adjustment. Many providers and organizations are moving to an informed consent model for hormones, but surgery still needs involvement of psychology and psychiatry. Psychiatric care may need to be continued for many years after gender-realignment surgery. The overall success of treatment depends partly on the technical success of the surgery, but more crucially on the psychological adjustment of the patient, and the support from family, friends, employers and the medical profession.

Evidence and Source Documents

There was no evidence review conducted for these criteria. They were developed in response to the Washington

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State RCW for the coverage of gender affirming services.

Applicable Codes (not all-inclusive) – all requests require clinical review

Members Assigned Male at Birth:

CPT® or HCPC Codes	Description
55970	Intersex Surgery; male to female
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
With diagnosis codes	
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

Members Assigned Female at Birth:

CPT® or HCPC Codes	Description
55980	Intersex Surgery; female to male
With diagnosis codes	
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

Electrolysis:

CPT® or HCPC Codes	Description
17380	Electrolysis epilation, each 30 minutes

Gender Affirming Facial Surgery

Forehead Recontouring/Augmentation:

CPT® or HCPC Codes	Description
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall

Brow Lift:

CPT® or HCPC Codes	Description
15824	Rhytidectomy; forehead
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

Hairline Correction/Scalp Advancement:

CPT® or HCPC Codes	Description
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area

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Jaw Contouring:

CPT® or HCPC Codes	Description
21299	Unlisted craniofacial and maxillofacial procedure
21209	Osteoplasty, facial bones; reduction

Chin Augmentation:

CPT® or HCPC Codes	Description
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21296	Reduction of masseter muscle and bone (e.g., for treatment of benign masseteric hypertrophy); intraoral approach

Fat Transfer:

CPT® or HCPC Codes	Description
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)

Rhinoplasty:

CPT® or HCPC Codes	Description
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)

Blepharoplasty:

CPT® or HCPC Codes	Description
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Dermal Filler:

CPT® or HCPC Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc

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11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc

Suction Assisted Lipectomy:

CPT® or HCPC Codes	Description
15876	Suction assisted lipectomy; head and neck

Rhytidectomy:

CPT® or HCPC Codes	Description
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad

Voice Modification Surgery

CPT® or HCPC Codes	Description
No specific codes – *commonly submitted with CPT code 31599 Unlisted procedure, larynx*	

***Note:** Codes list is not all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
12/15/2010	01/04/2011 [MDCRPC] ,11/01/2011 [MDCRPC], 09/04/2012 [MDCRPC], 07/02/2013 [MDCRPC], 05/06/2014 [MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC] , 02/01/2022[MPC], 02/07/2023[MPC]	06/06/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
11/2/2015	Added Providence Health & Services and link to Sound Health & Wellness Policy & ICD-10 codes
03/08/2016	Added PEBB link
09/02/2016	Added FtM Mastectomy criteria for adolescents 16 years and older
11/01/2016	MPC approved revised indication for Electrolysis
10/02/2017	Removed the requirement for testosterone treatment for members 16-18
02/06/2018	Added criteria for M-F breast augmentation
05/01/2018	Added facials and ultrasonic assisted lymphatic massage to the non-covered list
06/05/2018	Changed the mastectomy and breast augmentation criteria
06/11/2018	Added coverage language for facial hair removal
07/10/2018	Added coverage and revised criteria language for facial hair removal
10/02/2018	Updated evaluation criteria under genital reconstructive surgery requirements
12/04/2018	Added MtF criteria to add coverage for Layrngochrondroplasty (Tracheal Shave)
04/12/2019	Added Mons Resection code to genital reconstructive surgery
01/22/2020	Minor changes to Facial Hair removal criteria
05/4/2020	Added the following procedures to section V “Requirements for genital reconstruction surgery”: vulvectomy, colpocleisis and perineoplasty
12/18/2020	MPC approved to adopt clinical criteria for Facial Harmonization and updated exclusions for the non-covered list.
02/19/2021	Included non-binary patients for facial hair removal and mastectomy indications.

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10/04/2021	Updated terminology from female to male and male to female to assigned male at birth or assigned female at birth.
03/01/2022	MPC approved changes to criteria for hair removal, including the addition of criteria for coverage of body hair removal and updates to facial hair removal criteria.
04/05/2022	MPC approved to adopt coverage for voice modification surgery.
05/02/2023	Updated self-funded SHWT policy coverage details statement
05/08/2023	Updated additional exclusions provided by SHWT
06/06/2023	MPC has approved revisions to the clinical criteria for Gender Affirming Services, ensuring alignment with the updated guidelines from the World Professional Association for Transgender Health (WPATH). Requires 60-day notice, effective date 11/01/2023

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Clinical Review Criteria
Genetic Screening and Testing

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage).

Prevention and Invitae Corporation are the preferred labs for genetic testing, when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions
For the genetic test(s) listed below, please use the lab specified/refer to the link attached:

- ***Cell Free Fetal DNA testing* – Any of these three labs can be used:**
  - *Ariosa (Bioreference) Diagnostics, Inc. (81507) or*
  - *Invitae (81420) or*
  - *LabCorp (81420)*
  - *Quest-QNatal (81420)*
- ***Next Generation Sequencing for Advanced Cancer*** —Any of these three labs can be used:
  - *CellNetix SymGene Panel*
  - *Oncoplex (University of Washington)*
  - *Caris Life Sciences*
- Prenatal Chromosomal Microarray (samples typically obtained via amniocentesis/CVS)—Either of these two labs can be used:
  - Prevention
  - LabCorp
- Fetal diagnostic testing in cases of recurrent intrauterine fetal demise (definition)—Either of these two labs can be used:
  - Prevention
  - LabCorp
- Carrier Screening for Preconception Counseling—Either of these two labs can be used:
  - Prevention
  - Invitae
- Non-prenatal Chromosomal Microarray (sample obtained by blood draw)—Any of these three labs can be used:
  - Prevention
  - LabCorp

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- Invitae

Related Policies:
Genetic Panel Testing
Pharmacogenomic Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2) (Applies to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) breast and ovarian cancer.) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved Companion Diagnostic tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Guardant360 TissueNext (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.) MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets)) Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24)
Local Coverage Determinations or Articles (LCD/LCA)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Molecular Diagnostic Tests (MDT) (L36256) MolDX: Testing of Multiple Genes (A58121) MolDX: Next-Generation Sequencing for Solid Tumors (L38121) (Applies to diagnostic lab tests using NGS for solid tumors.) Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors (A57905)
Decision Memo	Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451)

General Coverage Rules – LCD 24308 (retired)

1. Genetic tests for cancer are only a covered benefit for a beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test

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for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:

The MolDX Program has determined certain gene tests do not meet Medicare's medical necessary requirements, and that the inclusion of these genes will result in an entire panel to be denied. MolDX has determined that testing for the below genes is a statutorily excluded service. Unless indicated otherwise, panels that include these genes will be denied. Please see the individual Test Coding and Billing Guidelines for each gene.

Palmetto GBA is the Medicare contractor for Molecular Diagnostic Testing – this site has the most up to date Medicare coverage guidelines for genetic testing.
MolDX® Program (Administered by Palmetto GBA)

Local Coverage Decisions and Articles (LCD/LCA) *not all-inclusive – refer to the MolDX® Program link above*

ID	Title	Codes *(not all-inclusive)*
L36163	08/20/2022 Noridian retired LCD MolDX: BRCA1 and BRCA2 Genetic Testing These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT).	81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81432, 81433, 0102U, 0103U, 0129U
L36386	MolDX: Breast Cancer Assay: Prosigna	81520
L37824	MolDX: Breast Cancer Index® Gene Expression Test	81518
L36186	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	81206, 81207, 81208, 81219, 81270, 81279, 81338, 81339, 81450, 0027U, 0040U
L36159	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)	81240, 81241, 81291

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L36374	08/20/2022 Noridian retired LCD MolDX: Genetic Testing for Lynch Syndrome These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36374 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT).	81210, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81317, 81318, 81319, 81432, 81433, 0101U
L36192	MolDX: MGMT Promoter Methylation Analysis	81287
L36544	MolDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36544) **not covered per LCD*	81383
L36256	MolDX: Molecular Diagnostic Tests (MDT)	See LCA*: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527) **Presence of a code on this LCA does not indicate coverage*
L38333	MolDX: Blood Product Molecular Antigen Typing	0001U, 0084U
L36329	08/08/2022 Noridian retired LCD MolDX: ConfirmMDx Epigenetic Molecular Assay These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36329 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT)	81551
L38341	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease *(Decipher and similar, i.e., Prolaris)*	81541, 81542, 0047U
L36452	01/01/2018 Noridian retired LCD MolDX: Chromosome 1p/19q Deletion Analysis (L36452). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36452 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT).	
L36891	MolDX: Percepta© Bronchial Genomic Classifier	81479
L38816	MolDX: Minimal Residual Disease Testing for Cancer L38816 MolDX: Minimal Residual Disease Testing for Hematologic Cancers A58997 (refers to coverage for ClonoSEQ for specific cancers)	81479, 0340U

For Non-Medicare Members

Members must meet **ALL the following** criteria:

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1. The member is at clinical risk for a genetic condition because of current documented symptoms being displayed or a strong family history of the condition.
2. The test is scientifically valid and can be adequately interpreted.
3. The results will directly affect a member's clinical management or reproductive decisions.
4. After appropriate clinical work-up, and informed consent by the appropriate practitioner, the genetic test is indicated.

Genetic testing is not covered for the medical management of a family member who does not have Kaiser Permanente coverage.

Carrier Screening is limited to once per lifetime.

*For **specific tests listed** below the member must meet the criteria above **AND** the specific test criteria below:*

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

Cardiology	Criteria
Arrhythmogenic Right Ventricular Cardiomyopathy – ARVC Genes	MCG* A-0627
Brugada Syndrome Channelopathy Genes	MCG* A-0594
Catecholaminergic Polymorphic Ventricular Tachycardia Genes	MCG* A-0636
Coronary Artery Disease - 9p21 Allele	MCG* A-0657: This is not covered per MCG*
Coronary Artery Disease - KIF6 Gene	MCG* A-0656: This is not covered per MCG*
Coronary Artery Disease Genetic Panel	MCG* A-0658: This is not covered per MCG*
Familial Dilated Cardiomyopathy – Gene and Gene Panel Testing	MCG* A-0648
Familial Hypertrophic Cardiomyopathy, Nonsyndromic – Gene and Gene Panel Testing	MCG* A-0633
Thoracic Aortic Aneurysm and Aortic Dissection (Hereditary) - Gene Panels	There is insufficient evidence in the published medical literature to show clinical utility.
Ehlers-Danlos Syndrome (Vascular) - COL3A1 Gene	MCG* A-0910
Loeys-Dietz Syndrome - Gene and Gene Panel Testing	MCG* A-0909
Long QT Syndrome (Hereditary) - Gene Panel	MCG* A-0918

Endocrinology	Criteria
Diabetes Mellitus, Type 2 - KCNJ11, KCNQ1, PPARG, SLC16A11 and TCF7L2 Genes	MCG* A-0826: This is not covered per MCG*
Diabetes Mellitus (Maturity-Onset Diabetes of the Young) - ABCC8, APPL1, BLK, CEL, GCK, HNF1A, HNF1B, HNF4A, INS, KCNJ11, KLF11, NEUROD1, PAX4, and PDX1 Genes	MCG* A-0598

Gastroenterology	Criteria
HLA Testing for Celiac Disease:	1. Is medically appropriate for symptomatic patients a. Despite being on a gluten free diet **OR** b. With indeterminate serology/biopsy results 2. It is not covered for a. Asymptomatic people **OR** b. Screening

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Gastroenterology	Criteria
Hemochromatosis - HFE Gene	Medical necessity review no longer required.
Pancreatitis, Hereditary – CFTR, CPA1, CTRC, PRSS1, and SPINK1 Genes	MCG* A-0646

Genomic Testing Methods and Technologies	Criteria
Broad Spectrum Tumor Molecular Profiling – Next Generation Sequencing (NGS)	There is insufficient evidence in the published medical literature to show clinical utility.
Tacrolimus Pharmacogenetics - CYP3A4 and CYP3A5 Genes	MCG* A-0775: This is not covered per MCG*
Chromosomal Microarray Testing	1) Chromosomal microarray testing may be considered medically necessary for genetic evaluation of an individual when **ALL** of the following criteria are met: a) Testing has been requested following evaluation and genetic counseling by a medical geneticist, pediatric neurologist, or neurodevelopment pediatrician; and b) Results have the potential to affect clinical management of the patient; and c) The patient meets one or more of the following: • Multiple anomalies not specific to a well-delineated genetic syndrome • Apparently non-syndromic developmental delay/intellectual disability • Autism spectrum disorder • Dysmorphic facial features • Abnormal growth not otherwise explained 2) Chromosomal microarray testing (CPT 81228, 81229) may be considered medically necessary for patients undergoing invasive prenatal genetic testing (i.e., amniocentesis, chorionic villus sampling (CVS), or fetal tissue sampling), or a patient who has had recurrent (two or more) intrauterine fetal demise. Genetic counseling is required. Prior authorization is not required if done at Invitae, Labcorp or Prevention but is required for all other vendors in advance of submitting a claim for payment. 3) Chromosomal microarray testing may be considered medically necessary for testing of one or both parents when a chromosomal deletion or duplication has been identified in one or more of their offspring and: a. Parental testing is necessary to guide a reproductive decision, or b. Parental testing is necessary to determine the clinical significance of the chromosome abnormality found in the child, and c. The result is expected to directly affect clinical management of the child The following are not covered: 4) Chromosomal microarray testing to confirm the diagnosis of a disorder or syndrome that is routinely diagnosed based on clinical evaluation alone.
Genome-Wide Association Studies	Does not require medical review

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Genomic Testing Methods and Technologies	Criteria
MicroRNA Detection - Cancer	MCG* A-0705: This is not covered per MCG*
MicroRNA Detection – Heart Failure	MCG* A-0838: This is not covered per MCG*
MicroRNA Detection - Inflammatory Bowel Disease	MCG* A-0839: This is not covered per MCG*
MicroRNA Detection - Ischemic Heart Disease	MCG* A-0840: This is not covered per MCG*
MicroRNA Detection – Kidney Disease	MCG* A-0841: This is not covered per MCG*
Molecular Profiling	MCG* A-0789: This is not covered per MCG*
Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Microdeletion Syndromes *81331 not medically necessary when performed using cell-free fetal DNA, 81422*	MCG* A-0848: This is not covered per MCG*
Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Monogenic Disorders	MCG* A-0849: This is not covered per MCG*
Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Sex Chromosome Disorders	MCG* A-0850: This is not covered per MCG*
Septin 9 (SEPT9) DNA Methylation Testing	MCG* A-0706: This is not covered per MCG*
Telomere Analysis	MCG* A-0672: This is not covered per MCG*
Integrated Molecular Pathology Testing (Topographic Genotyping) - PathFinderTG	MCG* A-0632: This is not covered per MCG*
Whole Exome Sequencing (WES)	Whole exome sequencing (WES) is considered medically necessary for a phenotypically affected individual when **ALL** of the following criteria are met: 1. Individual has been evaluated by a board-certified medical geneticist (MD) or other board-certified physician specialist with specific expertise in the conditions and relevant genes for which testing is being considered 2. Results have the potential to directly impact clinical decision-making and clinical outcome for the patient 3. A genetic etiology is the most likely explanation for the phenotype as demonstrated by **EITHER** of the following: A. multiple abnormalities affecting unrelated organ systems OR B. **TWO** of the following criteria are met: a. abnormality affecting a single organ system b. significant intellectual disability, symptoms of a complex neurodevelopmental disorder (e.g. self-injurious behavior, reverse sleep-wake cycles), or severe neuropsychiatric condition (e.g. schizophrenia, bipolar disorder, Tourette syndrome) c. family history strongly implicating a genetic etiology d. period of unexplained developmental regression (unrelated to autism or epilepsy) e. dysmorphic facial features f. abnormal growth not otherwise explained 4. No other causative circumstances (e.g. environmental exposures, injury, infection) can explain symptoms 5. Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing is available 6. The differential diagnosis list and/or phenotype warrant testing of multiple genes and ONE of the following: a. WES is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis

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Genomic Testing Methods and Technologies	Criteria
	b. WES results may preclude the need for multiple and/or invasive procedures, follow-up, or screening that would be recommended in the absence of testing *All requests must be approved by a KP geneticist, regardless of whether they have seen the patient.*

Hematology	Criteria
Alpha Thalassemia - HBA1 and HBA2 Genes	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0808
Beta Thalassemia - HBB Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0815
Fetal and Neonatal Alloimmune Thrombocytopenia - Human Platelet Antigen (HPA) Genotyping	MCG* A-0793
Factor V Leiden Thrombophilia-F5 gene	Does not require medical review
Fanconi Anemia - FANC Genes and Gene Panel Testing	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0683
Hemoglobin C and E – HBB Gene	MCG* A-0604
Hyperhomocysteinemia - MTHFR Gene	MCG* A-0629
Post-Transfusion Purpura - Human Platelet Antigen (HPA) Genotyping	MCG* A-0800: This is not covered per MCG*

Hematology	Criteria
Prothrombin Thrombophilia - F2 Gene	Does not require medical review
Sickle Cell Disease - HBB Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0864
Von Willebrand Disease-VWF Gene	MCG* A-0688

Metabolic and Developmental Disorders	Criteria
Angelman Syndrome - UBE3A Gene *Note: Guideline indications are related to tests performed using amniocentesis or chorionic villus sampling. Not medically necessary when performed using cell-free fetal DNA (see MCG A-0848).*	MCG* A-0708
Ashkenazi Jewish Genetic Panel	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0592
Autism Spectrum Disorders – Gene Panels	MCG* A-0914 This is not covered per MCG*
Beckwith-Wiedemann Syndrome - CDKN1C Gene	MCG* A-0765
Bloom Syndrome - BLM Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0682
Canavan Disease - ASPA Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0595
Deafness and Hearing Loss, Nonsyndromic - Microarray and Multigene Panels	MCG* A-0823
Deafness and Hearing Loss, Nonsyndromic - GJB2, MT-RNR1, MT-TS1, POU3F4, PRPS1, and SMPX Genes	MCG* A-0596
Developmental Delay - Gene Panels	MCG* A-0925 This is not covered per MCG*

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Metabolic and Developmental Disorders	Criteria
Fragile X-Related Disorders-FMR1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0602
Fragile X-Associated Primary Ovarian Insufficiency - FMR1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0829
Fragile X-Associated Tremor/Ataxia Syndrome - FMR1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0830
Gaucher Disease - GBA Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0603
Glycogen Storage Disease, Type 1 G6PC and SLC37A4 Gene	MCG* A-0684
Intellectual Disability - Gene Panels	MCG* A-0923 This is not covered per MCG*
Joubert Syndrome – Gene Testing and Gene Panels	MCG* A-0785
Lesch-Nyhan Syndrome - HPRT1 Gene	MCG* A-0606
Maple Syrup Urine Disease, Type 1 or Type 2 – BCKDHA, BCKDHB, and DBT Genes	MCG* A-0681
Maple Syrup Urine Disease, Type 3 - DLD Gene	MCG* A-0776
Mucolipidosis IV - MCOLN1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0686
Niemann-Pick Disease (Acid Sphingomyelinase Deficiency) - NPC1, NPC2, and SMPD1 Genes	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0611
Noonan Syndrome – Gene and Gene Panel Testing	MCG* A-0915
Prader-Willi Syndrome DNA Methylation Testing *Note: Guideline indications are related to tests performed using amniocentesis or chorionic villus sampling. Not medically necessary when performed using cell-free fetal DNA (see MCG A-0848).*	MCG* A-0707
Rett Syndrome – CDKL5, FOXG1 and MECP2 Genes	MCG* A-0687
Tay-Sachs Disease and Variants - HEXA Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0614
Usher Syndrome - ADGRV1 (GPR98), CDH23, CIB2, CLRN1, DFNB31, HARS, MYO7A, PCDH15, USH1C, USH1G, and USH2A Genes	MCG* A-0802
Fabry Disease - GLA Gene	MCG* A-0916

Miscellaneous	Criteria
Autosomal and X-Linked Recessive Disease Carrier Screening - Expanded Gene Panels	MCG* A-0768: This is not covered per MCG*
Familial Mediterranean Fever - MEFV Gene	MCG* A-0689
Hereditary Hemorrhagic Telangiectasia - ACVRL1, ENG, GDF2, and SMAD4 Genes	MCG* A-0704
Male Infertility - Y Chromosome Microdeletion Analysis	MCG* A-0803
Malignant Hyperthermia Susceptibility - CACNA1S and RYR1 Genes	MCG* A-0690

Nephrology	Criteria
Donor-derived cell-free DNA testing (e.g., Allosure)	*Please see separate criteria for **Donor-derived cell-free DNA testing for Kidney Transplant Rejection (e.g., AlloSure)**
Polycystic Kidney Disease (Autosomal Recessive) – DZIP1L and PKHD1 Genes and Gene Panels	MCG* A-0852

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Neurology	Criteria
Alzheimer Disease – (Early Onset) APP, PSEN1, and PSEN2 Genes	MCG* A-0590
Alzheimer Disease (Late Onset) - APOE Genotyping	MCG* A-0809: This is not covered per MCG*
Amyotrophic Lateral Sclerosis (ALS) - SOD1 Gene	No additional criteria need to be met beyond numbers 1 - 4 at the top of the Non-Medicare criteria (page 4).
Ataxia-Telangiectasia - ATM Gene	MCG* A-0593
CADASIL (Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy) - NOTCH3 Gene	MCG* A-0668
Charcot-Marie-Tooth Hereditary Neuropathy – Gene and Gene Panel Testing	MCG* A-0691
Epilepsies (Hereditary) - Gene Panels	MCG* A-0905 This is not covered per MCG
Epilepsies, Hereditary - SCN1A Gene	MCG* A-0904
Familial Dysautonomia - ELP1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0685
Familial Frontotemporal Dementia - C9orf72, GRN, and MAPT Genes	MCG* A-0906 This is not covered per MCG
Friedreich Ataxia - FXN Gene	MCG* A-0907
Huntington Disease - HTT Gene	MCG* A-0605
Muscular Dystrophies (Duchenne, Becker) - DMD Gene	MCG* A-0608
Myotonic Dystrophy – Type 1 - DMPK Gene	MCG* A-0609
Myotonic Dystrophy, Type 2 - CNBP Gene	MCG* A-0844
Narcolepsy - HLA Testing	MCG* A-1005 This is not covered per MCG
Nemaline Myopathy – Gene and Gene Panel Testing	MCG* A-0792
Parkinson Disease – Gene Testing and Gene Panels	MCG* A-0671 This is not covered per MCG
Spinal Muscular Atrophy - SMN1 and SMN2 Genes **Spinal Muscular Atrophy – Carrier Testing** References: American College of Obstetricians and Gynecologists (2017). Carrier screening for genetic conditions. Committee Opinion No. 691. *Obstet Gynecol. 129*:e41-45. Retrieved 10/20/21 from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/carrier-screening-for-genetic-conditions Gregg, A. R., Aarabi, M., Klugman, S., Leach, N. T., Bashford, M. T., Goldwaser, T., Chen, E., Sparks, T. N., Reddi, H. V., Rajkovic, A., & Dungan, J. S. (2021). Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics (ACMG). *Genetics in Medicine, 23*(10), 1793–1806. Retrieved 10/20/21 from: https://doi.org/10.1038/s41436-021-01203-z	Preconception or prenatal carrier testing for spinal muscular atrophy (SMA) with analysis of the SMN1 gene (CPT code **81329**), as described by the American College of Medical Genetics (ACMG) and the American College of Obstetricians and Gynecologists (ACOG), is considered medically necessary for a prospective biologic parent with the capacity and intention to reproduce. Testing is covered once in a lifetime. Kaiser Permanente will cover carrier testing for SMA (CPT 81329) without prior authorization when performed at a Kaiser Permanente lab, Invitae, or Prevention. Prior authorization will still be required for SMA carrier testing at any other lab in advance of submitting a claim for payment. All other spinal muscular atrophy genetic testing: Medical necessity review will be required for all other indications for SMN1/SMN2 gene testing using MCG* **KP-0659**. *Note – this is a KP hybrid, not MCG A-0659* (Includes CPT codes: 81336, 81337, 0236U)
Spinocerebellar Ataxia - Gene Testing and Gene Panels	MCG* A-0908

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Neurology	Criteria
Transthyretin Amyloidosis - TTR Gene	MCG* A-1010

Oncology	Criteria
Acute Lymphoblastic Leukemia - BCR-ABL1 Fusion Gene Testing	Does not require medical review
Acute Promyelocytic Leukemia - PML-RARA Fusion Gene Testing	Does not require medical review
Breast Cancer - HER2 Testing	MCG* A-0766
Breast Cancer Gene Expression Assays CPT - 81519	See Oncotype Dx
Breast Cancer - PALB2 Gene	MCG* A-0989
Breast or Ovarian Cancer, Hereditary - BRCA1 and BRCA2 Genes CPT 81211, 81212, 81213, 81162	MCG* A-0499
Cancer of Unknown Primary: Gene Expression Profiling – 81540; CancerTYPE ID	MCG* A-0673 This is not covered per MCG
Chronic Eosinophilic Leukemia/Hypereosinophilic Syndrome - FIP1L1-PDGFRA Fusion Gene Testing	MCG* A-0770
Chronic Myelogenous Leukemia - BCR-ABL1 Fusion Gene Testing	Does not require medical review
ClonoSEQ (often billed with miscellaneous code 81479)	ClonoSEQ is a new test whose current use is confined to clinical trials. It is not currently covered by KPWA
Cologuard	See Fecal DNA Testing
Colon Cancer - Oncotype DX	MCG* A-0651: This is not covered per MCG*
Colon Cancer Gene Expression Assay - GeneFx Colon	MCG* A-0821: This is not covered per MCG*
Colorectal Cancer (Hereditary) – Gene Panel	MCG* A-0774: This is not covered per MCG*
Cowden Syndrome - PTEN Gene	MCG* A-0585
DecisionDx - Choroidal/Uveal Melanoma	DecisionDX is covered for dx of choroidal/uveal melanoma
DecisionDx - Cutaneous Melanoma	There is insufficient evidence in the published medical literature to show clinical utility.
Familial Adenomatous Polyposis - APC Gene	MCG* A-0534
Gastric Cancer, Hereditary - CDH1 Gene	MCG* A-0779
Gastrointestinal Stromal Tumor (GIST) - KIT and PDGFRA Genes	Does not require medical review
Ovarian Cancer (Hereditary) - Gene and Gene Panel Testing	Criteria currently under revision to be completed by 9/1/2022. Send to MD for review.
Li-Fraumeni Syndrome - TP53 Gene	MCG* A-0584
Lymphoma - T-Cell Antigen Receptor (TCR) Gene Rearrangement Testing	Does not require medical review
Lynch Syndrome – EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes (see Genetic Panel Testing policy)	MCG* A-0533
Malignant Melanoma (Uveal) - BAP1 Gene	MCG* A-0836: This is not covered per MCG*
Malignant Melanoma (Cutaneous) – BAP1, CDK4 and CDKN2A Genes	MCG* A-0601: This is not covered per MCG*

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Oncology	Criteria
Melanoma (Cutaneous) - Gene Expression Profiling	MCG* A-0837: This is not covered per MCG*
Melanoma (Uveal) - Gene Expression Profiling	MCG* A-0670: This is not covered per MCG*
Multiple Endocrine Neoplasia (MEN) Syndrome, Type 2 - RET Gene	MCG* A-0842
Multiple Endocrine Neoplasia (MEN) Syndromes - MEN1 Gene	MCG* A-0582
MUTYH-Associated Polyposis - MUTYH Gene	MCG* A-0828
Myelodysplastic Syndromes (Somatic) - Gene Panels	MCG* A-0791: This is not covered per MCG*
Myeloproliferative Neoplasms - JAK2 Genes	Does not require medical review
Myeloproliferative Neoplasms - MPL Gene	Does not require medical review
Neuroblastoma - ALK, MYCN, and PHOX2B Genes and Gene Expression Profiling	MCG* A-0610
Neurofibromatosis - NF1 Gene	MCG* A-0581
Neurofibromatosis - NF2 Gene	MCG* A-0846
Non-Small Cell Lung Cancer – Gene Testing (Somatic or Therapeutic	MCG* A-0795 Includes indications for: Anaplastic Lymphoma Kinase (ALK) Fusion Gene Testing – medically necessary when indications met EGFR Gene Testing – medically necessary when indications met KRAS Gene Testing – not medically necessary for NSCLC per MCG*
OVA1- Assessment for Ovarian Cancer	There is insufficient evidence in the published medical literature to show clinical utility.
Pancreatic Cancer (Hereditary) - Gene Panel	MCG* A-0797
Paraganglioma-Pheochromocytoma (Hereditary) - Gene Testing and Gene Panel	MCG* A-0798
Peutz-Jeghers Syndrome - STK11 Gene	MCG* A-0799
Prostate Cancer - BRCA1 and BRCA2 Genes	MCG* A-0612
Prostate Cancer – ConfirmMDx (CPT Code 81551)	ConfirmMDx (81551) for men with prior negative biopsy when repeat biopsy is being considered, and the following criteria are met (must be ordered by treating urologist): • The beneficiary would benefit from treatment of prostate cancer and has greater than 10-year life expectancy • Previous biopsy within the past 12 months negative or atypical small acinar proliferation (ASAP) • Meets Age/PSA per table below • Serial testing not covered (this is a one-time test) • Concurrent testing with multiple assays is not medically necessary

TABLE 1. Age-Specific PSA Thresholds for Referral to Urology

Age Range (years)	PSA Threshold

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Oncology	Criteria
	<table><tr><td>40-49</td><td>>2.5 ng/ml</td></tr><tr><td>50-59</td><td>>3.5 ng/ml</td></tr><tr><td>60-69</td><td>>4.5 ng/ml</td></tr><tr><td>≥70</td><td>>6.5 ng/ml</td></tr></table>
Prostate Cancer (Hereditary) – Gene Panel	MCG* A-0854: This is not covered per MCG*
Prostate Cancer - PCA3 Gene	MCG* A-0855: This is not covered per MCG*
Prostate Cancer Gene Expression Testing - Decipher	MCG* A-0856: This is not covered per MCG*
Prostate Cancer Gene Expression Testing - Oncotype DX	MCG* A-0712: This is not covered per MCG*
Prostate Cancer Gene Expression Testing – Prolaris (CPT Code 81541)	Men with confirmed prostate cancer *on biopsy* may be covered for Prolaris if **ALL** the following indications are met (must be ordered by treating urologist): a. Must meet NCCN category* **(one):** • low-risk • favorable intermediate-risk • unfavorable intermediate-risk b. who have greater than 10 year life expectancy c. Meet **ONE of the following**: • has not received treatment for prostate cancer and is a candidate for active surveillance **or** definitive therapy; or • has intermediate-risk prostate cancer when deciding whether to add androgen-deprivation therapy to radiation; or • is appropriate for conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), or; • is appropriate for radiation therapy and yet would be eligible for the addition of a brachytherapy boost, or; • is appropriate for radiation therapy with short-term ADT yet would be eligible for the use of long-term ADT, or; • is appropriate for radiation with standard ADT yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy d. Patient has not had a prostatectomy (***The evidence is insufficient for or against the use of Prolaris test in patients with radical prostatectomy and it is not covered***) ▪ Very low risk patients should be considered active surveillance, Prolaris is unlikely to be helpful ▪ Serial testing is not covered (this is a one-time test) ▪ Concurrent testing with multiple assays is not medically necessary *NCCN Initial Risk Stratification and Staging workup for Clinically Localized Disease

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Oncology	Criteria

(see Tables)

Initial Risk Stratification and Staging Workup for Clinically Localized Disease			
Risk Group	Clinical/Pathologic Features		
Very Low	Has all of the following: • cT1c • Grade Group 1 • PSA <10 ng/ml • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core • PSA density <0.15 ng/mL/g		
Low	Has all of the following but does not qualify for very low risk: • cT1-cT2a • Grade Group 1 • PSA <10 ng/mL		
Intermediate	Has all of the following: • No high-risk group features • No very-high-risk features • Has one or more intermediate risk factors (IRFs): o cT2b-cT2c o Grade Group 2 or 3 o PSA 10-20 ng/mL	Favorable intermediate	Has all of the following: • 1IRF • Grade Group 1 or 2 • <50% biopsy cores positive (e.g., <6 of 12 cores)
		Unfavorable intermediate	Has one ore more of the following: • 2 or 3 IRFs • Grade Group 3 • ≥50% biopsy cores positive (e.g., ≥ 6 of 12 cores)
High	Has no very-high-risk features and has exactly one high-risk feature: • cT3a OR • Grade Group 4 or Grade Group 5 OR • PSA >20 ng/mL		
Very High	Has at least one of the following: • cT3b-cT4 • Primary Gleason pattern 5 • 2 or 3 high-risk features • >4 cores with Grade Group 4 or 5		

Grade Group	Gleason Score	Gleason Pattern
1	<6	<3 + 3
2	7	3 + 4
3	7	4 + 3
4	8	4 + 4, 3 + 5, 5 + 3
5	9 or 10	4 + 5, 5 + 4, 5 + 5

*NCCN Initial Risk Stratification and Staging Workup for Clinically Localized Disease

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Oncology	Criteria
Prostate Cancer – SelectMDx (CPT code 0339U)	There is insufficient evidence in the published medical literature to show clinical utility.
Proteomics - Ovarian Cancer Biomarker Panel (ROMA)	MCG* A-0858: This is not covered per MCG*
Proteomics (VeriStrat)	Epidermal Growth Factor Receptor Testing is covered when: 1) Diagnosis of NSCLC
Renal Cancer (Hereditary) - Gene Panel	MCG* A-0801: Considered medically necessary if indications in MCG A-0801 are met.
Retinoblastoma - RB1 Gene	MCG* A-0586
Thyroid Nodule Gene Expression Testing	

Test	Criteria
Afirma *81546* Thyroseq	There is insufficient evidence in the published medical literature to show clinical utility.
ThyGeNEXT® Thyroid Oncogene Panel + ThyraMIR Thyroid miRNA Classifier (CPT Codes *0245U+0018U)*	Molecular profiling of thyroid nodules with indeterminate cytology for ThyGeNext/ThyraMIR is medically necessary when specific criteria are met: • Thyroid nodule gene expression testing may be indicated when **ALL** of the following are present: o Thyroid nodule, as indicated by **ALL** of the following: ▪ Diameter of 1 cm or greater on ultrasound ▪ Indeterminate cytology on fine needle aspirate, as indicated by **1 or more** of the following): • Atypia of undetermined significance (ie, Bethesda System for Reporting Thyroid Cytopathology category III) • Follicular lesion of undetermined significance (ie, Bethesda System for Reporting Thyroid Cytopathology category III) • Follicular neoplasm or suspicious for follicular neoplasm (ie, Bethesda System for Reporting Thyroid Cytopathology category IV, excluding Hurthle cell type)

Von Hippel-Lindau Syndrome - VHL Gene	MCG* A-0583
Wilms Tumor - WT1	MCG* A-0615

Ophthalmology	Criteria
Age-Related Macular Degeneration - Gene Panels	MCG* A-0913 This is not covered per MCG
Retinal **Disorders** - Gene Panels	MCG* A-0912 This is not covered per MCG
Retinal Dystrophy - RPE65 Gene	MCG* A-1011

Orthopedics	Criteria
Ankylosing Spondylitis - HLA-B27 Testing	MCG* A-0762
Osteogenesis Imperfecta - Gene and Gene Panel Testing	MCG* A-0796

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Pulmonary	Criteria
Alpha-1 Antitrypsin Deficiency - SERPINA1 Gene Ambulatory Care > Genetic Medicine > Pulmonary >Alpha-1 Antitrypsin Deficiency - SERPINA1 Gene (A-1006)	MCG* **KP-**1006 *Note – this is a KP hybrid, not MCG A-1006*
Asthma - ADRB2 Gene	MCG* A-0763: This is not covered per MCG
Cystic Fibrosis-CFTR Gene and Mutation Panel:	Does not require medical review in the prenatal setting. For all other indications refer to MCG* **KP-**0597 *Note – this is a KP hybrid, not MCG A-0597*
Cystic Fibrosis Carrier Testing	Preconception or prenatal carrier testing for cystic fibrosis (CF) with targeted mutation analysis of 23 CFTR mutations (CPT code 81220) as described by the American College of Medical Genetics (ACMG) is considered medically necessary for a prospective biologic parent with the capacity and intention to reproduce. Any testing beyond the 23 gene CFTR mutations recommended by ACMG will not be covered as its utility has not been established. Testing is covered only once in a lifetime. ACMG Guideline - Minimum Mutation Panel for Population-Based Carrier Screening Purposes CF 3.3.1.
Congenital Central Hypoventilation Syndrome - PHOX2B Gene	MCG* A-0957

Risk Prognosticator Test	Criteria
• BREVAGen™ • Fibroblast Growth Factor Receptor 3 (FGFR3) • OVA1™ Test for the Assessment of Suspected Ovarian Cancer	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long- term outcomes than current standard services/therapies.
• MammaPrint Test (Gene-Expression Profiling Test, 70-Gene Prognostic Signature)	Medically necessary when **ALL** of the following criteria are met: 1. The patient has ER-positive, HER2-negative breast cancer ***and*** 2. One to three lymph nodes are positive for metastasis ***and*** 3. The patient is at high clinical risk for recurrence ***and*** 4. Outcome of testing will guide decision making regarding adjuvant chemotherapy.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Any genetic counseling notes if applicable Results of prior genetic testing
- Last 6 months of specialist notes of that is being reviewed (i.e., neurological notes, medical oncology notes, cardiology notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Evidence and Source Documents

Afirma
Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Intellectual Disability
ConfirmMDx for Prostate Cancer (MDxHealth Inc.)
Prolaris for Prostate Cancer
DecisionDx- Melanoma
HLA Testing for Celiac Disease
Micro Array for Evaluation of Intellectual Disability
OVA1 for Assessment of Ovarian Cancer
Risk Prognosticator Tests
SelectMDx for Prostate Cancer (MDxHealth Inc.)
Thyroid Nodule Gene Expression Testing (Afirma)
Whole Genome/Exome Sequencing for Developmental Delay (DD)/Intellectual Disability (ID)

Background

Genetic screening is used to identify the genetic disorders or the potential for transmission of genetic disorders in populations at risk for a particular genetic disorder. Genetic screening is only appropriate when the natural history of the disease is understood; the screening tests are valid and reliable; sensitivity, specificity, false-negative, and false-positive rates are acceptable; and effective therapy is available. A sufficient benefit must be derived from a screening program to justify its cost.

Medical Technology Assessment Committee (MTAC)

Afirma

BACKGROUND

Thyroid nodules are clinically identified in 5-7% of the population, and incidentally on ultrasonography in up to 50% of women and 20% of men over the age of 50. Thyroid nodules are typically benign, but 5-15% prove to be malignant. It is thus recommended that any identified nodule measuring one centimeter or more in diameter be diagnostically evaluated. Ultrasound-guided fine needle aspiration (FNA) biopsy is the most widely used method for clinical evaluation of a suspicious thyroid nodule. FNA is a safe and simple outpatient procedure that yields cellular material suitable for cytological analysis. It can identify approximately 50% of malignant nodules and 70% of benign nodules without the need to perform a diagnostic surgery. However, 15-30% of the biopsied nodules have indeterminate cytology and cannot be conclusively diagnosed by FNA biopsy alone. Most patients with indeterminate lesions or lesions suspicious for malignancy, according to the Bethesda classification* system, are referred to surgery for both diagnostic and therapeutic purposes. Surgery is the recommended and appropriate treatment for thyroid cancer, however 70-75% of the nodules with indeterminate FNA cytology are found to be benign on final surgical pathology. Thus, a large proportion of these patients may undergo unnecessary partial or complete thyroidectomy with its potential surgical complications and risk of long-term morbidity (Alexander 2012, Duick 2012, Walsh 2012, Ali 2013, Labourier 2015, Sacks 2016).

Molecular markers and assays have been investigated for their ability to preoperatively classify the indeterminate thyroid nodules. Each has its performance characteristics and diagnostic values. Ideally a molecular marker or panel of markers is accurate in differentiating benign from malignant in any lesion that is considered suspicious or indeterminate. Molecular tests should also be simple to use, reproducible by the different institutions/laboratories, and cost-effective.

Molecular genetic testing for cytologically indeterminate thyroid nodules fall in two approaches: the “rule in” and the “rule-out” disease approach. Tests that rule-in malignancy (such as BRAF, RAS mutations, RET/PTC and PAX8-PPAry) have high specificity and positive predictive values (PPVs) for malignancy by identifying specific mutations or gene rearrangements known to be present in thyroid cancer. However, they have limited sensitivity and negative predictive values (NPVs) and fail to detect as many as 30% of malignancies. Tests that rule-out the disease on the other hand, should have a high sensitivity and negative predictive value in order to exclude malignancy when the test results are benign. Because a majority of nodules with indeterminate cytology are found to be benign on surgical resection, a test that can preoperatively rule-out malignancy may spare a subset of these patient’s unnecessary diagnostic surgeries (Alexander 2012, Kouniavsky 2012, Ward 2013, Chaudhary 2016. Nishino 2016).

*2008 Bethesda classification system for thyroid cytology: Class I: Nondiagnostic or unsatisfactory, Class II. Benign, Class III: atypia or follicular lesion of undetermined significance (AUS/FLUS), Class IV: follicular neoplasm or suspicious for follicular neoplasm (FN), Class V: suspicious for malignancy (SUSP) and Class VI: malignant) (Kuo, 2016)

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Afirma gene expression classifier (GEC) is a molecular test developed by Veracyte Inc. (San Francisco, CA) with the intention of reducing unnecessary diagnostic surgeries in patients with thyroid nodules with indeterminate FNA cytopathologic results. It represents the "rule-out" approach by preoperatively identifying the benign thyroid nodules and ruling-out malignancy. Afirma GEC uses a proprietary diagnostic algorithm that analyses the mRNA expression of 167 genes to identify the signature of benign thyroid nodules. 142 of the 167 genes are in the main classifier, and 25 genes filter out rare neoplasms. The selected gene profile is based on the gene expression identified from FNAs of surgically proven benign and malignant thyroid nodules. During the Afirma GEC test RNA is extracted from the FNA sample, amplified and hybridized to a custom microarray to examine for gene patterns. These are compared with the GEC proprietary panel, which molecularly classifies them as either 'benign' or 'suspicious'. Insufficient RNA in the sample leads to 'no result' conclusion in approximately 10% of cases. Nodules with benign results, in addition to clinical judgement, are typically followed up clinically and ultrasonography, while those with suspicious results undergo diagnostic thyroid lobectomy with possible total thyroidectomy (Alexander 2012, Kim 2012, Ward 2013, Kuo 2016, Witt 2016).

Afirma GEC is a proprietary test commercially owned by Veracyte Corporation and is offered through a sole source, which is a Clinical Laboratory Improvement Amendments certified [CLIA] reference laboratory. During a routine FNA of a thyroid nodule, after the aspirates are obtained for cytopathologic examination, two more needle passes are obtained for Afirma analysis and immediately stored in a preservative. These are either 1. Sent to a Veracyte independent industry partner (Thyroid Cytopathology Partners [TCP], Austin, TX) that performs cytopathologic exam of the FNA sample, and only runs the Afirma test for indeterminate diagnoses on cytopathology, or 2. In Thyroid Cytopathology Medical centers designated as "Enabled centers" cytopathology is done in-house and specimens with indeterminate results based on the Bethesda criteria are sent for Afirma GEC testing. Afirma test is run only on nodules with indeterminate cytology. If the cytopathologic evaluation reveals any other diagnosis or is nondiagnostic due to insufficient FNA samples, the preserved samples are discarded. The goal of the test is to identify the benign nodules from among those with indeterminate cytopathology. It is not intended to assist with clinical decision making for patients who have an indication for surgery or meet criteria for surgical interventions (Alexander 2012, Duick 2012, Ward 2013, Kuo 2016. Yip 2016).

03/20/2017: MTAC REVIEW

Evidence Conclusion: Analytic validity of Afirma GEC (From an earlier MTAC review)

Evaluating the analytic performance of Afirma GEC includes studying the stability of RNA in FNAs during collection, storage, and shipment; reproducibility of the test; and its analytic sensitivity and specificity under various conditions e.g. interference of the assay with bloody FNA and genomic DNA. The literature search revealed one study (Walsh and colleagues, 2012) that evaluated the analytic performance of Afirma GEC in a number of sub-studies. The investigators obtained prospective FNA samples aspirated in vivo from 43 patients from outpatient clinics, preoperatively, or immediately after surgical excision. The samples were placed in FNAProtect preservative solution and shipped chilled or frozen, then stored at -80°C upon receipt. The RNA was extracted, and its yield examined for quantity and quality using positive (tissue lysate) and negative (water) as controls. Three different lots of controls were tested over several weeks of independent runs by 3 different operators to determine reliability of the test. Multiple lots of benign and malignant total RNA were manufactured and used as process controls to determine the analytic sensitivity of the test using different RNA input quantity and under different dilution of malignant FNA content. These studies indicated tolerance to variation in RNA input across a range of 5-25 ng. as well as dilution of malignant FNA material down to 20%. Analytic specificity of the test using malignant samples mixed with blood (up to 83%) and genomic DNA (up to 30%) showed minimal assay interference. However benign FNA samples mixed with relatively high proportions of blood had a potential for yielding false positive results. The investigators examined the stability of RNA in FNAs during collection and shipment and found that RNA content within FNAs preserved in FNAProtect was stable for up to 6 hours at room temperature with no change in RNA yield, and that the FNA storage and shipping temperatures had no significant effect on GEC scores. They also examined the reproducibility of the test and indicated that it was reproducible from extraction through GEC results, including variation across operators, runs, reagent lots, and laboratories. The investigators concluded that the analytical performance and reproducibility of the Afirma Gene Expression Classifier was successfully verified. The research was supported by Veracyte Corporation (the maker of Afirma GEC), and the authors of the study had financial ties to the corporation.

Clinical validity of Afirma GEC an ideal diagnostic test would have high sensitivity and specificity to correctly detect or exclude a condition. A molecular diagnostic test with high sensitivity offers a high negative predictive value (NPV) when the risk of malignancy is low and can "rule out'' malignancy. Conversely, a test with high specificity offers high positive predictive (PPV) value and can "rule in" malignancy. A preoperative diagnostic test would ideally have a high sensitivity in order not to miss a malignant nodule and have a high NPV to avoid surgery in patients

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with benign nodules. Predictive values do not only depend on the sensitivity and specificity of the test, but also on the prevalence of the disease; e.g. as the disease prevalence increases, the NPV decreases and vice versa. Afirma GEC test was validated in a. a double-blind prospective multicenter study (Alexander 2012 (Evidence table 1, reviewed earlier by MTAC). The study involved 265 nodules with indeterminate cytology that were selected for GEC analysis. Molecular results were compared to the gold standard of post-surgical histopathology. The malignancy rate was 32% and the Afirma sensitivity and specificity were 92% and 52% respectively with a NPV of 94-95% and PPV of 27-38% for Bethesda III/IV nodules. In the subgroup in patients with nodules suspicious for malignancy (SUSP) the NPV was only 85%, based on which, the authors concluded that GEC should not be used for cytology SUSP nodules. The study was conducted to validate the GEC accuracy by comparing it to surgical histopathology and did not compare its performance to repeat FNA or other immunochemical or molecular testing. A number of post-validation analyses were conducted by independent or industry supported investigators. In the initial validation study (Alexander 2012) the decision to resect the nodule was made independently of the GEC test results, while in the post-validation studies GEC was a factor influencing the decision whether to recommend a diagnostic surgical intervention. The published studies and analyses showed a wide variation in the NPVs and PPVs of Afirma GEC test results. The NPV and PPV of a test are neither absolute nor inherent in the test but depend on the pre-test probability of malignancy in the population studied, i.e. prevalence of malignancy in indeterminate nodules. This is made clear by Marti and colleagues (2014) who retrospectively analyzed all indeterminate thyroid nodules (ITNs) evaluated with GEC at two centers with widely different prevalence of malignancy in ITNs (Memorial Sloan Kettering Cancer Center [MSK] and Mount Sinai Beth Israel [MSBI]) (see table below).

The results of the validation study as well as post-validation studies are summarized in the following table.

Performance of GEC in the validation study and selected post-validation studies

Study	N FNA ITN undergoing GEC	Afirma results Suspicious	Afirma results Benign	Afirma results Inadequate RNA/ no result	Cancer prevalence in indeterminate FNA	NPV‡	PPV‡‡	Operative rate in GEC benign results
Alexander 2012 (multicenter Validation study)	265	62%	38%		32%	94-95%	27-38%	NA
Alexander, 2014 (5 centers)***	339	40%	55%	5%	--	99.4%	--	6.3%*
Harrell, 2014 (One practice)	58	62%	35%	3%	33-36%	88.3-89.6%	56%	25%**
McIver, 2014	72	61%	22%	17%	17%	94%	15.6%	25%
Marti, 2015 MSK center(tertiary) MSBI comprehensive health system)	 94 71	 74% 48%	 26% 52%	 -- --	 30-38% 10-19%	 86-92% 95-98%	 57.1% 14.3%	 8% 14%
Chaudhary, 2016†	158	54%	40%	6%		100%	38%	13%
Witt, 2016 (single-practice)	32	47%	44%	9%	21%	100%	--	0
Samulski, 2016 (single institution)	294	46%	49%	5%		81% for resected nodule, 98% for unrested benign GEC	39%	12%
Sacks, 2016 (single medical center)	140	55.7%	37.1%	7.1%	31.5%	92%††	33.3%	

All studies were performed in Institutional Enabled Centers, except for Harrell (2014) study where the cytology specimens were sent to Thyroid cytopathology partners (TCP).
* 1/11 (9.1%) was malignant (false negative)
** Of the 20 benign GEC patients 5 underwent surgery 2 of which (40%) were found to be malignant (False negative),
*** There were variation between the 5 study sites in the cytology distribution and Afirma GEC performance. GEC suspicious cases proved to be cancerous in 44% of cases (False positive in 56% of cases)
‡ The NPVs (the probability of cancer in GEC benign nodules) were all estimates and could not be directly assessed because not all patients had undergone surgery to determine surgical pathology or had long-term follow-up of the GEC benign nodules.
‡‡ The reported PPVs ranged between studies from 14-57% which limits the utility of the test as a rule-in test i.e. to predict the risk of malignancy.
† A comparison between pre- and post-GEC era showed no significant difference in surgical excision rates of FNA ITN. There were differences in the accuracy and predictive values of the GEC according to the cytomorphological features of the nodules. The authors concluded that the GEC test was found to reduce surgical excision of nodules with suspicious for follicular neoplasm (SFN), but not with FLUS / AUS or Hurthle cell neoplasm (HCN). They recommended repeating FNA rather than performing Afirma GEC test for FLUS/AUS, and be cautious when ordering GEC on HCN cases. 8 (13%) of the benign affirm underwent surgery and all were found benign
†† Estimated based on the prevalence. Cold not be calculated due o the low number of GEC-benign cases with surgical pathology
-- Not provided

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Based on the results of the published studies, some investigators suggest that Afirma GEC may provide useful information in practice settings where the prevalence of malignancy in indeterminate thyroid nodules is 15-21%. At this range and using the sensitivity and specificity data from the multicenter validation study the NPV would be >95% and the PPV >25%. It is suggested that GEC may also provide some useful information with the prevalence of malignancy ranging from 12-25% but is not expected to be useful in altering management if the prevalence is outside this range (Marti 2015, Zhang 2016). The Afirma GEC performance was found to be suboptimal for Hurthle cell neoplasms (HCNs). Wu and colleagues (2016) examined the clinical factors influencing the performance of GEC testing and found that the test has a limited clinical validity for HCNs due to the high rate of false positive results (specificity 22.7-26.1% and PPV 29.2%). Other studies also showed inconsistent and low performance of GEC testing for HCN nodules. In the clinical validation study only 4 of 21 (19%) FNA samples from Hurthle adenomas were classified as benign with GEC.

Limitations in the published studies These include but are not limited to the following:

- All analyses were retrospective with potential bias and confounding.
- There were intra- and inter-observer differences within and between studies in the histological interpretations.
- Only data for patients with GEC testing were analyzed and with the exception of one study, the results were not compared to repeat FNA or other tests.
- The NPVs were all estimates as only a very limited number of GEC benign nodules underwent surgery, and the follow-up duration was too short to determine the true benign nature of the GEC benign nodules.
- The majority of the published studies were industry sponsored.
- The predictive values of a test vary with the prevalence of the disease in a population studied and may not be generalized to other groups. A better analysis would be the likelihood ratios which are not affected by prevalence.

Santhanam and colleagues' meta-analysis (2013, Evidence table 2) pooled the results of 7 prospective and retrospective studies to determine the sensitivity and specificity of the GEC test in classifying FNA indeterminate thyroid nodules and evaluate its clinical utility. The results of the meta-analysis are summarized in the following table:

Pooled results

Pooled values	Value (95% CI)	P value
Sensitivity	95.7% (92.2-97.9)	0.09
Specificity	30.5% (26.0-35.3)	<0.01
Positive likelihood ratio*	1.20 (0.99-1.44)	<0.01
Negative likelihood ratio**	0.2 (0.11-0.36)	0.56
Diagnostic odds ratio	7.86 (4.1-15.01)	0.42
Prevalence of malignancy	37.1%	
Positive predictive value	44.8 (40.4-49.4)	

*A good test for ruling-in a disease is the one with the largest positive likelihood ratio (LR) A positive LR of 1 means that the test does not provide any information on ruling in the disease, LR >1<5 indicates a small effect, and LR>10 indicates a large effect on increasing the probability of a disease is presence.

** The better test to rule-out a disease is the one with the smaller negative likelihood ratio. LR <0.1 indicates that the result has a large effect on decreasing the probability of the disease (rule out), LR 0.1-0.5 indicates moderate effect, and >0.5 indicates a small effect. The meta-analysis had valid methodology, but a meta-analysis is as good as the studies it includes. Due to the lack of RCTs and comparative prospective studies Santhanam and colleagues pooled the results of observational prospective and retrospective studies. There was significant heterogeneity between the studies as they were performed at different institutions and included a wide distribution of patients with different indeterminate cytology results (the test may perform better for one type of neoplasm/cancer versus the other). The meta-analysis had the advantage of calculating likelihood ratios which are not affected by prevalence the condition as

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the predictive values. However, likelihood ratios are calculated based on the sensitivity and specificity of the test, which may have not been accurate as the majority of GEC benign cases did not undergo surgery or were followed up for a sufficient duration to assess the actual accuracy of the test, and not all GEC suspicious cases underwent surgery. More recently in 2016, an international panel of pathologists and clinicians reclassified a clinically indolent malignant tumor (encapsulated follicular variant of papillary thyroid carcinoma [EFVPT]) as a benign neoplasm (noninvasive follicular thyroid neoplasm with papillary-like nuclear features [NIFTP]) (Niktforov 2016). This reclassification may affect the calculated performance of the current Afirma GEC as it has not been validated with these changes. In one study Samulski and colleagues (2016) reported that of 11 NIFTP cases in their cohort, only one was classified as benign with the GEC test.

Clinical utility of Afirma GEC the clinical utility of Afirma GEC would be guiding the management decisions by clearly ruling out malignancy in FNA indeterminate nodules to avoid unnecessary diagnostic surgery. The published studies on the impact of Afirma GEC on the management of patients with FNS ITNs were retrospective in nature, performed in different sites with intra- and inter-rater variability, which are potential sources of selection and performance bias. In addition, the studies only focused on nodules that underwent Afirma GEC testing and did not investigate the effect of FNA results on overall thyroidectomy rates, or include a comparison group to examine the impact of a repeat FNA or other tests for nodules with indeterminate cytopathology. Santhanam and colleagues (2013, Evidence table 2) discussed in the previous section on clinical validity of Afirma GEC also evaluated its clinical utility of the test. The authors calculated that for patients with FNA indeterminate nodule, one thyroid surgery can be avoided for every two Afirma GEC tests, assuming that >90% of the patients with benign GEC are followed conservatively. They noted however, that according to the American Cancer Society, the 5-year survival of stage I and stage II follicular and papillary thyroid cancer is 100%. The morbidity and mortality rates in patients with FNA indeterminate thyroid nodules are reported to be more likely low, and thus the diagnosis of suspicious nodules with GEC testing may represent a lead-time bias with little change in overall survival.

Sacks and colleagues (2016 Evidence table 3) performed a retrospective analysis to evaluate the impact of Afirma GEC testing on cytopathology diagnosis, rate of surgery, and the rate of malignancy on all indeterminate nodules (ITNs) before and after the introduction of Afirma GEC testing at a high-volume thyroid center. The study was a retrospective analysis of patient data from one institution, with no direct comparison to a control group. However, it had the advantage of reporting on outcomes of repeat FNAs, comparing two cohorts' pre-and post-Afirma, and reporting on thyroidectomy rates among all cases irrespective of GEC testing. The calculated PPV for the test was 33.3%, and the estimated NPV was 92% (an accurate NPV could not be calculated due to small number of GEC benign cases with surgical pathology). There was a significant increase Bethesda III-IV diagnosis in the post Afirma cohort compared to the pre-Afirma cohort (13.4% vs. 10.7%, $p<0.005$), with a corresponding significant decrease in benign cytology (Bethesda II) post-Afirma (74.6% compared to 68.8% pre-Afirma, $p<0.001$), despite the use of the same guidelines, practice, reporting scheme, and personnel. In an attempt to explain the reason for this shift, the authors supposed that cytopathologists, especially those with less experience, may be less likely to classify nodules as Bethesda II knowing that the GEC testing will help stratify them. No significant changes were observed for Bethesda I, V, or VI, or in the rate of repeat FNA for ITNs. The author noted that while Afirma may reduce the rate of thyroidectomy for nodules with benign GEC results, the "suspicious label" may increase it. Only 33.3% of GEC suspicious cases were found to be malignant. The analysis shows that 35.2% of patients with ITNs who underwent a repeat FNA were classified as non-ITN and avoided Afirma testing. Overall, the results of the analysis indicate that the use of Afirma GEC testing was associated with an increase in the rate of FNA indeterminate diagnosis, and a decrease in the incidence of benign diagnosis. GEC testing did not reduce the overall rate of thyroidectomies which is its main goal. As indicated earlier the study had its disadvantages, which may limit generalization of the results.

Abeykoom and colleagues (2016), performed a similar respective analysis in a single endocrine clinic comparing the rate of surgeries pre-and post GEC testing for nodules with indeterminate cytopathology (N=61 [27 before and 34 after GEC implementation]). The results were however, inconsistent with Sack's 'findings. The analysis showed no significant difference before and after GEC implementation in the rate of ITNs, but there was a significant decrease in the recommendation for surgery for patients with ITNs from 81.5% pre-GEC implementation to 50% post GEC ($p=0.01$). The surgical pathology for those who underwent an operation was read as malignant in 20% and 85.7%. of patients before and after Afirma GEC respectively ($p<0.01$). The study was retrospective, small, included patients from a single center over two-time periods with different pathologists analyzing the specimens, which are potential sources of confounding and bias that may limit generalization of the results.

Duick and colleagues (2012, Evidence table 4, from an earlier MTAC review) performed a chart review for 21 endocrinology practices in 11 states. They analyzed data for 368 patients with 395 cytologically indeterminate thyroid nodules with Afirma GEC benign results. 7.6% of these patients underwent surgery and 94.4% were

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managed nonoperatively.

The study did not have a comparison group, but the authors compared the 7.6% surgical rate in nodules with benign GEC results to a 74% historical rate of diagnostic surgery (P<0.001). The main indications for surgery for those with GEC benign results were the rapid growth or larger size of the nodules, local pressure symptoms, or the presence of a second suspicious nodule or malignant nodule.

The study was retrospective, used a historical comparison, and investigated the decision-making of endocrinologists experienced in managing patients with thyroid nodules, which may differ from that made by primary care providers or other specialists. In addition, the authors of the study did not provide data on long-term follow-up of those who were managed by watchful waiting rather than surgery.

Sipos and colleagues (2016), retrospectively analyzed data recorded for 98 patients with a benign GEC over a mean duration of 36 ±3 months (range 0-44 months) treated at multiple centers. 17 of these 98 patients (17.3%) underwent surgery during this period. 88% of the surgeries were performed in the first 2 years after the benign GEC results with the rate leveling after the first year. The most common indications for surgery were the nodules rapid growth and large size. The authors concluded that the study shows that benign GEC test results are associated with low operative rates. The study had its limitations and the authors did not provide data on the pathology results of the resected nodules.

Articles: The updated literature search revealed a number of retrospective analyses performed after the Afirma GEC validation study, a meta-analysis that pooled the results of selected studies, and three retrospective studies on the clinical utility of the test. The study on the analytic validity, the two clinical validation studies as well as two retrospective studies on clinical utility were reviewed earlier by MTAC. The meta-analysis and the more recent studies on the clinical validly and clinical utility of Afirma GEC test were reviewed and their results summarized.

04/12/2022: MTAC Review
Thyroid Nodule Molecular Testing
Evidence Conclusion: Analytical validity: One study showed that Afirma GSC test has a strong analytic performance and is reproducible. Clinical validity: Low quality evidence suggests that: Afirma GSC test has a good diagnostic performance. Comparison to ThyroSeq v3 and ThyraMIR/ThyGeNEXT: the diagnostic performance cannot be ranked due to lack of head-to-head comparisons. Clinical utility: The evidence is insufficient (very low quality) for or against the use of Afirma GSC to reduce unnecessary surgery in patients with indeterminate thyroid nodules.

Articles: PubMed was searched through October 26, 2021. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Search terms included: (Afirma Genomic Sequencing Classifier OR Genomic Sequencing Classifier OR GSC OR Afirma OR Veracyte) AND (thyroid) through 10/21/21.
For Thyroseq v3, search terms included ThyroSeq v3Regarding ThyGeNEXT and ThyraMIR, search terms included Interpace or ThyGeNEXT or ThyraMIR. Afirma GSC: The search yielded several articles. After screening through abstracts and/or full text, 9 studies were retained and reviewed. The studies consisted of 1 analytical validity study, four clinical validity studies, and four clinical utility studies. Thyroseq v3: The search yielded several articles. Studied retained are critically appraised. ThyGeNEXT and ThyraMIR: The search yielded several articles. Studied retained are critically appraised. See Evidence tables.

The use of Thyroid Nodule Molecular Testing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Intellectual Disability

BACKGROUND
Intellectual disability, also termed mental retardation or cognitive disability, affects approximately 1-3% of the general population and is defined as a significant impairment in cognitive and adaptive functions, with the age of onset before 18 years. It is a serious and lifelong condition that presents significant challenges to families and to public health. Determining the specific etiology of intellectual disability may help to provide answers related to prognosis, recurrence risk, and treatment. Intellectual disability can be caused by anything that damages or interferes with the growth or maturation of the brain; however, genetic (chromosomal) abnormalities are one of the main causes of intellectual disability (Galasso 2010, Sagoo 2009). Chromosomal abnormalities are deletions and duplications of genomic material and are commonly referred to as copy number variations. Conventional methods for detecting these abnormalities include karyotyping and florescent in situ hybridization (FISH). Karyotyping

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involves visualizing the chromosome for large gains or losses in chromosomal material and is generally the first step in cytogenetic analysis. Karyotyping can detect chromosomal abnormalities such as deletions, duplications, inversions, and translocations across the entire genome; however, it lacks the resolution necessary to detect abnormalities smaller than 3-5 megabases (Mb; 3-5 million base pairs). FISH uses florescent-labeled chromosome-specific probes to detect chromosomal abnormalities. FISH can detect submicroscopic abnormalities and is often used in situations where the karyotype is normal, but there is a high clinical suspicion of a deletion syndrome. However, FISH is a targeted method and requires prior knowledge of the chromosome region(s) of interest to request the appropriate FISH test. Additionally, FISH can only screen a limited number of genomic regions at a time (Breman 2009, Fruhman 2010, Galasso 2010, Gropman 2010). Array comparative genomic hybridization (aCGH) is a more recent technology used to identify copy number variations by comparing patient DNA with reference DNA. It is currently used as an adjunct to conventional methods. There are two types of aCGH: targeted and whole-genome. Targeted arrays are designed to interrogate areas of the genome with known clinically significant abnormalities. Whole genome arrays provide high resolution coverage of the entire genome. This can lead to the discovery of new copy number variations. Compared to conventional methods, aCGH has a higher resolution and is able to simultaneously detect copy number variations in multiple regions of the genome. Additionally, unlike FISH, knowledge of the chromosome region(s) of interest does not need to be determined in advance because a single array assay detects all genomic variants represented on the array. Array CGH is not without limitations. It cannot detect totally balanced translocations or inversions; it performs suboptimally for polyploidy; and has not been optimized for prenatal diagnosis of point mutations. Because aCGH cannot identify the exact location of a duplicated chromosome, further testing with karyotype or FISH may be necessary. Another limitation is the potential to identify novel copy number variants with unknown clinical significance (Fruhman 2010, Moeschler 2008). Array CGH is a laboratory-developed test and is commercially available from several different laboratories. Laboratory-developed tests are licensed under the Clinical Laboratory Improvement Amendments (CLIA) and do not require clearance from the FDA.

The use of Gene Expression Classifier (Afirma®) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

4/18/2011: MTAC REVIEW
Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Intellectual Disability
Evidence Conclusion: Analytic validity The BCBS review identified several studies that evaluated the sensitivity of aCGH. The sensitivity of aCGH testing compared to conventional methods (karyotype and/or FISH) ranged from 73% to 100%. As false-positive rates were inconsistently reported, specificity could not be determined (BCBS 2009). Clinical validity
Articles: No studies were identified that evaluated the impact of conventional methods or aCGH on patient outcomes other than diagnostic yield. Results from the BCBS review suggest that diagnostic yield in patients with intellectual disability ranged from 5 to 16.7%, which represents a significant improvement compared to conventional methods. The number needed to test by aCGH to detect one clinically relevant abnormality ranged from 25 to 6 depending on the diagnostic yield. Limitations of these studies include: different aCGH resolution, patient selection criteria ranged from none too stringent criteria, and three different types of arrays were used (targeted, whole-genome, and those that combined targeted and whole-genome arrays) (BCBS 2009).

Diagnostic yield[1] of aCGH, karyotype, and FISH

	aCGH	FISH	karyotype
Diagnostic yield	4-7% (In those negative by karyotype and FISH)	5-6% (In those negative by karyotype)	3-5%

[1]Estimates from Stankiewicz 2007.

Clinical utility The BCBS review included two small studies with a high risk of bias and found that there was insufficient evidence to determine the clinical utility of aCGH testing (BCBS 2009). Conclusion: Analytic validity: There is fair evidence that aCGH testing had good sensitivity compared to conventional methods; however, there is insufficient evidence to determine the specificity or reproducibility of this test. Clinical validity: There is fair evidence that aCGH increases diagnostic yield over conventional methods; however, this is an intermediate outcome. Clinical utility: There is insufficient evidence that patients managed with the genetic test had better outcomes than patients managed without the genetic test.
In 2009, Blue Cross and Blue Shield (BCBS) evaluated the use of aCGH for the genetic evaluation of patients with developmental delay/ mental retardation. Studies were selected for review if they were published after the 2009 review and did not support the BCBS recommendations. No studies were identified that would

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change the BCBS recommendations. The following review was critically appraised: Blue Cross and Blue Shield Association.
Special report: aCGH for the genetic evaluation of patients with developmental delay/mental retardation or autism spectrum disorder. Assessment Program. Volume 23, No. 10. April 2009.

The use of Array Comparative Genomic Hybridization (aCGH) for the genetic evaluation of patients with intellectual disability does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

HLA Testing for Celiac Disease

BACKGROUND

Celiac disease is a chronic, autoimmune disorder that affects approximately 1% of children and adults in the United States. In individuals with celiac disease, the ingestion of gluten proteins found in wheat, rye, and barley lead to an autoimmune reaction that causes small intestine mucosal injury. Damages in the small intestine can cause gastrointestinal symptoms and interfere with the absorption of nutrients from food. This may lead to malnutrition-related problems such as anemia, vitamin deficiencies, osteoporosis, and neurological disorders. A gluten-free diet typically resolves symptoms and can prevent long-term consequences (Tack 2010). There are a variety of tests available to diagnose celiac disease. The gold-standard for diagnosing celiac disease is a small intestine biopsy. However, this test is not a perfect gold-standard as false positive and false-negative results may occur due to interobserver variability, patchy mucosal damage, low-grade histological abnormalities, and technical limitations. Additionally, histological features are not unique to celiac disease. Serum antibody tests are used as an initial screening tool to detect and support the presence of celiac disease and to select which patients should undergo a biopsy. Two of the most sensitive and specific serological tests for diagnosing celiac disease are tests that assess the presence of IgA autoantibodies against the endomysium of connective tissue (EMA) (sensitivity 62-81%, specificity 80-99%) and against tissue transglutaminase (tTGA) (sensitivity 81-88%, specificity 84-99%). While these tests are accurate, they are not without limitations. For example, the EMA test correlates with the degree of mucosal damage. As such, the sensitivity of this test is lower in patients with milder cases (higher chance of false negative results). Additionally, false negative results may occur in patients with an IgA deficiency and in patients who are already on a gluten-free diet. In patients with an IgA deficiency, serum IgA testing can be replaced by using IgG assays, which are less sensitive than IgA assays. Another test that can be used to rule out the diagnosis of celiac disease is human leukocyte antigen (HLA) genotyping. It has been reported that approximately 90-95% of patients with celiac disease are carriers of the HLA-DQ2 heterodimer and most of the remaining patients carry the HLA-DQ8 heterodimer. Since virtually all patients with celiac disease carry one of these heterodimers, celiac disease is highly unlikely when both are absent. It has been proposed that using HLA genotyping as an initial screening tool may avoid future concerns about the condition and eliminate further diagnostic testing. However, HLA typing is not a perfect solution since around 25-40% of the general population carries either HLA-DQ2 or DQ8, of which the majority never develop the disease. Other situations where HLA genotyping may be useful is when the diagnosis of celiac disease is unclear based on serological and/or histological findings. Additionally, HLA genotyping can be performed in patients who are already on a gluten free diet (Tack 2010, Hadithi 2010).

4/18/2011: MTAC REVIEW

HLA Testing for Celiac Disease

Evidence Conclusion: Analytic validity There are a variety of methods used for HLA genotyping. Each of these assays has its advantages and limitations (Monsuur 2008, Lavant 2009). Clinical validity A recent prospective cohort study evaluated the accuracy of serologic tests and HLA-DQ genotyping used alone and in combination for diagnosing celiac disease compared to small intestine biopsy. Results from this study suggest that both tTGA and EMA are sensitive and specific tests for diagnosing celiac disease. HLA-DQ testing was also highly sensitive but was not as specific as serologic testing. The addition of HLA-DQ genotyping to serum antibody tests did not increase test performance compared to serologic testing alone. Results should be interpreted with caution as only 16 patients were diagnosed with celiac disease (Hadithi 2007). Sensitivity and specificity of serologic testing and HLA-DQ typing for diagnosing celiac disease

	Sensitivity (95% CI)	Specificity (95% CI)
HLA-DQ testing		
HLA-DQ2 or DQ8	100 (79-100)	57 (52-62)
Serologic testing using IgA		
tTGA	81 (54-95.9)	99.1 (97.7-99.7)
EMA	81 (54-95.9)	99.1 (97.7-99.7)
tTGA & EMA	81 (54-95.9)	99.3 (98-99.9)

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Both serologic testing & HLA-DQ testing		
tTGA & HLA-DQ	81 (54-95.9)	99.3 (98-99.3)
EMA & HLA-DQ	81 (54-95.9)	99.1(97.7-99.8)
tTGA, EMA, & HLA-DQ	100 (79-100)	99.3 (98-99.9)

Abbreviations: EMA= antiendomysium antibody; tTGA= antitransglutaminase antibody.

Another observational study investigated whether HLA genotyping would be useful to identify first-degree relatives of patients with celiac disease who do not need further screening for celiac disease. Fifty-four families with at least two siblings with celiac disease were selected to participate in the study. In total, 245 (52.5%) first-degree relatives agreed to participate. The diagnosis of celiac disease was based on duodenal biopsy and medical records. Of all of the first-degree relatives, 17.6% (N=43) did not carry any of the celiac disease risk alleles. Of these relatives, only one was diagnosed with celiac disease (Karinen 2010). Clinical utility
Because of its low specificity HLA genotyping may not be an ideal initial screening test for diagnosing celiac disease. However, HLA genotyping may be useful in certain situations, such as when the diagnosis of celiac disease is unclear based on serologic and histologic findings and when patients are already on a gluten free diet, to rule out celiac disease. Additionally, as negative serologic or histologic test results do not exclude the development of celiac disease later in life, the use of HLA genotyping in patients who are at increased risk for celiac disease may prevent unnecessary serologic and histologic testing. Conclusion: Analytic validity: There are a variety of methods used for HLA genotyping. Each of these assays has its advantages and limitations. Clinical validity: There is fair evidence that HLA genotyping may be a useful adjunct in the diagnosis of celiac disease as it has a high negative predictive value. Clinical utility: No studies were identified that addressed the clinical utility of HLA genotyping for celiac disease; however, early identification and treatment of the disease can prevent short- and long-term complications.

Articles: Articles were selected for review if they included at least 25 subjects and assessed the accuracy of HLA genotyping compared to the small intestine biopsy. A prospective cohort study was selected for review. The following study was critically appraised: Hadithi M, von Blomberg ME, Crusius BA, et al. Accuracy of serologic tests and HLA-DQ typing for diagnosing celiac disease. *Ann Intern Med 2007;* 147:294-302. See Evidence Table

The use of HLA testing for celiac disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Micro Array for Evaluation of Intellectual Disability

BACKGROUND

Intellectual disability, also termed mental retardation or cognitive disability, affects approximately 1-3% of the general population and is defined as a significant impairment in cognitive and adaptive functions, with the age of onset before 18 years. It is a serious and lifelong condition that presents significant challenges to families and to public health. Determining the specific etiology of intellectual disability may help to provide answers related to prognosis, recurrence risk, and treatment.

Intellectual disability can be caused by anything that damages or interferes with the growth or maturation of the brain; however, genetic (chromosomal) abnormalities are one of the main causes of intellectual disability (Galasso 2010, Sagoo 2009).

Chromosomal abnormalities are deletions and duplications of genomic material and are commonly referred to as copy number variations. Conventional methods for detecting these abnormalities include karyotyping and florescent in situ hybridization (FISH). Karyotyping involves visualizing the chromosome for large gains or losses in chromosomal material and is generally the first step in cytogenetic analysis. Karyotyping can detect chromosomal abnormalities such as deletions, duplications, inversions, and translocations across the entire genome; however, it lacks the resolution necessary to detect abnormalities smaller than 3-5 megabases (Mb; 3-5 million base pairs).

FISH uses florescent-labeled chromosome-specific probes to detect chromosomal abnormalities. FISH can detect submicroscopic abnormalities and is often used in situations where the karyotype is normal, but there is a high clinical suspicion of a deletion syndrome. However, FISH is a targeted method and requires prior knowledge of the chromosome region(s) of interest to request the appropriate FISH test. Additionally, FISH can only screen a limited number of genomic regions at a time (Breman 2009, Fruhman 2010, Galasso 2010, Gropman 2010).

Array comparative genomic hybridization (aCGH) is a more recent technology used to identify copy number variations by comparing patient DNA with reference DNA. It is currently used as an adjunct to conventional methods. There are two types of aCGH: targeted and whole-genome. Targeted arrays are designed to interrogate areas of the genome with known clinically significant abnormalities. Whole genome arrays provide high resolution coverage of the

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entire genome. This can lead to the discovery of new copy number variations. Compared to conventional methods, aCGH has a higher resolution and is able to simultaneously detect copy number variations in multiple regions of the genome. Additionally, unlike FISH, knowledge of the chromosome region(s) of interest does not need to be determined in advance because a single array assay detects all genomic variants represented on the array. Array CGH is not without limitations. It cannot detect totally balanced translocations or inversions; it performs suboptimally for polyploidy; and has not been optimized for prenatal diagnosis of point mutations.
Because aCGH cannot identify the exact location of a duplicated chromosome, further testing with karyotype or FISH may be necessary. Another limitation is the potential to identify novel copy number variants with unknown clinical significance (Fruhman 2010, Moeschler 2008).

Array CGH is a laboratory-developed test and is commercially available from several different laboratories. Laboratory-developed tests are licensed under the Clinical Laboratory Improvement Amendments (CLIA) and do not require clearance from the FDA.

Date: 07/09/2018 MTAC REVIEW
Chromosomal microarray for Intellectual Disability (ID)/ Developmental delay (DD)
BACKGROUND
Intellectual disability is a disorder marked by deficits in intellectual and adaptive functioning and starts before 18 years of age. Its management requires early diagnosis and extensive supports. Intellectual disability is caused by any conditions disrupting brain development. Of these conditions, genetic abnormalities are the most common known etiologies (Rauch et al., 2012) with Down syndrome being the leading cause. Conventional cytogenetics (karyotype analysis and fluorescence in situ hybridization (FISH)) can identify the cause but detect less than 10% of chromosomal abnormalities in patients with intellectual disability (ID) or developmental delay (DD) (Shaffer, Beaudet, et al., 2007; Shaffer, Bejjani, et al., 2007). Chromosomal microarray analysis (CMA) has become the primary test for most patients with intellectual disability (Miller et al., 2010). CMA includes array-based comparative genomic hybridization (aCGH) or single nucleotide polymorphism (SNP) microarray analysis.

Array-based comparative genomic hybridization (aCGH), also known as oligonucleotide array comparative genomic hybridization utilizes both patient and control genomes. These DNAs are marked with fluorescent dyes and applied to the microarray. This step is followed by hybridization. Hybridization occurs when patient and control DNAs compete to attach to the microarray which is comprised of thousands of DNA segments (bacterial artificial chromosome clones of > 10 kilobases or oligonucleotides of 50–70 base pairs). Fluorescent signals are assessed by a scanner and a computer analyzes the data and generates a plot. This results in the identification of copy number changes (Theisen et al., 2008(Shaffer et al., 2008)). It is believed that the aCGH concurrently detects copy number variants (CNVs) (deletions, duplications), and/or amplifications across the genome. However, the array-based comparative genomic hybridization cannot detect low-level mosaicism or balanced chromosomal rearrangements (Brady & Vermeesch, 2012). The results of the CMA are interpreted as benign with no impact on phenotype, or pathogenic/clinical significant, or uncertain clinical significance. In the latter category, samples from parents are required for assessment of the clinical significance (Miller et al., 2010; Paciorkowski & Fang, 2009). If the CMA does not detect a cause, whole exome sequencing (WES) may be performed. Single nucleotide polymorphism (SNP) arrays is a variation of DNA sequence that occurs when there is a discrepancy between a single nucleotide and a reference sequence in the same person. Single nucleotide polymorphism is used as the probes. Only the patient sample is hybridized onto the array(Das & Tan, 2013). SNP can detect copy number changes, uniparental disomy, consanguinity, and balanced translocations (Conlin et al., 2010; Schaaf, Wiszniewska, & Beaudet, 2011; Wiszniewska et al., 2014). No FDA regulatory information was found on FDA website on March 12, 2018. However, genetic tests are controlled under the Clinical Laboratory Improvement Amendments (CLIA). The technology is being assessed for the first time on Medical Technology Assessment Committee (MTAC).

Evidence Conclusion:
Conclusion:

- **Analytic validity:** Four studies were reviewed and showed high sensitivity and specificity with high concordance in comparison to FISH or karyotyping. This suggests that chromosomal microarray can accurately detect copy number variants in children and adolescents with developmental delay or intellectual disability. The studies were retrospective in design or case series resulting in low evidence.
- **Clinical validity:** Nine studies (please refer to “other studies table” and table 2) in addition to those included in Milliman review (evidence table 1) were evaluated. In children and adolescents with unexplained developmental delay or intellectual disability, chromosomal microarray (aCGH) diagnosed genomic alterations that were not detected by conventional cytogenetic tests including karyotype or FISH. This suggests that the

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detection rate of chromosomal microarray is higher than conventional cytogenetic tests. However, the studies reviewed were case series or retrospective chart review resulting in low evidence.

- **Clinical utility:** Two studies (please refer to "other studies table" and table 2) in addition to those included in Milliman review (evidence table 1) were evaluated. The clinical utility revolved around referrals to specialists, recommendation for screening of other anomalies, provision of recurrent risk for affected subsequent pregnancies, and avoidance of unnecessary testing. However, the studies were surveys and retrospective review with small sample size resulting in low evidence.
- Milliman Care guidelines indicated that there is a net benefit in evaluating children and adolescents with intellectual disability with chromosomal microarray analysis (CMA). The use of CMA to detect copy number variants affects medical management and this includes referrals to specialists, treatment intervention for special findings, reduction of unnecessary procedures, and screening for associated anomalies. However, the evidence is of low certainty.

The use of Chromosomal microarray for Intellectual Disability (ID)/ Developmental delay (DD) meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/18/2011: MTAC REVIEW

Array Comparative Genomic Hybridization (aCGH)

Evidence Conclusion: Analytic validity - The BCBS review identified several studies that evaluated the sensitivity of aCGH. The sensitivity of aCGH testing compared to conventional methods (karyotype and/or FISH) ranged from 73% to 100%. As false-positive rates were inconsistently reported, specificity could not be determined (BCBS 2009). Clinical validity - No studies were identified that evaluated the impact of conventional methods or aCGH on patient outcomes other than diagnostic yield. Results from the BCBS review suggest that diagnostic yield in patients with intellectual disability ranged from 5 to 16.7%, which represents a significant improvement compared to conventional methods. The number needed to test by aCGH to detect one clinically relevant abnormality ranged from 25 to 6 depending on the diagnostic yield. Limitations of these studies include: different aCGH resolution, patient selection criteria ranged from none to stringent criteria, and three different types of arrays were used (targeted, whole-genome, and those that combined targeted and whole-genome arrays) (BCBS 2009).

Diagnostic yield[1] of aCGH, karyotype, and FISH

	aCGH	FISH	karyotype
Diagnostic yield	4-7% (In those negative by karyotype and FISH)	5-6% (In those negative by karyotype)	3-5%

[1]Estimates from Stankiewicz 2007.

Clinical utility- The BCBS review included two small studies with a high risk of bias and found that there was insufficient evidence to determine the clinical utility of aCGH testing (BCBS 2009).

Conclusion:

1. Analytic validity: There is fair evidence that aCGH testing had good sensitivity compared to conventional methods; however, there is insufficient evidence to determine the specificity or reproducibility of this test.

2. Clinical validity: There is fair evidence that aCGH increases diagnostic yield over conventional methods; however, this is an intermediate outcome.

3. Clinical utility: There is insufficient evidence that patients managed with the genetic test had better outcomes than patients managed without the genetic test.

Articles: In 2009, Blue Cross and Blue Shield (BCBS) evaluated the use of aCGH for the genetic evaluation of patients with developmental delay/ mental retardation. Studies were selected for review if they were published after the 2009 review and did not support the BCBS recommendations. No studies were identified that would change the BCBS recommendations. The following review was critically appraised: Blue Cross and Blue Shield Association.

Special report: aCGH for the genetic evaluation of patients with developmental delay/mental retardation or autism spectrum disorder. Assessment Program. Volume 23, No. 10. April 2009.

The use of Array Comparative Genomic Hybridization (aCGH) for the genetic evaluation of patients with intellectual disabilities does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

Risk Prognosticator Test

BREVAGen

BACKGROUND

According to the American Cancer Society, breast cancer is the second leading cause of death in women in the United States after lung cancer. Current methods of assessing breast cancer risk include the Breast Cancer Risk Assessment Tool (BCRAT) otherwise known as the Gail model. This model incorporates individual risk factors such as basic demographic information, reproductive history and medical history. Recent genome wide association studies have identified several single nucleotide polymorphisms (SNPs) associated with an increased risk of breast cancer leading to an additional dimension and understanding of risk (Easton, Pooley et al. 2007; Stacey, Manolescu et al. 2007; Stacey, Manolescu et al. 2008). The BREVAGen™ (Phenogen Sciences, Inc., Charolette, NC) is a risk stratification test for sporadic breast cancer. Intended for use as an adjunct to the Gail model, the test consists of two parts, the first, a series of questions to determine clinical risk and the second, a buccal swab to analyze specific genetic markers. The latter part of the test, includes a panel of seven SNPs associated with breast cancer risk and does not include either of the BRCA mutations. Ultimately, a patient's risk is calculated by multiplying the product of the individual SNP risks by the Gail model risk. According to the BREVAGen™ website, the test is only suitable for women of European descent aged 35 years or older. No test combining the results of SNP analysis with clinical factors to predict breast cancer risk has been approved or cleared by the U.S. Food and Drug Administration (FDA). BREVAGen™ is offered as a laboratory developed tests and only requires oversight under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The development and use of this laboratory developed test is restricted to laboratories certified as high complexity under CLIA. Under the current regulatory program, CLIA requires that laboratories demonstrate quality systems which includes validation and proficiency testing.

12/16/2013: MTAC REVIEW

BREVAGen

Evidence Conclusion:

Conclusion: There is no evidence to determine the analytic validity of the BREVAGen™. There is some evidence to suggest that the addition of the BREVAGen™ panel is superior in determining breast cancer risk compared to Gail score alone. There is no evidence to determine the clinical utility of the BREVAGen™.

Articles: A search of PubMed was completed for the period through November 2013 for studies on the accuracy of BREVAGen™ for detecting the absence or presence of certain common genetic variations associated with an increased risk for developing breast cancer. The search strategy used the terms BREVAGen, Breast Cancer Risk Tool, Gail Model, genetic risk, single nucleotide polymorphism, breast cancer, and sporadic with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Articles were limited to those published in the English language with human subject enrollment. The search was supplemented by an examination of article reference lists in addition to the PubMed related articles function. The literature search for BREVAGen™ revealed one publication that clinically validates the Breast Cancer Risk Model in combination with the genetic and clinical information. The following study was selected for review: Mealiffe ME, Stokowski RP, Rhees BK, et al. Assessment of clinical validity of a breast cancer risk model combining genetic and clinical information. *Journal of the National Cancer Institute*. 2010;102(21):1618-1627. See Evidence Table.

The use of BREVAGen does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Fibroblast Growth Factor Receptor 3 (FGFR3) for Urothelial Carcinoma

BACKGROUND

It is estimated that approximately 70,530 new cases of bladder cancer will be diagnosed in the United States in 2010, and 14,680 will die of the disease (Jemal 2010). The most commonly occurring form of bladder cancer in the United States is urothelial carcinoma (also known as transitional cell carcinoma). The clinical spectrum of urothelial carcinoma can be divided into 3 categories: non-muscle-invasive, muscle-invasive, and metastatic disease. This review will focus on non-muscle-invasive urothelial cancer (NMIUC), which makes up approximately 75-80% of urothelial carcinoma. NMIUC includes stage Ta (noninvasive papillary carcinoma), Tis (carcinoma in situ), and T1 (tumor invades subepithelial connective tissue) tumors. The standard treatment for stage Ta, Tis, and T1 tumors is transurethral resection of bladder tumor (TURBT). Depending on prognosis adjuvant intravesical chemotherapy or immunotherapy may also be considered. However, despite treatment a significant number of patients will develop recurrence within 1 to 2 years of the initial treatment. Because of the high risk of recurrence careful surveillance is required for patients with NMIUC (Chou 2010, Cheng 2011, NCCN 2011, Pollard 2010). Assessing the risk of progression and recurrence is important for planning therapy. The risk for tumor progression

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and recurrence is estimated using factors such as histological grade, stage, depth of invasion, and extent of disease; however, the ability of these factors to predict clinical outcome is limited (Burger 2008, Cheng 2011, NCCN 2011). Recently, it has been suggested that molecular biomarkers such as fibroblast growth factor receptor 3 (FGFR3) may be useful for predicting clinical outcome and planning therapy. FGFR3 regulates cell growth, differentiation, and angiogenesis. More than 70% of low-grade noninvasive papillary urothelial carcinomas harbor FGRF3 mutations. Studies suggest that urothelial carcinomas that harbor FGFR3 mutations may be associated with improved prognosis (Cheng 2011). The CertNDx molecular grading assay (Predictive Biosciences, Inc.) was designed as a tool to be used in conjunction with clinical and histological parameters to aid in the clinical management of NMIUC. This test uses two biomarkers to determine molecular grade. The first biomarker is FGFR3 and the second is Ki-67, which is a marker of cell proliferation (Cheng 2011). Patients with molecular grade 1 (mG1) have FGFR3 mutations and low Ki-67 levels. Patients with molecular grade 2 (mG2) have FGFR3 mutations with high Ki-67 levels or wild-type FGFR3 and low Ki-67 levels. Patients with molecular grade 3 (mG3) are FGFR3 wild-type and have high Ki-67 levels. Patients with molecular grade 1 have favorable prognosis, patients with molecular grade 2 have intermediate prognosis, and patients with molecular grade 3 have poor prognosis.

10/17/2011: MTAC REVIEW
Fibroblast Growth Factor Receptor 3 (FGFR3) for Urothelial Carcinoma
Evidence Conclusion: Analytic validity- No studies were identified that addressed the analytic validity of the CertNDx molecular grading assay. Clinical validity - A recent prospective observational study evaluated the prognostic value of both WHO 1973 and 2004 grading systems, markers CK20, FGFR3, and Ki-67, and molecular grade (combination of FGFR3 and Ki-67) in 221 patients with urothelial carcinoma. In univariate analysis, WHO grade 1973, WHO grade 2004, pathological stage, FGFR3, Ki-67 status, and molecular grade were significantly associated with progression in stage; however, in a multivariate model, only WHO grade 1973 and 2004 remained significantly associated with progression in stage. None of the variables measured were significantly associated with recurrence-free survival (Burger 2008). Another study that included 255 patients with primary urothelial carcinoma also found that the combination of FGFR3 and Ki-67 status was not an independent predictor of recurrence-free or disease-specific survival (van Oers 2007). However, an observational study that included 286 patients with urothelial carcinoma found that in a multivariate analysis, the combination of FGFR3 and Ki-67 status predicted progression, recurrence rate, and disease-specific survival (van Rhijn 2003). Clinical utility -
No studies were identified that addressed the clinical utility of the CertNDx molecular grading assay.
Conclusion: Analytic validity: No studies were identified that addressed the analytic validity of the CertNDx molecular grading assay. Clinical validity: Results from observational studies regarding the prognostic value of molecular grade (FGFR3/Ki-67) are mixed. Clinical utility: No studies were identified that addressed the clinical utility of the CertNDx molecular grading assay.
Articles: No studies were identified that addressed the analytic validity or clinical utility of the CertNDx molecular grading assay. Several studies were identified that evaluated the clinical validity of the CertNDx molecular grading assay. The most recent study was selected for review. The following study was critically appraised: Burger M, van der Aa MN, van Oers JM, et al. Prediction of progression of non-muscle-invasive bladder cancer by WHO 1973 and 2004 grading and by FGFR3 mutation status: a prospective study. *Eur Urol.* 2008;54:835-843. See Evidence Table.

The use of FGFR3 for urothelial carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

MammaPrint Test
BACKGROUND
Breast cancer affects almost 10% of women in western countries and is a major cause of morbidity and mortality. Most patients with lymph node negative disease may be successfully treated with surgery and local irradiation. Those with more aggressive disease may benefit from adjuvant chemotherapy and hormone therapy which could significantly improve their overall and disease-free survival. It is generally accepted that breast cancer patients with the poorer prognosis would gain the most benefits from systemic adjuvant therapy. The use of this adjuvant therapy is thus one of the most critical treatment decisions during the clinical management of breast cancer patients. Currently those with aggressive breast cancer are identified according to a combination of criteria including age, clinical stage and size of the tumor, histological type and grade of cancer, axillary node status, and hormone-receptor status. The ability of these criteria to predict outcome and disease progression is imperfect. Within a given patient population at a specific predicted risk of recurrence, there are some patients whose actual clinical outcome does not match that predicted by the indicators. As a result, some of those who need adjuvant therapy do not receive it, while others may receive unnecessary toxic therapy (Kallioniemi 2002, DeVigier 2002).

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To overcome these issues, scientists are attempting to identify more accurate prognostic indicators. Microarray technology is revolutionizing researchers' understanding of cancer biology through the simultaneous study of the expression of tens of thousands of genes. Molecular profiling is the classification of tissue or other specimens for diagnostic, prognostic, and predictive purposes based on multiple gene expression. The potential value of gene expression profiling in assessing the risk of post-surgical breast cancer recurrence has been extensively investigated over the last few years. This has led to important insights in the molecular heterogeneity of cancers by revealing biologically and clinically relevant subtypes of tumors previously indistinguishable by the conventional approaches (Bertucci 2005). Due to the biological heterogeneity of breast cancers, women with the same stage of the disease may vary widely in their response to treatment and prognosis. Several gene expression-based predictors for breast cancer have been developed but have not been used in routine clinical practice. According to researchers, this is mainly due to the limited validation and the limited clinical description of the molecular subtypes. Validation is a major challenge for microarray studies especially those with clinical implications as it requires a large sample size and because the results are influenced by the patient selection and by choice of the methods used to analyze gene expression data (Calza 2006, Hu 2006, Ioannidis 2007). The Amsterdam 70-gene profile (MammaPrint ®) was first developed using supervised gene expression profiling analysis of frozen tumor samples from two distinct patient populations. All were <55 years of age and had lymph node negative disease. 44% had distant metastases within 5 years of completing treatment and 56% did not. By comparing the gene expression profile of patients with or without metastases, a signature 70-gene set that correlated with the outcome was identified and internally validated with the same group (van't Veer 2002), and externally validated in two retrospective groups (Van De Vijver 2002 and Buyse 2006, see evidence tables). MammaPrint ® from Agendia is a qualitative in vitro diagnostic test service performed in a single laboratory using the gene expression profile of breast cancer tissue samples to assess a patient's risk for distant metastases. The MammaPrint assay uses a panel of the Amsterdam 70-gene profile described above. It is a microarray-based gene expression analysis of RNA extracted from breast tumor tissue. The MammaPrint ® analysis is designed to determine the activity of specific genes in a tissue sample compared to a reference standard. Its index ranges from -1.0 to +1.0. Tumor samples with an index above the threshold of +0.4 are classified as low risk, and those with an index equal to or less than the threshold is classified as high risk. The test requires fresh frozen samples which are shipped to the Agendia reference laboratory in the Netherlands. It is performed for breast cancer patients <61 years old, with Stage I invasive breast cancer or Stage II node negative invasive breast cancer, with tumor size <5 cm. It is indicated for use by physicians as a prognostic marker only, along with other clinicopathological factors. It is not intended for diagnosis, or for predicting or detecting response to therapy, or to help select the optimal therapy for patients (FDA).

08/06/2007: MTAC REVIEW
MammaPrint Test
Evidence Conclusion: The identification and validation of gene expression panels to improve risk prediction or treatment outcomes is a multistep process that starts by 1. Identifying the candidate genes (analytic validity), followed by 2. Evaluating the genetic panel associations with risk prediction or treatment outcomes in preliminary performance studies in relevant population (clinical validity), and 3. Determining whether the use of the multigenetic assay would direct the management of patients and improve outcomes (clinical utility). The most reliable method for validation is to derive a prognostic/predictive gene set from a training set and then apply it to a completely independent set, the test set, (Simon 2003, Ionnidis 2006, and Hu 2006). The MammaPrint test was developed based on research performed in the Netherlands Cancer Institute, The training set was derived from a study by van't Veer and colleagues that included 98 women < 55 years of age at diagnosis, with primary breast cancer (34 developed distant metastases within 5 years, 44 were disease free after at least 5 years). All patients were lymph node negative. 5 µg total RNA was isolated from frozen tumor material for each patient. The authors used inkjet-synthesized oligonucleotide microarrays that included 25,000 genes. Following several techniques 5000 genes were selected from the microarray, and then optimized to 70 genes with which a prognosis profile was established. The authors conducted a cross validation and concluded that a classification system based on these 70 genes outperformed all clinical variables in predicting the likelihood of distant metastases within five years.
They noted however, that a selection of the patients based on the outcome (distant metastases or disease free in 5 years) was a limitation to the study. The same research team followed the initial study with a validation study (Van De Vijver, 2002) that included 295 women with either lymph node negative or lymph node positive breast cancer. The authors calculated the correlation coefficient of the level of expression of the 70- predictor genes identified in their initial study. They then classified the women with a correlation coefficient > 0.4 as having a good prognosis gene expression signature, and all the others as having a poor prognosis gene expression signature. In this validation set however the authors included 61 patients from the original training group used to derive the RNA expression signature, which could overestimate the relative risk and inflate the discriminating power of the test.
The validation study included women < 55 years of age, with small tumors and at stage I or II of the disease which

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may not represent the entire spectrum of patients with breast cancer. Adjuvant hormone therapy or chemotherapy or both were given to most of the patients with lymph node positive disease. The Translational Research Network of the Breast International group (TRANSBIG) also conducted an independent validation study of the prognostic signatures in a retrospective series of 302 untreated patients in five European countries. The study included only women node negative early stage breast cancer who had not received systemic adjuvant therapy, and thus may not represent the all patients with breast cancer. Its overall results showed that the 70-gene signature provided prognostic information on time to distant metastases and overall survival independent of the other clinical predictors. In conclusion, the selection of the 70- predictor genes were based on analyses of tumors from patients < 55 years of age with lymph node negative cancer who do not represent all women with breast cancer. The test proved to perform well as an independent prediction tool among the selected women studied. This, however, does not necessarily indicate that it would predict treatment response. To date there are no published studies that show if modification of adjuvant therapy based on this test would improve disease free or overall survival. A large randomized controlled trial (Microarray for Node negative Disease may Avoid Chemotherapy [MINDACT]) that will evaluate the clinical utility of MammaPrint is underway. The trial will directly compare the use of prognostic information provided by the standard clinicopathological criteria vs. the MammaPrint test to decide whether to offer adjuvant chemotherapy to node-negative breast cancer patients. The MINDACT plans to prospectively include 6000 women and follow-them up for a long duration in order to determine 5-year disease free-survival rate.
Articles: The literature search revealed multiple articles on molecular and gene-expression profiling in general. For the MammaPrint test in particular, there was a published study on the training set (to develop or derive the predictive classifier or model) by Van't Veer and colleagues, and three validation studies to evaluate the predictive accuracy of the model (Van De Vijver 2002, Buyse 2006, and Glas 2006). All studies were reviewed but only the first two validation studies were critically appraised, Glas, et al's study was not selected for critical appraisal due to patient overlap with the van De Vijver study. It is to be noted that Van De Vijver, van't Veer, and several other principal authors are named inventors on a patent application for the 70-gene signature used in the studies. All studies also had financial ties to the manufacturer. *The following studies were critically appraised:*
Van De Vijver MJ, He YD, van't Veer LJ, et al. A gene expression signature as a predictor of survival in breast cancer. N Engl J Med 2002:347:1999-2009. See Evidence Table. Buyse M, van't Veer, L, Viale G et al on behalf of the TRANSBIG Consortium. Validation and clinical utility of a 70-gene prognostic signature for women with node negative breast cancer. J Natl Cancer Inst 2006:98:1183-1192. See Evidence Table.

The use of the MammaPrint test in the treatment of recurring cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

OVA1™ Test for the Assessment of Suspected Ovarian Cancer

BACKGROUND

In the United States, ovarian cancer is the fifth leading cause of all cancer-related death among women. It is estimated that in 2010, there were 21,880 new cases of ovarian cancer and 13,850 deaths from ovarian cancer (Jemal 2010). The incidence of ovarian cancer increases with age with approximately two thirds of cases being diagnosed in women over the age of 55. Women with a family history of ovarian or breast cancer or who are carriers of the BRCA gene mutations are also at increased risk for ovarian cancer (Clarke-Pearson 2009). For patients with early stage disease, survival rates are greater than 90%; however, they are less than 30% for patients with advanced disease. Because of the lack of specific symptoms during the early stage approximately 70% of cases are diagnosed with advanced disease (Carter 2011). The most commonly used tests for the detection of ovarian cancer are transvaginal ultrasound (TVS) and serum CA-125. Recently, the FDA approved the OVA1™ test (Quest Diagnostics, Inc.) to be used as an adjunct to clinical/radiological evaluations for women planning surgery for an adnexal mass. This test measures the serum levels of 5 potential biochemical markers for ovarian cancer (transthyretin, apolipoprotein A1, transferring, CA-125, and β2-mocrogloublin). The results of the test are then interpreted using a proprietary algorithm to yield a single score ranging from 0 to 10 to indicate the likelihood that the adnexal mass is benign or malignant. A high probability for malignancy is defined as a score of at least 5.0 in premenopausal women or 4.4 in postmenopausal women. The goal of the OVA1™ test is to provide additional information to aid in identifying patients who should be referred to a gynecologic oncologist for surgery (Carter 2011, Muller 2010). Studies suggest that women who receive their initial surgical care from an experienced gynecologic oncologist have improved outcomes and greater overall survival. Because of this the National Comprehensive Cancer Network (NCCN) recommends that all patients should undergo surgery by an experienced gynecologic oncologist (NCCN 2011). It is important to emphasize that this test is not approved for ovarian cancer screening and is not intended for use as a standalone test. Another limitation of this test is that assay interference may occur in patients with rheumatoid factor levels of at least 250 IU/mL and triglyceride levels greater than 4.5 g/L (Muller 2010). In 2009, the FDA approved the use of this test for women over the age of 18 with an ovarian adnexal mass for which surgery is planned and have not yet been referred to an oncologist.

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10/17/2011: MTAC REVIEW
OVA1™ Test for the Assessment of Suspected Ovarian Cancer
Evidence Conclusion:
Conclusion: Analytic validity: No studies were identified that evaluated analytic validity of the OVA1™ test. Clinical validity: Results from a recent observational study suggest that the when added to physician assessment or substituted for CA 125, the OVA1™ test increased the sensitivity and negative predictive value of these assessments but decrease the specificity and positive predictive value. Clinical utility: No studies were identified that evaluated the clinical utility of the OVA1™ test.
Articles: No studies were identified that assessed the analytic validity or clinical utility of the OVA1™ test. Two studies were identified that addressed the clinical validity of the OVA1™ test. Both of these studies were selected for review. The following studies were selected for critical appraisal: Ueland FR, Desimone CP, Seamon LG, et al. Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors. *Obstet Gynecol 2011;* 117:1289-1297. See Evidence Table. Ware Miller R, Smith A, DeSimone CP, et al. Performance of the American College of Obstetricians and Gynecologists' ovarian tumor referral guidelines with a multivariate index assay. *Obstet Gynecol.* 2011; 117:1298-1306. See Evidence Table.

The use of OVA1 for ovarian tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Review

SelectMDx for Prostate Cancer (MDxHealth Inc.)

According to the testing laboratory, the SelectMDx test is a noninvasive, urine-based molecular screening test that, when combined with patient clinical risk factors, can aid physicians in determining if a patient is at higher risk (defined by laboratory as detecting GS ≥ 7 prostate cancer upon biopsy) or lower risk for prostate cancer and can avoid biopsy (MDxHealth, 2019a). The test is intended for men who have not been previously diagnosed with prostate cancer. The SelectMDx test requires a first void post-digital rectal examination (DRE) urine sample, which is analyzed for the mRNA level of 2 cancer-related biomarkers, DLX1 and HOXC6 (MDxHealth, 2016; MDxHealth, 2019b).

Hayes Rating: D2
For use of the SelectMDx for Prostate Cancer test to aid physicians in determining if a patient is at higher risk (defined by laboratory as detecting Gleason score (GS) ≥ 7 prostate cancer upon biopsy) or lower risk for prostate cancer and can avoid biopsy.

Conclusion: There is insufficient evidence supporting use of the SelectMDx test. Additional studies are needed to demonstrate the clinical validity and, ultimately, clinical utility of the test and whether the test results would improve patient management outcomes, including avoiding unnecessary prostate biopsies.

Reference
Hayes. Hayes Molecular Test Assessment. SelectMDx for Prostate Cancer (MDxHealth Inc.). Dallas, TX: Hayes; February 25, 2021. Retrieved November 29, 2021 from https://evidence.hayesinc.com/report/gte.selectmdx3769

Thyroid Nodule Gene Expression Testing (Afirma)

BACKGROUND
Thyroid nodules are very common; they are clinically identified in 5-7% of the population, and incidentally on ultrasonography in up to 50% of women and 20% of men over the age of 50. The thyroid nodules are typically benign, but 5-15% prove to be malignant. It is thus recommended that any identified nodule measuring one centimeter or more in diameter be diagnostically evaluated. Thyroid fine needle aspiration (FNA) biopsy is the most widely used method for clinical evaluation of a suspicious thyroid nodule. FNA is a safe and simple outpatient procedure that yields cellular material suitable for cytological analysis. However, 15-30% of the biopsied nodules has indeterminate cytology and cannot be conclusively diagnosed by FNA biopsy alone. Most patients with indeterminate lesions (defined in the Bethesda System as Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significance, suspicious for Follicular or Hurthle Cell neoplasm and suspicious for malignancy) are referred to surgery. Currently, surgery is performed for both diagnostic and therapeutic purposes in these patients with indeterminate aspirates. Surgery has high operative efficacy in removal of thyroid cancer, however approximately three-quarters of the nodules with indeterminate FNA cytology are ultimately found to be benign on final surgical pathology. Thus, a large proportion of patients with indeterminate nodules may undergo unnecessary partial or complete thyroidectomy with its potential surgical complications and risk of long-term morbidity (Alexander 2012, Duick 2012, Walsh 2012, Ali 2013). In an attempt to preoperatively classify the indeterminate thyroid nodules

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different novel diagnostic tests and molecular markers have been investigated. These include immunohistochemistry, mutation and gene rearrangement testing, and gene expression and microarray analysis. Each has its performance characteristics and diagnostic values. Ideally a molecular marker or panel of markers would be accurate in differentiating benign from malignant in any lesion that is considered suspicious or indeterminate. It should be simple to use, reproducible by all institutions, and cost-effective. Genetic markers associated with malignancy such as mutation markers (e.g. BRAF, RAS) and gene rearrangements (e.g. RET/PTC and PAX8-PPAry) have high specificity and positive predictive values; and when detected they can "rule in" the diagnosis of thyroid cancer, However, they have limited sensitivity and negative predictive values as they fail to detect a large proportion of malignant samples that do not contain one of the mutations or rearrangements being tested, i.e. mutation or rearrangement markers cannot 'rule out' malignancy when not detected (Alexander 2012, Kouniavsky 2012, Ward 2013). Microarray techniques seek to identify patterns of expressed RNA in the human genome that are predictive of benign or malignant thyroid disease. Unlike single gene mutations or rearrangements, microarray diagnostic tests involve tens to hundreds of expressed genes. The currently available diagnostic microarray for use in thyroid nodule analysis is the Afirma Gene Expression Classifier (GEC) recently developed by Veracyte, Inc. It is a genomic test designed with the intention of preoperative identification of benign thyroid nodules in patients with indeterminate FNA cytopathological results. The test assesses gene expression from mRNA isolated from thyroid FNA samples by comparing the mRNA expression detected in a thyroid FNA against a panel of 167 molecular genes. It uses a multidimensional algorithm to identify the thyroid FNA samples with a benign gene expression pattern (Alexander 2012, Kim 2012, Ward 2013). Afirma GEC is commercially owned by Veracyte Corporation; South San Francisco, California and is offered through a sole source, Clinical Laboratory Improvement Amendments (CLIA), a certified reference laboratory. Afirma CEC analysis is indicated only for nodules with indeterminate cytology, and is not performed on cytologically benign, malignant, or nondiagnostic (insufficient FNA samples) nodules. The assay classifies nodule as either benign or suspicious for malignancy. With a preoperative identification of a nodule that is benign rather than malignant, observation or ultrasound follow-up could be recommended instead of thyroid surgery, i.e. potentially avoids unnecessary surgery (Alexander 2012, Duick 2012, Ward 2013).

10/21/2013: MTAC REVIEW
Thyroid Nodule Gene Expression Testing (Afirma)
Evidence Conclusion: Analytic validity Evaluating the analytic performance of Afirma GEC includes studying the stability of RNA in FNAs during collection, storage, and shipment; reproducibility of the test; and its analytic sensitivity and specificity under various conditions e.g. interference of the assay with bloody FNA and genomic DNA. The literature search revealed one study (Walsh and colleagues, 2012) that evaluated the analytic performance of Afirma GEC in a number of sub studies. The investigators obtained prospective FNA samples aspirated in vivo from 43 patients from outpatient clinics, preoperatively, or immediately after surgical excision. The samples were placed in FNAProtect preservative solution and shipped chilled or frozen, then stored at -80°C upon receipt. The RNA was extracted, and its yield examined for quantity and quality using positive (tissue lysate) and negative (water) as controls. Three different lots of controls were tested over several weeks of independent runs by 3 different operators to determine reliability of the test. Multiple lots of benign and malignant total RNA were manufactured and used as process controls to determine the analytic sensitivity of the test using different RNA input quantity and under different dilution of malignant FNA content. These studies indicated tolerance to variation in RNA input across a range of 5-25 ng. as well as dilution of malignant FNA material down to 20%. Analytic specificity of the test using malignant samples mixed with blood (up to 83%) and genomic DNA (up to 30%) showed minimal assay interference. However benign FNA samples mixed with relatively high proportions of blood had a potential for yielding false positive results. The authors also examined the stability of RNA in FNAs during collection and shipment and found that RNA content within FNAs preserved in FNAProtect was stable for up to 6 hours at room temperature with no change in RNA yield, and that the FNA storage and shipping temperatures had no significant effect on GEC scores. They also examined the reproducibility of the test and indicated that it was reproducible from extraction through GEC results, including variation across operators, runs, reagent lots, and laboratories. The authors concluded that the analytical performance and reproducibility of the Afirma Gene Expression Classifier was successfully verified. The research was supported by Veracyte Corporation, (the maker of Afirma GEC), and the authors of the study were either employed by or were consultants to the corporation. Clinical validity A perfect test would have high sensitivity and high specificity in correctly detecting or excluding a condition. A molecular diagnostic test with high sensitivity offers a high negative predictive value when the risk of malignancy (ROM) is low and can "rule out'' malignancy. Conversely, a test with high specificity offers high positive predictive value and can "rule in" cancer. To be of use in avoiding surgery, a test that better distinguishes benign from malignant nodules needs to have high sensitivity and high negative predictive value. The literature search identified two published studies on the validation of Afirma GEC (Chudova et al, 2010, and Alexander et al. 2012); both funded by Veracyte Corporation the maker of Afirma GEC. The more recent and larger validation study by Alexander and colleagues (evidence table 1), was a double-blind prospective multicenter validation study. 4,812

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thyroid FNAs were obtained from 3,789 patients. 577 (12%) samples were classified as indeterminate, and less than half (46%) were ultimately selected for GEC analysis. Molecular results were compared to the gold standard of post-surgical histopathology interpreted by a panel of blinded endocrine histopathologists for clinical validation. The overall sensitivity of the Afirma test was 92% with a negative predictive value (NPV) of 93% (95% for atypical or follicular lesions of undetermined significance (AUS/FLUS), 94% for a follicular neoplasm, and 85% for a lesion suspicious for malignancy). It is to be noted that the predictive values of a test vary with the prevalence of the disease in the population studied and may not be generalized to other groups. A better analysis would be the likelihood ratios which are not affected by prevalence. Seven of the 85 (8.2%) overall cancers were diagnosed incorrectly by the GEC as benign (false negative). The authors attributed the false negative results to insufficient RNA in the FNA sample used for GEC. The test had an overall low specificity and positive predictive values (52% and 47% respectively). Atypical or follicular lesions of undetermined significance (AUS/FLUS) accounted for almost 50% of the indeterminate thyroid FNAs samples. 43% of these FNA were reclassified with the GEC as benign and 57% remained in their suspicious category. Other investigators showed that repeat FNAs without a molecular test can also accurately reclassify >50% of the nodules in the AUS/FLUS category as benign (Faquin 2013). The study was conducted to validate the GEC accuracy by comparing it to surgical histopathology, and the authors did not compare its performance to repeat FNA or other immunochemical testing. Clinical utility: The clinical utility of Afirma GEC was evaluated in a retrospective study by Duick and colleagues, 2012, (Evidence table 2). They obtained their data from 21 endocrinology practices in 11 states. The authors conducted a chart review of 368 patients with 395 cytologically indeterminate thyroid nodules that were GEC benign. 7.6% of these patients with Afirma GEC benign nodules underwent surgery and 94.4% were managed nonoperatively. The study did not have a comparison group, but the authors compared the 7.6% surgical rate to a 74% historical rate of diagnostic surgery (P<0.001). The indications for surgery for those with GEC benign results included a large size or rapid growth of the nodules, local pressure symptoms, or the presence of a second suspicious nodule or malignant nodule. The authors explained that these were similar to indications for surgery on nodules with benign FNA cytologically. The study was retrospective, used a historical comparison, and investigated the decision-making of endocrinologists experienced in managing patients with thyroid nodules, which may differ from that made by primary care providers or other specialists. In addition, the authors of the study did not provide data on long-term follow-up of those who were managed by watchful waiting rather than surgery. In conclusion, there is insufficient evidence to determine whether Afirma GEC is more accurate than repeat FNA or immunochemical testing in reclassifying cytologically indeterminate thyroid nodules. There is also insufficient evidence to determine the impact of Afirma GEC on clinical management and net health outcomes in patients with indeterminate thyroid nodules.

Articles: The literature search for gene expression classifier for preoperative identification of benign thyroid nodules with indeterminate fine needle aspiration cytopathology revealed a number of articles on molecular diagnostic tests. Many were reviews, editorials, letters, or were unrelated to the current review. The search identified a study on the analytic validity of the test, two on its clinical validity, and retrospective study on its clinical utility. The following studies were selected for critical appraisal. Alexander EK, Kennedy GC, Baloch ZW, et al. Preoperative diagnosis of benign thyroid nodules with indeterminate cytology. *N Engl J Med*. 2012; 367:705-715. See Evidence Table Duick DS, Klopper JP, Diggans JC, et al. The impact of benign gene expression classifier test results on the endocrinologist-patient decision to operate on patients with thyroid nodules with indeterminate fine- needle aspiration cytopathology. *Thyroid.* 2012 22:996-1001. See Evidence Table

The use of does Afirma® Thyroid FNA Analysis (Gene Expression Classifier) for Thyroid Nodules with Indeterminate Fine Needle Aspiration Cytopathology not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

ConfirmMDx for Prostate Cancer

BACKGROUND

Prostate cancer is the second most leading cause of cancer in men around the globe (Fitzmaurice et al., 2017). In the United States, one in six men has a lifetime risk of prostate cancer (Siegel, Ward, Brawley, & Jemal, 2011). Prostate cancer screening is subject to controversy due to overdiagnosis, overtreatment, and harms. Major guidelines highlight the importance of informed decision-making. Despite the controversy, prostate specific antigen (PSA) and or digital rectal examination (DRE) can be performed.

After undetermined or abnormal results are reported on prostate cancer screening, more tests such as prostate biopsy is indicated for prostate cancer diagnosis. A high proportion (62%) of initial biopsies are negative and up to 43% will have second/repeat biopsies. Of these repeat biopsies, 26% – 35% will be diagnosed with prostate cancer (Auprich et al., 2012). False negative results are non-negligible since biopsy can miss cancer (Bhindi et al., 2017). In addition, prostate biopsies may result in several complications. As a result, it is crucial to find other ways to avoid or decrease repeat biopsies and predict with accuracy prostate cancer in patients with negative initial biopsies. ConfirmMDx is an assay that evaluates molecular alterations of three genes to detect prostate cancer.

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The following description of the test is from the manufacturer website (https://mdxhealth.com/confirmmdx-physician/). ConfirmMDx is a tissue test to enhance the detection of previously negative biopsy patients at high risk for clinically significant prostate cancer. It rules out patients with no cancer and prevent them from unnecessary repeat biopsies and screening procedures, thus alleviating stress and reduce complications. According to the manufacturer, ConfirmMDx is believed to be the most significant predictor of patient outcome among all currently available clinical factors.

ConfirmMDx uses methylation-specific PCR (MSP) and epigenetic biomarkers to detect prostate cancer. The MSP, unlike histopathology, can detect DNA methylation changes (molecular alterations) in tissues surrounding cancer foci. This epigenetic effect is the molecular mechanism by which MSP detects occult prostate cancer in men with negative initial biopsy. ConfirmMDx measures DNA methylation of 3 genes including GSTP1, APC, and RASSF1. In patients with negative prostate biopsies results, the test can enhance accuracy for predicting repeat biopsy outcome in comparison to the standard risk factors (Waterhouse et al., 2019). The test can also indicate the likelihood of detecting Gleason score ≤ 6 (low grade) and ≥7 (high grade) prostate cancer upon repeat biopsy. Patient report indicates if DNA methylation is positive, the likelihood of detecting prostate cancer, probability of detecting Gleason score ≤ 6 and ≥7 prostate cancer on repeat biopsy (https://mdxhealth.com/wp-content/uploads/2020/07/MDX-C152-ConfirmMDx-Case-Study-1-v3.pdf).

The test is indicated when there is a need to perform repeat biopsy on patients with initial negative biopsy result (benign, high-grade prostatic intraepithelial neoplasia (HGPIN), or atypical small acinar proliferation (ASAP)) within the past 24 months and high-risk clinical factors for occult prostate cancer. The results of the test should be interpreted in addition to clinical and other laboratory data.

Eligible patients include those with the following biopsy results:

- Negative/benign
- HGPIN (high-grade prostatic intraepithelial neoplasia)
- Atypia (atypical glands suspicious for malignancy)
- ASAP (atypical small acinar proliferation)
- PIA (proliferative inflammatory atrophy, or lesion)

07/11/2022: MTAC REVIEW
ConfirmMDx for Prostate Cancer
Evidence Conclusion:
- Analytical validity: Very low-quality study shows that the assay can measure the methylation status of the three genes including GSTP1, APC, and RASSF1.
- Clinical validity: Low quality evidence support ConfirmMDx in ruling out prostate cancer on repeat biopsy.
- Clinical utility: There is insufficient evidence for or against the clinical utility of ConfirmMDx for prostate cancer.
- **Overall, the evidence is insufficient for or against the use of ConfirmMDx.**

Articles: PubMed was searched on 03/29/2022 with the search terms ConfirmMDx OR Episcore OR MDxHealth OR (GSTP1 AND APC AND RASSF1 AND prostate) OR (Epigenetic assay AND prostate cancer) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded a number of articles. Seven studies were reviewed (1 analytical validity study, 4 clinical validity studies, and 2 clinical utility studies). See Evidence Table.

The use of ConfirmMDx for Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Hayes Review

ConfirmMDx for Prostate Cancer (MDxHealth Inc.)

According to the laboratory, ConfirmMDx is for men with a previous histopathologically cancer-negative prostate biopsy within the past 24 months who have clinicopathological risk factors for prostate cancer to (MDxHealth, 2017; MDxHealth, 2018a):

- Identify men at risk for undetected prostate cancer (a false-negative biopsy result).
- Rule out men who are prostate cancer free to prevent unnecessary repeat biopsies and screening procedures, resulting in reduced complications, patient anxiety, and healthcare expenses.

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In addition, the ConfirmMDx test result claims to predict the likelihood of (MDxHealth, 2017):

- Detecting Gleason score ≤ 6 prostate cancer on repeat biopsy.
- Detecting Gleason score ≥ 7 prostate cancer on repeat biopsy.

Hayes Rating: **D2**
For use of ConfirmMDx test, using residual prostate biopsy specimens, to: (1) rule out men who are prostate cancer free; and (2) identify men at risk for undetected prostate cancer by predicting the likelihood of detecting Gleason score ≤ 6 and ≥ 7 prostate cancer on repeat biopsy in men with an initial negative biopsy yet high-risk clinicopathological features suggestive of prostate cancer.

Conclusion: There is positive but insufficient evidence supporting the use of the ConfirmMDx test to help rule-out prostate cancer in repeat biopsy and insufficient evidence for the use of the test to predict the likelihood of Gleason score ≤ 6 prostate cancer and Gleason score ≥ 7 prostate cancer on repeat biopsy. Available studies do not evaluate whether the test results, when used to influence patient repeat biopsy decisions, result in improved patient outcomes in men with high-risk clinicopathological features suggestive of prostate cancer.

Reference

Hayes. Hayes Molecular Test Assessment. ConfirmMDx for Prostate Cancer (MDxHealth Inc.). Dallas, TX: Hayes; February 14, 2021. Retrieved November 29, 2021 from https://evidence.hayesinc.com/report/gte.confirm2766

Prolaris for Prostate Cancer

BACKGROUND
Prostate cancer is the second most leading cause of cancer in men around the globe (Fitzmaurice et al., 2017). In the United States, one in six men has a lifetime risk of prostate cancer (Siegel, Ward, Brawley, & Jemal, 2011). Its natural history varies and is difficult to predict. Some men have indolent disease that can be safely managed with active surveillance, whereas others have an aggressive cancer and are treated with a variety of therapeutic options. Accurate prediction of disease behavior is critical because radical treatment is associated with high morbidity (J. Cuzick et al., 2012).

Clinical variables including Gleason score, tumor stage, and PSA have been considered at the time of diagnosis to predict disease outcome. However, predictions based on these variables are not accurate, resulting in hesitation among physicians and patients about the best course for initial treatment (J. Cuzick et al., 2012). Tests to make accurate prediction and determine treatment decision are necessary.

Description:
Prolaris is a genetic test that measures the growth of tumor cell. In combination with PSA and Gleason score, the test determines the aggressiveness of prostate cancer. PSA and Gleason only show the progression of prostate cancer. However, when these tests are combined to Prolaris test, the aggressive progression of the cancer over the next ten years is determined. The information on the aggressiveness of cancer is specific to each individual.

Testing process:
The same tissue from the original biopsy is utilized to run the test. Therefore, additional biopsies are not required. The tissue sample is sent to Myriad to determine the aggressiveness of the prostate cancer. After the test is complete, the results are sent back to the provider. The result is comprised of a personalized Prolaris Score and a 10-year prostate cancer mortality risk and the risk of metastasis.
The Prolaris Molecular Score is computed by measuring the expression of 31 cell cycle progression (CCP) genes (measured by qRT-PCR and normalized by 15 housekeeping genes). Most of the scores range between 1-11. The higher the score, the more aggressive the cancer. Over- and under-expression of the 31 CCP genes results in positive and negative CCP score, respectively (Shangguan et al., 2021).

Benefits of Prolaris test:
The benefits are to identify mortality risk, the risk of metastasis, and to help determine the best course of treatment.

Prolaris is supported by NCCN guidelines as a 2A recommendation which is considered standard of care. Prolaris testing is indicated in men who have been diagnosed with localized prostate cancer.

07/11/2022: MTAC REVIEW

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PROLARIS FOR PROSTATE CANCER

Evidence Conclusion:

- **PROLARIS BIOPSY TEST**
  - Low quality evidence shows that CCP testing is reproducible and precise.
  - Very low to low quality evidence indicate that CCP & CCR scores may help predict prostate cancer mortality and metastasis. It may help improve risk stratification in men with localized prostate cancer.
  - Low quality evidence shows that Prolaris test may influence physician treatment decision.
  - Overall, low quality evidence supports Prolaris test to predict prostate cancer related clinical outcomes.

- **PROLARIS POST-PROSTATECTOMY**
  - The evidence is insufficient for or against the use of Prolaris test in patients with radical prostatectomy.

Articles: PubMed was searched through April 11, 2022 with the search terms (Prolaris OR cell cycle progression OR CCP OR cell cycle risk OR CCR) AND (prostate) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. ***See*** **Evidence Table.**

The use of Prolaris Prostate Cancer (Biopsy and Post-Prostatectomy) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/20/2015: MTAC REVIEW
DecisionDx - Melanoma
Evidence Conclusion:
DecisionDx - Melanoma
BACKGROUND
Skin cancer is extremely common accounting for nearly half of all cancers in the United States. Melanoma, the most aggressive type of skin cancer, occurs as a result of abnormal melanocytes, most often caused by over- exposure to ultraviolet radiation from the sun. When detected early, cutaneous melanoma can be surgically excised resulting in a 5-year overall survival rate of 91%-97%. Despite these odds, however, the clinical behavior of cutaneous melanoma is highly variable and some melanomas, that appear less risky, will develop into advanced disease and require extensive treatments such as additional surgery, immunotherapy, targeted therapy, chemotherapy and radiation therapy (ACS 2015). As with all cancers, a primary challenge is predicting prognosis. Conventional methods of melanoma staging are characterized by the American Joint Committee on Cancer (AJCC) TNM System. The TNM system specifically refers to Tumor thickness, spread to nearby lymph Nodes, and Metastasis. Based on history and physical exam, as well as, biopsy, imaging and pathology, the TNM system groups patients with melanoma into stages, 0-IV based on the advanced nature of the disease (Balch, Gershenwald et al. 2009). The stage of the melanoma is an estimate of prognosis and will ultimately guide treatment options. Recently, gene expression profiling (GEP) has been proposed for use in cancer management. The technique specifically analyzes the patterns of genetic material contained in tumor cells and has the potential ability to predict clinical outcomes associated with cancer. One such test, the DecisionDx-Melanoma™, developed by Castle Biosciences Inc. (Friendswood, TX), is described to more accurately classify stage I and II melanoma.
Proposed as an adjunct to conventional staging systems, the DecisionDX-Melanoma test includes 31 genes, 28 of which have previously been associated with melanoma and the remaining three, controls (Winnepenninckx, Lazar et al. 2006). The results of the DecisionDx-Melanoma test is further claimed to stratify stage I and II melanomas into one of two classes; class one identifying patients as low risk of metastasis, or class two indicating high risk.
The developer claims that the information provided by the DecisionDx-Melanoma test enables physicians to tailor, patient specific, surveillance and treatment plans informing, for example, the intensity of surveillance, need for referral to specialists, evaluation of adjuvant treatments and clinical trial eligibility (CastleBiosciencesInc. 2015).

04/20/2015: MTAC REVIEW
DecisionDx - Melanoma
Evidence Conclusion: The study aimed to develop a prognostic genetic signature based on previous analyses of cutaneous melanoma tumors. To do this, the investigators included 268 archived tissue samples and divided the sample into two cohorts, development (n=164) or validation (n=104). The investigators compared the patient clinical outcomes at five years with the GEP test prediction. Overall, Kaplan-Meier analysis indicated that the five-year disease-free survival (DFS) rates in the validation cohort were 97% and 31% for predicted class 1 and 2, respectively ($p<0.0001$). These results were comparable to the DFS rated in the development cohort, 100% and 38% for class 1 and class 2, respectively ($p<0.0001$). The investigators ultimately concluded that in patients with

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primary cutaneous melanoma, the GEP signature accurately predicts metastasis risk (Gerami, Cook et al. 2015). [Evidence Table 1] The investigators had the clear intent to develop and validate a GEP for predicting metastatic risk in stage I and II cutaneous melanoma. The patient sample was well defined and the study design, cohort, appeared to be appropriate for the development of the genetic signature. To validate the test, however, the study relied on archived tumor samples with at least five years of follow-up. While this is a sufficiently long time to detect the outcome of interest, and the investigators used an independent sample, a prospective study would be a more appropriate design for validation. With that said, the investigators report that samples were collected at a similar point in the course of the disease, diagnosis, however the diseases progression at diagnosis may have varied between patients and it is not clear if the investigators were blinded to prognostic factors. On a final note, the study was funded by the test manufacturer and at least two of the investigators have financial ties with Castle Biosciences, Inc. Conclusions: There is limited evidence to conclude that the DecisionDx-Melanoma test is valid. There is insufficient evidence to conclude that the DecisionDx-Melanoma test has prognostic accuracy in predicting metastatic risk. There is insufficient evidence to conclude that the DecisionDx-Melanoma test is not harmful to patients. There is insufficient evidence to establish the clinical utility and therapeutic impact of the DecisionDx-Melanoma test.
Articles: The literature search was carried out to identify studies relating to the prognostic value of the DecisionDx-Melanoma test. The search revealed a variety of publications discussing the use of GEP and one publication identifying the genes associated with melanoma progression and prognosis (Winnepenninckx, Lazar et al. 2006). No studies were identified in which the DecisionDX-Melanoma was prospectively analyzed and followed- up in populations with Stage I and II melanoma. A search of the NIH Clinical Trials database identified two manufacturer sponsored prospective studies currently in the enrollment stage. The best, currently available, evidence was a development and validation study published by Castle Biosciences, Inc. The following articles were selected for critical appraisal: Gerami P, Cook RW, Wilkinson J, et al. Development of a prognostic genetic signature to predict the metastatic risk associated with cutaneous melanoma. Clinical Cancer Research. 2015:21(1);175-183. See Evidence Table.

The use of DecisionDx-Melanoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

OVA1 Assessment for Ovarian Cancer

BACKGROUND

Ovarian cancer is the most lethal gynecological malignant worldwide. The five-year overall survival is over 90% in patients with stage I disease and only 20-40% for stages III and IV. Unfortunately, because of the lack of specific symptoms during the early stage approximately 70% of cases present with an advanced stage disease. Detection of ovarian cancer at an early stage would have a significant impact on reducing mortality, however to date; there is no screening or biomarker test that meets the criteria for a beneficial screening test in asymptomatic women with early ovarian cancer (Carter 2011, Cohen 2014, Leung 2014). Serum CA-125, a high molecular weight glycoprotein, remains the most widely used biomarker for the confirmation of diagnosis and management of ovarian cancer. Serum CA-125 however, is more prominently expressed in patients with late stage serous tumors; it is elevated in 50-60% of women with stage I epithelial ovarian cancer, and in 75-90% of patients with advanced stage disease. Elevated circulating CA-125 has also been documented in uterine fibroids, endometriosis, pregnancy, menstruation, benign ovarian neoplasms, liver cirrhosis, and other malignancies making it a less useful marker for the detection of ovarian cancer (Autelitano 2012, Cohen 2014). Improvements have been made in the preoperative diagnosis of ovarian cancer by combining serum CA-125 concentration with ultrasound score and menopausal status, into a Risk of Malignancy Index (RMI) which was found to outperform CA-125 alone in discriminating between a benign and malignant pelvic mass. Over the past two decades diagnostic triage methods incorporating clinical algorithms, serum biomarkers, imaging, or a combination of these techniques have been investigated to improve its diagnostic efficiency in predicting ovarian malignancy in women with adnexal masses. The Risk of malignancy Algorithm (ROMA) and OVA1 test are two algorithms recently developed for the assessment of malignancy risk in these women. These are not screening tests but are potential tools to further triage women to the appropriate provider once the decision for surgical intervention has been made (Autelitano 2012, Bristow 2013, Cohen 2014). Combining multiple variables or markers in a single biomarker assay (in vitro diagnostic multivariate assay [IVDMIA, or MIA]) has the potential advantage of complementing the information provided by a single-valued index. The inclusion of biomarkers in an IVDMIA requires that they are complementary and collectively outperform a single marker with respect to its intended uses. CA-125 remains the best tumor marker, and the selection of additional biomarkers is based mainly on their ability to detect malignancy in cancer patients with low CA-125 level or to reduce false positive results among non-cancer patients with elevated serum CA-125 levels (Zhang 2012). Ova1™ test (developed by Vermillion and licensed to Quest Diagnostics, Inc.) is the first IVDMIA of protein biomarkers cleared by the FDA to be used as an adjunct to clinical and radiological evaluations for women over the age of 18 who have planned to undergo surgery for an adnexal mass and have not been referred to a gynecologic oncologist. Studies suggest that women who receive their initial surgical care

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from an experienced gynecologic oncologist are more likely to have better outcomes including surgical staging, optimal debulking, and improved median and overall-5-year survival. Ova1™ test is a qualitative test that measures the serum levels of 5 potential biochemical markers for ovarian cancer (CA-125, prealbumin, apolipoprotein A-1, β2-microgloublin, and transferrin). The results of the test are then interpreted using a proprietary algorithm to yield a single score ranging from 0 to 10 to indicate the likelihood that the adnexal mass is benign or malignant. A high probability for malignancy is defined as a score of ≥ 5.0 in premenopausal women or ≥ 4.4 in postmenopausal women. The decision for selecting these cutoff values was made to emphasize the need for high sensitivity to minimize the risk of false negative results for patients who actually have a malignant lesion. A limitation to OVA1™ is that all the included markers with the exception of CA-125 are acute phase reactants that may be nonspecific for ovarian cancer. Another limitation is interference of triglyceride levels greater than 4.5g/L or rheumatoid factor levels more than 250IU/mL with the biomarkers assay (Muller 2010, Carter 2011, Zheng 2012, Leung 2014).

04/20/2015: MTAC REVIEW
OVA1 Assessment for Ovarian Cancer
Evidence Conclusion: The main purpose of adding biomarkers to an established tumors biomarker as CA-125, in a multivariate index assay (MIA), is to achieve a very high sensitivity without sacrificing the specificity. However, the published studies evaluating OVA1™ showed the test improved the sensitivity of the physicians' assessment in predicting ovarian malignancy in women with adnexal masses, but at the cost of reducing the specificity and positive predictive value. The FDA cleared the OVA1™ test based on the results of Ueland and colleagues' study that was reviewed earlier by MTAC in 2011. The study compared the sensitivity, specificity, and predictive values of physician assessment with or without adding the multivariate index assay (MIA) in identifying high-risk ovarian tumors. The study enrolled 590 women (524 evaluable with both MIA and CA-125-II) with a documented ovarian mass on imaging and planned surgery within 3 months of imaging. 53% of the women were enrolled by non-gynecologic oncologists and the rest by gynecological oncologist. The MIA index assay test was performed on preoperative serum samples, and the results were correlated with preoperative physician assessment. There was no specific protocol for the clinical assessment. Using surgical pathology as the gold standard, 161 women were diagnosed with a malignant and 363 with a benign ovarian tumor. The results of the analysis showed that the sensitivity of non-gynecologic oncologists' assessment increased from 72% to 92% with the addition of the MIA test (78% and 99% respectively for gynecologic oncologists). The negative predictive value increased slightly with the addition of the MIA test. On the other hand, the specificity and positive predictive values dropped significantly with the addition of the assay (the specificity was reduced from 83% to 42% for non-gynecologic oncologists and from 75% to 26% for gynecologic oncologists and the positive predictive value dropped from 60% to 36% and from 63% to 43% in the two groups of respectively).The studies published after that pivotal study were conducted mainly by the same group of investigators who either analyzed the results of women enrolled in some or all 44 sites participating in the study. The studies were sponsored by Vermillion Inc., and the investigators had financial ties to the company. The largest and most recent of these studies (Longoria et al 2014) (Evidence table 1) compared the accuracy and predictive values of the multivariate index assay, OVA1™ to clinical assessment, CA-125-II, and the modified American Congress of Obstetricians and Gynecologists (ACOG) guidelines, for the detection of early-stage ovarian cancer in 1,016 women undergoing surgery for an adnexal mass. The authors did not indicate whether the assessors were blinded to the other tests and/or clinical evaluation results. The study did not include women without adnexal masses or with other disorders that may lead to elevated levels of CA-125 or any of the other biomarkers included in the assay. Overall, similar to the Ueland and colleagues' study, as well as the other published studies using MIA test, Longoria, et al's study showed that the addition of OVA1™ to clinical assessment may significantly improve the sensitivity of detecting early-stage ovarian cancer, but at the expense of reducing the specificity, which would result in referral of more patients with benign conditions to gynecologic oncologists for surgery. The overall results of the study show the following: ***Comparative performance for evaluable women in all cancer cases (from evidence table 1)***

	Sensitivity %	Specificity %	PPV %	NPV %
OVA1	92.2%	49.4%	37.9%	94.9%
Clinical assessment*	74.5%	86.3%	64.6%	91.0%
OVA1 + clinical assessment	95.3%	44.2%	36.4%	96.6%
CA 125-II	70.6%	89.6%	69.5%	90.1%
Modified ACOG guidelines**	80.0%	76.5%	53.3%	91.9%

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*The authors did not clearly explain that clinical assessment included CA125-II for all women
** Included: very elevated CA125 (>67U/mL), ascites, and evidence of abdominal or distant metastasis for premenopausal women. For postmenopausal women the ACOG criteria were Elevated CA125 (>35 u/mL, nodular or fixed pelvic mass, ascites, and evidence of abdominal or distant metastasis.

The studies had enrolled selected groups of women with adnexal masses who were referred to surgery in multiple centers with no standardized process for data collection or referral practice. The referral pattern was retrospectively analyzed, and the impact of the test on health outcomes was not evaluated. In addition, the studies were funded by Vermillon Inc, the developer of the test, and the principal investigators had financial ties to the company. The performance of OVA1™ was not compared to other risk assessment algorithms as ROMA, ultrasound-based risk assessment models, or other diagnostic tools that may lead to similar sensitivity and superior specificity to OVA1™. Conclusion: The published studies do not provide sufficient evidence to determine the clinical utility and impact of using OVA1™ assay on health outcomes of women with ovarian tumors.

The use of OVA 1 does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Date: 07/09/2018 MTAC REVIEW
Whole Genome/Exome Sequencing for Developmental Delay (DD)/Intellectual Disability (ID)
BACKGROUND
Intellectual disability is a disorder marked by deficits in intellectual and adaptive functioning and starts before 18 years of age. Its management requires early diagnosis and extensive supports. Intellectual disability is caused by any conditions disrupting brain development. Of these conditions, genetic abnormalities are the most commonly known etiologies (Rauch et al., 2012) with Down syndrome being the leading cause. Conventional cytogenetics (karyotype analysis and fluorescence in situ hybridization (FISH)) can identify the cause but they detect less than 10% of chromosomal abnormalities in patients with intellectual disability (ID) or developmental delay (DD) (Shaffer, Beaudet, et al., 2007; Shaffer, Bejjani, et al., 2007). Chromosomal microarray analysis (CMA) has become the primary test for most patients with intellectual disability (Miller et al., 2010). However, if CMA fails to identify the etiology, whole genome/exome sequencing may be considered.
Whole genome sequencing (WGS) is a process that determines the complete DNA sequence of the entire genome. In contrast, whole exome sequencing (WES) determines the DNA sequence of a small part of the genome. The small part which is the coding part of the genome is 1% of the entire genome.
(Biesecker & Green, 2014) Genome and exome sequencing (GES) begins with extraction of DNA from white cells followed by disintegration of DNA and determination of sequences with sequencing instrument. Using computer, the sequences are placed into specific positions in the human genome reference sequence for assessment of similarities and differences. This results in the determination of the specific genotype at each position in the exome or genome. This leads in output file which is filtered for variants that explain the phenotype. Sequencing can be performed on unaffected or affected parents or affected siblings. Clinical GES can detect single-nucleotide substitutions and insertions or deletions of 8 to 10 nucleotides or smaller. However, it is less accurate for other types of genomic variation. GES is indicated in patients with suspicion of mendelian genetic disease. It is also considered when CMA fails to identify the cause of intellectual disability. (Biesecker & Green, 2014)
This review focuses on developmental delay (DD) or intellectual disability (ID).
As this is a laboratory test, no FDA approval is required. Genetic tests are controlled under the Clinical Laboratory Improvement Amendments (CLIA). The technology is being assessed for the first time on Medical Technology Assessment Committee (MTAC).
Evidence Conclusion:
Conclusion:

- **Analytical validity:** Studies assessing analytical validity were scarce. Only two studies reported that the performance of WES/WGS was high. However, the evidence is insufficient to draw conclusion on analytical validity.
- **Clinical validity:** Thirteen studies were evaluated. Most studies have included children with moderate to severe intellectual disability/developmental delay. In most studies, WES or WGS was performed in patients on whom previous genetic evaluations (molecular karyotyping, microarray) failed to diagnose the etiology or were negative. The diagnostic yield ranged from 21% to 60% (including new mutations) suggesting higher detection rate than traditional genetic tests including microarray. Nevertheless, the studies provide low evidence and demonstrate that WES/WGS has high detection rate overall and even in children with undiagnosed or unexplained intellectual disability or developmental delay.
- **Clinical utility:** The evidence on clinical utility is conflicting. More studies are warranted.
- Milliman Care Guidelines was reviewed and indicated that the evidence is poor, or conflicting, or insufficient to assess the net benefit of this test versus harm; additional research is recommended.

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The use of Whole Genome/Exome Sequencing for Developmental Delay (DD)/Intellectual Disability (ID) doesn't meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Next Generation Sequencing (NGS) - Broad Spectrum Tumor Molecular profiling

Background

All cancers begin in cells. A normal become cancerous largely because of mutations in their genes. Often many mutations are needed before a cell becomes a cancer cell. Some gene changes may increase production of a protein that makes cells grow and others may result in the production of a misshape leading to a nonfunctional form of a protein that normally repairs cellular damage. Genetic changes that promote cancer may be inherited (germline) or more commonly acquired (somatic) during a person's lifetime, either because of errors that occur as cells divide or from exposure to DNA-damaging carcinogens. There are many types of DNA genetic changes; these may affect just one unit of DNA (a nucleotide) or involve larger stretches of DNA (NIH, American Cancer Society).

Somatic mutations include point mutations, small insertions/deletions, and copy-number alterations that direct therapeutic options. Thus, in some cases, knowledge of the genetic alterations in a cancer patient can help determine a treatment plan as some treatments, particularly targeted therapies, are effective only for people whose cancer cells have specific genetic alterations that cause the cells to grow out of control (Wagle 2011, National Cancer Institute).

In the past decade, investigators have focused on searching for oncogenes and tumor suppressor genes that drive cancer. This is moving systemic cancer treatment away from the paradigm of treating histologically defined disease with cytotoxic chemotherapy, towards the use of molecularly targeted drugs prescribed to selected subsets of patients across multiple tumor types. Theoretically targeted therapies that inhibit the abnormally activated proteins, are more specific to cancer cells, potentially safer and more efficacious than the cytotoxic gents that target cell replication (Frampton 2013, Uzilov 2016, Tourneau 2015, Beaubier 2018).

To deliver personalized cancer targeted therapy, it is essential to use diagnostic tests that would accurately and comprehensively characterize the genomic alterations within individual tumors. Several technologies including Sanger sequencing (SGS, the gold standard), PCR, mass spectrometric genotyping, and other tests are currently used for the clinical assessment of a limited number of oncogenic markers. These tests may not perform parallel investigations of multiple targets and cannot address the increasing number and variety of therapeutically relevant gnomic alterations that occur in hundreds of cancer related genes with the amount of material obtained from biopsies (Frampton 2013, Rehm 2013, Arsenic 2015, Beaubier 2018).

Next generation sequencing (NGS), is becoming an attractive clinical diagnostic technology to detect most genomic alterations in the therapeutically relevant cancer genes in a single assay. NGS is not a test. but is an umbrella term for massively parallel DNA sequencing technology. The term NGS is used to emphasize the difference from the initial traditional gold standard single gene-based sequencing approaches that involve sequencing of one DNA strand at a time. NGS encompasses a variety of technologies that permit rapid parallel sequencing of millions of DNA segments, up to the entire genomes. These can perform three main levels of analysis: exome sequencing, genome sequencing, and disease targeted gene panels (Frampton 2013, Regier 2018).

A NGS cancer panel involves a complex 2-step process: 1. Wet bench process, which includes the handling of patient samples, extraction of nuclei acid, fragmentation and barcoding, target enrichment, adaptor ligation, library preparation, and generation of sequence reads. 2. Bioinformatics analysis of sequence data. This includes mapping sequence reads to the human reference genome, variant calling, annotation, and reviewing data in the right clinical context. Each of these steps require separate standards (Behjati 2013, Frampton 2013, McCourt 2013, Rehm 2013, American College of Medical Genetics and Genomics).

The number and scope of genes to be tested depend on the purpose of the test. A companion diagnostic test for standard care would require a limited number of genes, whereas NGS-based tests used for stratifying patients require the interrogation of a broader range of genes. Currently, there are several NGS platforms that perform sequencing of millions of small fragments of DNA in parallel. The platforms use different sequencing technologies, and due to the complexity and amount of sequencing data, and concerns about the reliability of the different NGS panels, several working groups (including the College of American Pathologists (CAP) and the American College of Medical Genetics and Genomics [ACMG]) have issued guidelines for NGS clinical testing. The assays or platforms should have a high-test sensitivity as cancer specimens may have a low percentage of tumor cells, i.e.

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high level of normal cell contamination. The test should also have a high specificity as a false positive result will have a negative impact on the choice of therapy (Frampton 2013, Kim 2017).

Cancer panel tests are mainly focused on actionable genomic alterations (variants) whose presence may help identify the most promising treatment approach. Different definitions of "actionable variants" have been used by researchers. While the majority defined it as the variant that can be targeted by a currently available drug (either FDA approved, off label use of an FDA approved drug, or a drug under investigation), others expanded the definition to include change in patient management on the prognostic implication or change in risk stratification. It is estimated that as many as one third of actionable changes in tumor analysis may be incorrectly classified as somatic changes. It is thus recommended to use matched tumor-normal DNA for genomic analysis to accurately identify and interpret actionable somatic and genetic changes that would have an important impact on the diagnosis and therapeutic management of cancer patients (Jones 2015, Kim 2017, Tan 2017, Regier 2018).

In recent years, several academic centers have adopted the use of NGS panels at the point of care to study cancer genomics and personalize patient care (precision oncology). However, the application of the NGS technology in the clinical context as a routine test to support the selection of therapy for cancer patients has its challenges. Most of cancer specimens are formalin-fixed paraffin embedded tissue (FFPE) which can degrade the DNA and RNA. This would require the application of robust nucleic acid extraction and sequencing library construction. In addition, many samples available for testing contain limited amount of tissue and in turn a limited amount of nucleic acid. The assays also need to be sensitive enough to detect gene alterations in specimens with a low tumor percentage. The use of the technology requires an infrastructure e.g. computer capacity and storage, as well as the application of rigorous statistical and analytical approaches to validate the accuracy of NGS technology for use in the clinical setting. An additional reported challenge is the personnel expertise required to comprehensively analyze and interpret the subsequent data, as well as skillfully extract and manage the clinically important information from the volume of data obtained. NGS has the potential to uncover a significant quantity of complex clinically and non-clinically actionable results with wide ranging implications for the patients and their families. Targeted therapies are limited by several factors including the availability, effectiveness and /or specificity of molecular inhibitor (targeted drug therapies) based on patients 'genetic information, heterogeneity the disease, resistance to a targeted therapy, and access to the treatment. It has also been reported that targeted therapies may be successful for some tumor types but not for others (Behjati 2013. Frampton 2013, Radovich 2016, Beaubier 2018).

FoundationOne CDx™ (F1CDx, Foundation Medicine, Inc.) a NGS test, was granted marketing approval by the US Food and Drug Administration (FDA) on November 30, 2017 to detect genetic mutations in 324 genes and two genomic signatures in any solid tumor type. The test can also identify which patients with non-small cell lung cancer (NSCLC), melanoma, breast cancer, colorectal cancer, or ovarian cancer may benefit from 15 different FDA-approved targeted treatment options (FDA website).

01/14/2019: MTAC Review
Evidence Conclusion:

- As indicated earlier in the report, it is difficult to set standards for assuring the analytical validity of NGS tests due to the amount and complexity of cancer genome sequencing and the different NGS technologies used. In general, however, the published validation studies suggest that NGS tests may have a high analytic validity, and lower clinical validity.
- There is insufficient evidence from published randomized clinical trials to determine that incorporating NGS into cancer care improves patient outcomes, such as treatment response and disease-free survival, or to support the use of molecularly targeted agents outside their indications based on tumor molecular profiling.
- More RCTs are needed to provide evidence on the utility of cancer genomics in clinical practice.

Articles: The literature search identified over 1,000 articles on NGS; the great majority of which were reviews, abstracts or articles not related to the current review. The search was filtered and narrowed down according the inclusion criteria based on PICO. Selected studies comparing the performance of NGS versus Sanger sequencing as well as randomized or nonrandomized studies evaluating the effectiveness and safety of applying the technology to cancer patients were included in the review. See Evidence Table

The use of Broad-Spectrum Tumor Molecular Profiling - Next Generation Sequencing (NGS) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Decipher Prostate Genomic Classifier
10/10/2022: MTAC Review

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Evidence Conclusion:

Decipher genomic testing using biopsy specimen

- There is insufficient evidence for or against the analytical validity and clinical utility of Decipher test. Low quality evidence supports the clinical validity of Decipher test. Overall, the evidence is insufficient for or against the use of Decipher genomic testing using biopsy specimen.

Decipher genomic testing using radical prostatectomy specimen

- Analytical validity: There is a lack of studies.
- Clinical validity: Low quality evidence from retrospective studies demonstrate that the Decipher Genomic Classifier is consistently superior in its prognostic and discriminatory ability in comparison to clinicopathologic variables for metastasis & prostate cancer-specific mortality.
- Clinical utility: Low quality evidence supports the clinical utility of Decipher testing. Decipher may influence treatment recommendations change in post prostatectomy patients with adverse pathologic characteristics.
- Overall, low quality evidence supports the use of Decipher genomic testing using radical prostatectomy specimens.

Articles: PubMed was searched through September 2022 with the search terms (Decipher OR genomic classifier OR 22-gene) AND (prostate). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded several studies. See Evidence Table.

The use of Decipher Prostate Genomic Classifier does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

***Note:** Codes listed in the criteria above may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
1997	10/04/2011[MDCRPC], 8/07/2012[MDCRPC], 11/06/2012[MDCRPC], 04/02/2013[MDCRPC], 05/07/2013[MDCRPC], 06/04/2013[MDCRPC], 08/06/2013[MPC], 03/04/2014[MPC], 06/03/2014[MPC], 07/01/2014[MPC], 10/07/2014[MPC], 11/04/2014[MPC], 02/03/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC],06/06/2023[MPC]	04/24/2023

/[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
05/11/2015	Array-Based Comparative Genomic Hybridization (aCGH): Removed MCG and reactivated GHC insufficient evidence criteria
06/02/2015	MPC approved MTAC recommendation of insufficient evidence for OVA1 & DecisionDx-Melanoma Testing
06/04/2015	Added Cologuard
06/30/2015	Added LCD link for cytogenetic studies
08/27/2015	Add LCD for CYP Genes
09/08/2015	Revised LCD CYP2C19 (CPT-81225), CYP2D6 (CPT-81226), CYP2C9(CPT81227), and VKORC1(CPT-81355) Genetic Testing (L36311), Cytogenetic Studies L34067

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10/13/2015	Added Medicare molecular testing LCD
10/27/2015	Added codes that do not need review
11/18/2015	Added Medicare MolDX links
03/01/2016	Discontinue review for Factor II & V
08/30/2016	Combined Risk Prognosticator Test to Genetic Screening criteria
09/06/2016	Added Prostate Cancer Gene Expression Testing- Oncotype DX MCG A-0712 to criteria
10/24/2016	Changed Veristrat to match Pharmacogenomic policy
11/01/2016	MPC approved to accept the genetic testing recommendations from the MCG 20th edition as outlined
01/23/2017	Added LCD 36544 & LCD 36186
04/04/2017	Added MTAC Review
05/16/2017	Added Percepta LCD
08/28/2017	Added ThyGeNEXT Oncogene Panel
09/18/2017	HFE gene – review no longer required CPT 81256
10/03/2017	Adopted MCG 21st ed. guidelines: A-0910, A-0909, A-0916, A-0907, A-0904, A-0908, A-0918, A-0926
10/11/2017	Removed MCG A-0917
12/05/2017	Adopted clinical criteria for Cystic Fibrosis testing
02/06/2018	MPC approved to adopt criteria for Decision Dx- Choroidal/Uveal Melanoma
03/26/2018	Added Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer
04/25/2018	Added language to BRAF testing
05/03/2018	Updated name changes with the MCG 22nd Edition
06/05/2018	MPC approved to adopt MCG* A-0823 and MCG* A-0957
08/07/2018	Added MTAC review from 7/9/18 for Microarray and Whole Exome for DD/ID
08/29/2018	Move code 81301 to no review at this time.
10/02/2018	Updated Micro Array for Evaluation of Intellectual Disability criteria
12/04/2018	MPC approved to adopt MCG* A-0598 Diabetes Mellitus (Maturity-Onset Diabetes of the Young)
01/08/2019	MPC approved to adopt criteria for Whole Exome Sequencing
02/05/2019	MPC approved to adopt policy of no coverage for Next Generation Sequencing (NGS) - Broad Spectrum Tumor Molecular profiling; added 01/2019 MTAC review
02/26/2019	Mammaprint: Send all cases to MD for review until criteria has been developed
04/02/2019	MPC approved to adopt criteria for Mammaprint
12/03/2019	MPC approved a non-coverage policy for Donor-derived cell-free DNA testing (e.g., Allosure)
04/07/2020	MPC approved non-coverage policy for 81540 CancerTYPE ID
04/29/2020	Removed code 81528
06/02/2020	Added section: “Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees.”. Requires 60-day notice, effective date 10/01/2020. Moved CPT codes 81402, 81403 and 81270 under Applicable Codes section that do not need review.
06/23/2020	Added CPT codes 81277, 81307, 81308, 81309, 81522, 81542, 81552, 875630087U, 0080U, 0081U, 0088U, 0089U, 0090U, 0091U, 0092U, 0105U, 0106U, 0107U, 0108U, 0109U, 0110U, 0111U, 0112U, 0113U, 0114U, 0115U, 0116U, 0117U, 0118U, 0119U, 0120U, 0121U, 0122U, 0123U, 0124U, 0125U, 0126U, 0127U, 0128U, 0129U, 0130U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, 0138U
07/22/2020	Removed CPT codes that do not require review: 81220, 81221, 81240, 81241, 81261, 81340, 81341, 81342, 81372, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81402, 81403, 81270.

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

10/06/2020	MPC approved to adopt MCG 24th ed. guidelines for the following: Narcolepsy - HLA Testing: A-1005, Transthyretin Amyloidosis - TTR Gene: A-1010, Retinal Dystrophy - RPE65 Gene: A-1011, Breast Cancer- PALB2: A-0989, Alpha-1 Antitrypsin Deficiency - SERPINA1 Gene: KP-1006, Paraganglioma-Pheochromocytoma (Hereditary) - Gene Testing and Gene Panel: A-0798; added exception for NGS for Advanced Cancer (CellNetix lab) to Invitae as preferred lab section. Removed codes section; will defer to pre-authorization code check tool.
05/04/2021	Updated Medicare LCD links, MCG Guideline information, and applicable codes. MPC approved to adopt MCG 25th edition guidelines for the following: Malignant Melanoma (Cutaneous) – BAP1, CDK4, and CDKN2A; Malignant Melanoma (Cutaneous) – BRAF V600 Testing; Renal Cancer (Hereditary) – Gene Panel; and Noonan Syndrome – Gene and Gene Panel Testing. Requires 60-day notice, effective date 10/1/2021.
08/03/2021	Updated Nephrology section, referencing separate criteria for Donor-derived cell-free DNA testing for Kidney Transplant Rejection (e.g., AlloSure).
11/02/2021	MPC approved to expand coverage for Spinal Muscular Atrophy (SMA) Carrier Testing. Requires 60-day notice, effective date 04/01/2022.
12/07/2021	MPC approved to adopt expansion of coverage for Chromosomal Microarray testing to members who are undergoing invasive prenatal genetic testing (i.e., amniocentesis). Requires 60-day notice, effective date 05/01/2022.
12/07/2021	MPC approved to adopt a policy of non-coverage for the ConfirmMDx and SelectMDx genetic tests for prostate cancer. Requires 60-day notice, effective date 05/01/2022.
04/05/2022	MPC approved to adopt MCG* A-0782 with new indications in the 26th edition. Gene/gene panel testing for hereditary ovarian cancer criteria are in the process of being updated and will all be reviewed by the Medical Director on a case-by-case basis until finalized.
06/07/2022	MPC approved to adopt MTAC's recommendation of non-coverage and to continue the existing policy of insufficient evidence.
08/16/2022	MCG* A-0822 and A-0847 were deleted from the 26th edition guidelines; deleted from criteria
09/22/2022	Added Oncoplex (University of Washington) and Caris Life Sciences as preferred lab vendors for NGS
311/01/2022	Updated criteria for Chromosomal Microarray Testing to remain compliant with revisions to the WAC; also updated other related prenatal genetic testing that were mandated to no longer require medical review. Effective immediately to comply with WAC 246-680-010. 60-day notice required.
11/01/2022	MPC approved to adopt criteria for Thyroid Nodule Gene Expression Testing (ThyraMIR/ThyGeNEXT CPT 0245u+0018U), Prostate Cancer Gene Expression Testing (Prolaris 81541) and Prostate Cancer (ConfirmMDx CPT 81551). Requires 60-day notice, effective date 04/01/2023.
11/14/2022	Added the July 2022 MTAC reviews for ConfirmMDx and Prolaris for Prostate Cancer. Replaced SelectMDx temporary CPT code 81479 with new CPT code 0339U, effective 10/1/22.
12/06/2022	MPC approved to remove NRAS genetic test from this page as it is currently on pharmacogenomic page. MPC approved to remove BRAF testing from genetic screening page and move to Pharmacogenomic page. Effective immediately.
12/12/2022	Added ClonoSEQ 81479 to flag for medical director review.
01/03/2023	Clarified language on ClonoSEQ indications. Added Medicare LCD L38816 and LCA A58997.
01/18/2023	Added the MTAC review for Decipher Prostate Genomic Classifier.
01/25/2023	For Prolaris-clarified use in setting of radical prostatectomy.
04/03/2023	Updated Medicare links and applicable code 0340U for Medicare LCD L38816.
04/24/2023	Added Quest-QNatal as a preferred vendor for Cell Free Fetal DNA testing.

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Clinical Review Criteria
Genetic Panels using Next Generation Sequencing (germline/blood testing, excluding Advanced Cancer)

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage).

Prevention and Invitae Corporation are the preferred labs for genetic testing, when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions
For the NGS testing for Advanced Cancer, see below:
- ***Next Generation Sequencing for Advanced Cancer***

Related Policies:

Genetic Screening and Testing

Pharmacogenomic Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2) (Applies to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) breast and ovarian cancer.) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.)

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	MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets))
Local Coverage Determinations (LCD)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Next-Generation Sequencing for Solid Tumors (L38121) (Applies to diagnostic lab tests using NGS for solid tumors.)

General Coverage Rules – LCD 24308

1. Genetic tests for cancer are only a covered benefit for a beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:

The MolDX Program has determined certain gene tests do not meet Medicare's medical necessary requirements, and that the inclusion of these genes will result in an entire panel to be denied. MolDX has determined that testing for the below genes is a statutorily excluded service. Unless indicated otherwise, panels that include these genes will be denied. Please see the individual Test Coding and Billing Guidelines for each gene.

Palmetto GBA is the Medicare contractor for Molecular Diagnostic Testing – this site has the most up to date Medicare coverage guidelines for genetic testing.
MolDX® Program (Administered by Palmetto GBA)

Local Coverage Decisions (LCD)/Articles (LCA) *not all-inclusive – refer to the MolDX® Program link above*

ID	Title	Codes *(not all-inclusive)*

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L36163	8/20/2022 Noridian retired LCD MolDX: BRCA1 and BRCA2 Genetic Testing. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.	81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81432, 81445, 81455, 0102U, 0103U, 0129U
L36386	MolDX: Breast Cancer Assay: Prosigna	81520
L37824	MolDX: Breast Cancer Index® Gene Expression Test	81518
L36186	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	81206, 81207, 81208, 81219, 81450, 0027U
L36159	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)	81240, 81241, 81291
L36374	8/20/2022 Noridian retired LCD MolDX: Genetic Testing for Lynch Syndrome. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.	81210, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81301, 81317, 81318, 81319, 81433, 81435, 81436, 0101U
L36192	MolDX: MGMT Promoter Methylation Analysis	81287
L36544	MolDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36544) **not covered per LCD*	81383
L36256	MolDX: Molecular Diagnostic Tests (MDT)	*See LCA: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)
L38333	MolDX: Blood Product Molecular Antigen Typing	0001U, 0084U
L36329	08/08/2022 Noridian retired LCD MolDX: ConfirmMDx Epigenetic. Molecular Assay. MolDX: Genetic Testing for Lynch Syndrome. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L39007MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer.	81551, 81313 Billing and Coding: MolDX: Molecular Biomarkers to Risk Stratify Patients at Increased Risk for Prostate Cancer

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L38341	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease *(Decipher and similar, i.e., Prolaris)*	81541, 81542
L36339	MolDX: NRAS Genetic Testing	81311, 81479
L36557	01/01/2018 Noridian retired LCD MolDX: Chromosome 1p/19q Deletion Analysis (L36557). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36557 for determining medical necessity, along with L36256 MolDX: Molecular Diagno2stic Tests (MDT).	
L36891	MolDX: Percepta© Bronchial Genomic Classifier	81479

For Non-Medicare Members

Kaiser Permanente considers genetic testing panels medically necessary when the results are expected to directly affect treatment, management, surveillance or reproductive decisions and when all genes or genetic variants included in the panel have high quality, evidence-based guidelines established to direct clinical management based on results.

Testing for individual components of a panel may be medically necessary in some clinical situations. Separate clinical criteria for these components may apply.

Members must meet ALL the following criteria:

1. The member is at clinical risk for a genetic condition because of current documented symptoms being displayed or a strong family history of the condition.
2. The test is scientifically valid and can be adequately interpreted.
3. The results will directly affect a member's clinical management or reproductive decisions.
4. After appropriate clinical work-up, and informed consent by the appropriate practitioner, the genetic test is indicated.

Genetic testing is not covered for the medical management of a family member who does not have Kaiser Permanente coverage.

1.) If Kaiser Permanente Clinical criteria for BRCA genetic testing using MCG* A-0499 are met AND
   a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
   b. One of the following NGS panels can be covered:
      i. Invitae Breast Cancer STAT Panel
      ii. Invitae Breast Cancer Guidelines – Based Panel
      iii. Invitae Breast and Gynecological Cancers Guidelines – Based Panel
      iv. Prevention – Breast Cancer- High Risk Panel

2.) If Kaiser Permanente Clinical Review Criteria for Lynch syndrome genetic testing using MCG* A-0533 are met AND
   a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
   b. One of the following NGS panels can be covered:
      i. Invitae Lynch Syndrome Panel
      ii. Invitae Colorectal Cancer Guidelines – Based Panel
      iii. Prevention Lynch Syndrome Panel

3.) If Kaiser Permanente Clinical Review Criteria for both BRCA and Lynch syndrome genetic testing are met

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a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
b. The following NGS panel can be covered
    i. Invitae Breast and Gynecological Cancers Guidelines – Based Panel
    ii. Prevention Hereditary Breast and Ovarian Cancer – High Risk and Lynch Syndrome Panel

***If a member has had prior negative BRCA1 & 2 gene testing:** In most cases, further genetic testing would not be considered necessary. However, in cases where there is a very strong personal or family history suggesting a genetic disposition, testing for additional evidence-based cancer susceptibility genes is warranted. One of the Invitae NGS panels listed in section 1b above could be covered.

Criteria for other Genetic Panel Tests:
Refer to the Genetic Screening and Testing clinical review criteria to see information about review criteria for specific genetic tests *not* described above; please also check Invitae Test Catalog or Prevention Test Catalog

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

*MCG are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following genetic panels are **not considered medically necessary** because the current scientific evidence is not yet sufficient to establish how test results from all components of these panels should be used to direct treatment decisions. There is also insufficient evidence to establish that use of these genetic panels to guide treatment decisions results in improved patient health outcomes.

This list is not all-inclusive as new genetic panel tests are frequently being developed.

Test	Laboratory
BRCANext™ or BRCANext-Expanded™	Ambry Genetics™
BROCA Cancer Risk Panel	University of Washington
CancerNext™ or CancerNext-Expanded™	Ambry Genetics™
ColoNext™	Ambry Genetics™
Cell Search	Veridex
ColoSeq™	University of Washington
Comprehensive Mitochondrial Nuclear Gene Panel	GeneDx
Counsyl™ Panel	Counsyl Genomics
Cxbladder	Pacific Edge Laboratory
DetoxiGenomic®	Profile Test Genova®
FirstStepDx PLUS©	Lineagen
FoundationOne™	Foundation Medicine, Inc.
Galleri®	Grail, Inc
Gene Trails AML/MDS Genotyping Panel	Oregon Heath & Science Univ
Gene Trails NSCLC Genotyping Panel	Oregon Heath & Science Univ
Gene Trails Solid Tumor Panel	Oregon Heath & Science Univ
Genomind Professional PGx Express	Genomind, Inc.
GeneSight® Psychotropic test	Myriad®
Guardant360 CDx	Guardant Health
Leigh Syndrome Nuclear Gene Panel	GeneDx
Monogenic Hypertension Evaluation Panel	Athena Diagnostics

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Test	Laboratory
myRisk® Hereditary Cancer Panel	Myriad®
Horizon™ Advanced Carrier Screening	Natera, Inc.
PancNext™	Ambry Genetics™
Prometheus IBD sgi® Diagnostic (Serology)	Prometheus Laboratories
Anser TM ADA for Adalimumab (Humira) Antibodies Anser TM IFX test for Infliximab (Remicade) Antibodies	Prometheus Laboratories See the Medical Policy "Prometheus Lab Testing"
OncotypeDx Genomic Prostate Score **MCG* A-0712**	Genomic Health
Proteomics – Ovarian Cancer Markers (OVA1) **MCG* A-0709**	
Proteomics – Prostate Cancer Markers	
RenalNext®	Ambry Genetics™
Signatera™	Natera™
CancerTYPE ID®	Biotheranostics
Vascular Aneurysm Genetic Panel	University of Washington
NeurodevelopmentNext™	Ambry Genetics™
X-linked Intellectual Disability Panel	NTD Genetics
X-linked Intellectual Disability Sequencing Panel	Greenwood Genetic Center

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The emergence of new genetic testing technology, including next generation sequencing and chromosomal microarray, has made possible the ability to examine many genes simultaneously. This in turn has resulted in a proliferation of new genetic testing panels. The intended use for these panels varies.

For example, for hereditary disorders, a clinical diagnosis may already be established, in which case genetic testing is performed to determine the specific causative mutation and a diagnostic genotype. In other cases, the clinical findings may suggest a number of possible etiologies, in which case genetic testing is performed in the hope of making a specific diagnosis.

For cancer panels, intended uses also differ. Some panels may be intended to identify the presence of a hereditary syndrome predisposing to the development of certain cancers. Other panels look for somatic mutations in a tumor biopsy specimen with the intent of identifying a cancer's primary site of origin and/or identifying a molecular target to help in selecting treatment.
Panels using next generation sequencing technology are currently available in the areas of cancer, cardiovascular disease, neurologic disease, and for prenatal testing and screening. These panels are intuitively attractive to use in clinical care because they can analyze multiple genes quickly and may lead to greater efficiency in the work-up of genetic disorders. It is also possible that in some cases these "bundled" gene tests can be performed more cost efficiently than individual sequencing, although this may not be true in all cases.

On the other hand, the use of newer sequencing techniques is associated with a higher rate of results which may be of uncertain clinical significance and/or for which there are no reliable evidence-based guidelines regarding management or surveillance. This can potentially lead to unnecessary follow-up testing and procedures, which have their own inherent risks and cost.

The design and composition of genetic panel tests are not standardized. The make-up of each panel is determined by the specific laboratory that has developed the test. In addition, the composition of any individual panel is likely to change over time, as new genetic variations are discovered and added to the existing panels.

Evidence and Source Documents

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)
Coloseq ™ Colon Cancer Panel

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Medical Technology Assessment Committee (MTAC)

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)

BACKGROUND

Understanding the underlying genetic contribution to cancer can give insight to individual and familial risk. This is especially important with hereditary cancer since risk-reducing strategies for additional primary cancers can vary based on molecular diagnosis. Identifying an underlying genetic cause can also aid in the diagnostic process since relying on family history alone can be challenging. Numerous genetic mutations are associated with certain types of hereditary cancer. Traditionally, Sanger sequencing has been considered the gold standard in mutation detection and is still the method of choice for most diagnostic labs. However, since multiple genes are implicated in each type of cancer, testing by traditional sequencing can be burdensome and expensive. Advancements in sequencing technologies have made it possible to generate a large amount of data quickly and cost effectively (Choi, Scholl et al. 2009). Next generation sequencing (NGS) provides investigators with the required capacity to analyze large panels of genes or whole genomes in a single run (panel testing) (Previati, Manfrini et al. 2013). As a result, these technologies are enabling new tailor-made approaches to diagnostic testing with an increasing number of commercially available genetic panels (Walsh, Lee et al. 2010; Michils, Hollants et al. 2012). Ambry Genetics offers four different genetic testing panels for hereditary cancers (Keiles 2013). These panels address three specific types of cancer that may be inherited including breast, ovarian and colorectal. The mutations included in these panels are associated with varying levels of risk of developing cancer, and only some of the mutations are associated with well-defined cancer syndromes which have established clinical management guidelines (Burke, Petersen et al. 1997).

TABLE 1: PANEL NAME AND DESCRIPTION

PANEL NAME	DESCRIPTION
BreastNext™	Next-generation sequencing panel that simultaneously analyzes 16 genes that contribute to increased risk for breast cancer including BRCA1 and BRCA2.
OvaNext™	Next-generation sequencing panel that simultaneously analyzes 21 genes that contribute to increased risk for breast ovarian and/or uterine cancers.
Colonext™	Next-generation sequencing panel that simultaneously analyzes 14 genes that contribute to increased risk for colon cancer.
CancerNext™	Next-generation sequencing panel that simultaneously analyzes 24 genes that contribute to increased risk for breast colon, ovarian, uterine and other cancers.

There is no standardization to the make-up of genetic panels. Composition of the panels is variable, and different commercial products for the same condition may test a different set of genes. The make-up of the specific panels is determined by the specific lab that has developed the test. In addition, the composition of any individual panel is likely to change over time, as new mutations are discovered. The majority of cancer panel tests are laboratory derived tests that are not subject to U.S. Food and Drug Administration (FDA) approval. Labs are subject to Clinical Laboratory Amendment (CLIA) regulations that monitor high-complexity testing.

10/21/2013: MTAC REVIEW

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)

Evidence Conclusion: Analytic Validity According to Ambry Genetics, the analytic sensitivity for the 22 genes analyzed on their cancer susceptibility panels by next generation sequencing is 96-99% (Keiles 2013), however, no publications were found to support these claims. No published literature addressed the analytic validity of the Ambry Genetics' Next-Gen Cancer Panels. Clinical Validity While it may be possible to evaluate the clinical validity of sequencing of individual genes found on these panels, the clinical validity of Ambry Genetics' Next-Gen Cancer Panels, which include mutations associated with unknown or variable cancer risk, is uncertain. No published literature addressed the clinical validity of panel testing for cancer susceptibility with NGS. Clinical Utility Theoretically, identifying an individual with a genetic mutation that indicates a high risk of developing cancer could lead to changes in clinical management and improved health outcomes including modifications in cancer surveillance and treatment guidance. However, identifying mutations that have intermediate or low risk of developing cancer is of limited clinical utility. With potential harms, such as psychological stress and unnecessary prophylactic intervention, the management for patients found to have one of these mutations is not well defined. No published literature addressed the clinical utility of the Ambry Genetics' Next-Gen Cancer Panels. Conclusion There is insufficient evidence to determine the analytic validity, clinical validity or clinical utility of the Ambry's Next-Gen Cancer Panels.

Articles: A search of PubMed was completed for the period through August 2013 for studies on the accuracy of NGS for predicting risk of hereditary breast ovarian and colon cancer. The search strategy used the terms *next*

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generation, cancer panel, BreastNext, breast cancer, ColoNext, colon cancer, OvaNext, ovarian cancer and CancerNext with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Articles were limited to those published in the English language with human subject enrollment. The search was supplemented by an examination of article bibliographies in addition to the PubMed *related* articles function.

The use of Ambry next generation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Coloseq™ Colon Cancer Panel

BACKGROUND

Approximately 2% to 5% of colorectal cancer (CRC) can be attributed to inherited syndromes such as Lynch syndrome (also known as hereditary non-polyposis colon cancer), familial adenomatous polyposis (FAP), and MUTYH-associated polyposis. Patients with these syndromes are at higher risk for CRC and, therefore, require more intensive surveillance programs. Lifetime CRC risk is 50-80% for patients with Lynch syndrome, 100% for patients with FAP, and 80% for patients with MUTYH-associated polyposis compared to 5-6% for patients without these syndromes (Kaz and Brentnall 2006; Jasperson, Tuohy et al. 2010). There are several different strategies used to identify families at high-risk for developing these syndromes, however, genetic testing is the gold standard for diagnosing Lynch syndrome and FAP. To date, clinical diagnostic criteria for MUTYH- associated polyposis have not been fully established; however, genetic testing may be warranted in individuals with more than 10 colorectal adenomas who are negative for APC mutations (Jasperson, Tuohy et al. 2010). Genetic testing of high-risk families allows for a more accurate diagnosis and more specific targeting of clinical screening and surveillance protocols to gene carriers in the family. Additionally, genetic testing allows for the identification of family members who did not inherit the mutation and therefore do not warrant intensive surveillance programs. Coloseq™ is a comprehensive genetic test for the prediction and diagnosis of hereditary colon cancer that uses next generation sequencing to detect mutations in multiple genes associated with Lynch syndrome, FAP, and MUTYH-associated polyposis. Initially, the panel was developed to include seven genes that have a well-established role in clinical decision making for patients with Lynch or polyposis syndromes. Since then, however, the panel has undergone several evolutions to include four additional genes in June of 2012, two more genes in January of 2013 and, most recently, the addition of six genes in October of 2013. With a total of 19 genes now included, the panels utility has now expanded into the realms of endometrial, breast, and thyroid cancer, to name a few. Coloseq is not approved by the Food and Drug Administration (FDA) but clinical laboratories that develop and validate tests for in-house use are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

10/16/2013: MTAC REVIEW

Coloseq™ Colon Cancer Panel

Evidence Conclusion: *Analytic Validity* One publication from the Journal of Molecular Diagnostics was identified that addressed the analytic validity of ColoSeq™ (Pritchard, Smith et al. 2012). The study presents 99.4%-100% sensitivity and 99.4%-100% specificity. The paper was limited to the seven genes that were included on the original panel and thus does not provide sufficient evidence for the 19 gene panel that is currently used. No publications were identified that validated the entire 19 gene panel that has since evolved. *Clinical Validity* Pritchard and colleagues present that the clinical validity is achieved by targeting and validating only genes that, when mutated, are well-established causes of hereditary colon cancer leading to the conclusion that incorporating the results of the ColoSeq™ testing into clinical-decision making was now straightforward. The addition of new genes and inclusion of additional cancers compromise this claim. No publications were identified that addressed the clinical validity of the ColoSeq™ cancer panel. *Clinical Utility* Originally, the ColoSeq panel was designed to focus only on genes that have a well-established role in clinical decision making and patient management. The recent expansion of the ColoSeq panel compromises the overall clinical utility. No published literature addressed the clinical utility of the ColoSeq™ cancer panel.

Conclusion**:** There is insufficient evidence to determine the analytic validity, clinical utility and clinical validity of Coloseq™ for the identification of hereditary colon cancer.

Articles: A search of PubMed was completed for the period from April 2012 to November 5th, 2013 for studies on the accuracy of ColoSeq™ for detecting hereditary colon cancer. The search strategy used the terms *Coloseq™, genetic testing, Lynch syndrome, familial adenomatous polyposis (FAP), MUTYH-associated polyposis,* and *colon cancer* with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Selected articles were limited to those published in the English language enrolling human subjects. The search was supplemented by an examination of article reference lists in addition to the PubMed *related articles* function. **Screening of articles:** The literature search for ColoSeq™ revealed one July 2012 publication on the development and validity of the assay (Pritchard, Smith et al. 2012). Due to recent additions (October 2013) to the Coloseq™ cancer panel, this publication is no longer applicable and was not reviewed.

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The use of Coloseq™ does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

***Note:** Codes listed in the criteria above may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
3/04/2014	3/04/2014[MPC], 6/3/2014[MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/15/2023

[MPC] Medical Policy Committee

Revision History	Description
06/30/2015	Added Medicare LCD links and PROOVE® panels.
08/27/2015	Added LCD 35850 and LCD 35504
09/08/2015	Revised LCD Circulating Tumor Cell Marker Assays LCD L35096 and L34066, Breast Cancer Genetic Assay L35500 and L36316, GeneSight® Assay for Refractory Depression L36324 and L36325, Genetic Testing L34101, LCD for ConfirmMDx Epigenetic Molecular Assay (L36328),
12/06/2016	Added Cx Bladder & My Risk Panel to the non-covered list
05/16/2017	Added Percepta LCD
06/15/2017	Added Invitae Stat Panel coverage
10/19/2017	Added Health Diagnostics to the non-covered panel list
03/26/2018	Added Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer
06/13/2018	Moved 81381 to the no review list
08/29/2018	Moved 81307 to no review at this time
06/02/2020	Added section: "Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees." Requires 60-day notice, effective date 10/01/2020. Moved CPT codes 81402, 81403 and 81270 under Applicable Codes section that do not need review.
06/24/2020	Added CPT codes 0084U, 0085U, 0093U, 0094U, 0095U, 0097U, 0098U, 0099U, 0100U, 0101U, 0102U, 0103U, 0104U
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020. Removed CPT codes that do not require review: 81220, 81221, 81240, 81241, 81261, 81340, 81341, 81342, 81372, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81402, 81403, 81270.
10/06/2020	Removed codes section; will defer to pre-authorization code check tool.
05/04/2021	Removed genetic panel tests that are no longer available. Updated Medicare LCD links and applicable codes.
09/27/2022	Added Prevention as a preferred lab vendor for genetic panel testing. Removed Caris and Oncoplex from the non-inclusive list of genetic panel tests. 60-day notice required; effective 03/01/2023.
01/19/2023	Removed Prolaris from the non-covered list. MPC approved to adopt criteria for Prostate Cancer Gene Expression Testing (Prolaris 81541) and Prostate Cancer (ConfirmMDx CPT 81551), effective 4/1/2023- see Genetic Screening Criteria for details.
03/08/2023	Added Signatera to the non-covered panel list
05/15/2023	Updated Medicare Links including—newly retired policies L36163, L36329 and L36374

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Clinical Review Criteria
Treatment of Gastroesophageal Reflux Disease - GERD

- CR BARD's Endoscopic Suturing System
- Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter
- LINX Reflux Management System
- Stretta Procedure
- Transoral (Endoluminal) Gastroplication or Suturing (Esophyx)

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Criteria

For Medicare members

Procedure(s):	CPT Code(s)	CMS Coverage Guidelines – NCD, LCD, LCA	Kaiser Permanente Medical Policy
Transesophageal radiofrequency energy ***Examples:*** CSM Stretta™ System, or the Stretta procedure	43257	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines.
Transoral incisionless fundoplication (TIF) ***Examples:*** EsophyX	43210	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Transoral (Endoluminal) Gastroplication or Suturing*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Kaiser Permanente has elected to use the Transoral (Endoluminal) Gastroplication or Suturing (A-0205) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines.
LINX® Reflux Management System	43284, 43285	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical	Kaiser Permanente has elected to use the Implantable Magnetic Esophageal Ring (Linx) (A-0990) MCG* Care Guideline for medical necessity determinations.

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		Review Criteria, ***Implantable Magnetic Esophageal Ring (Linx)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	This is not covered per MCG guidelines.
Endoscopic injection of a bulking agent ***Examples:*** pyrolytic carbon-coated zirconium oxide spheres (Durasphere®)	43192, 43201	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).
Endoscopic submucosal implantation or injection of a biocompatible polymer ***Examples:*** • Enteryx, • polymethylmethacrylate [PMMA] beads (1) the Gatekeeper Reflux Repair system	43192, 43201	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).
Transesophageal endoscopic gastroplasty ***Examples:*** • EndoCinch • Plicator • StomaphyX	No specific codes – *often submitted using 43499*	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).

For Non-Medicare members

Service	Criteria
Implantable Magnetic Esophageal Ring (LINX® Reflux Management System)	Kaiser Permanente has elected to use the Implantable Magnetic Esophageal Ring (Linx) (A-0990) MCG* Care Guideline for medical necessity determinations. This is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)	Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Transoral (Endoluminal) Gastroplication or Suturing (Esophyx)	Kaiser Permanente has elected to use the Transoral (Endoluminal) Gastroplication or Suturing (A-0205) MCG*

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	Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
• CR BARD's Endoscopic Suturing System (EndoCinch Therapy, Endoluminal Plication) • Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (GI, general surgeon)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastroesophageal reflux disease (GERD) is a common disease worldwide with an estimated prevalence of 10-20% in the Western population. It is defined as a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications. GERD has a wide clinical spectrum ranging from mild reflux symptoms to severe regurgitation but is typically characterized by heartburn and acid regurgitation. Other symptoms of GERD include epigastric pain, dysphagia, chronic cough, chronic laryngitis, and asthma (Vakil 2006, Zhang 2016, Savarino 2017).

Therapeutic approaches to GERD included lifestyle modification, medical therapy with gastric acid secretion inhibitors, and surgical interventions. Proton pump inhibitors (PPIs) are the standard medical therapy and aim at suppressing the normal acid production in the stomach to alleviate the acid reflux symptoms. PPIs can only inhibit gastric acid secretion, but do not prevent reflux nor address the incompetent lower esophageal sphincter (LES). It is reported that up to 40% of the GERD patients fail to respond either partially or completely to PPIs and will continue to have reflux symptoms or endoscopic evidence of esophagitis (Reynolds 2016, Saino 2016, Chen 2017).

Laparoscopic Nissen fundoplication (LNF) is currently the gold standard surgical treatment for patients who fail medial therapy. Nissen fundoplication reconstructs the defective LES to restore its normal function as an anti-reflux barrier. The surgery is safe and very effective in reducing GERD symptoms. However, the procedure is technically demanding and requires significant anatomical disruption to mobilize the gastric fundus and wrap it around the esophagus. It may also be associated with side effects including difficulty swallowing, bloating, early satiety, and inability to vomit or belch. As a result, only very few GERD patients will opt for the surgery (Saino 2015, Reynolds 2016, Zadeh 2018).

The Magnetic sphincter augmentation device (MSA) (LINX®, Torax Medical Shoreview, MN) was introduced in 2008 as a potential less invasive anti-reflux surgical option for patients with uncomplicated GERD who do not respond to PPIs, and still have some LES function. I.e. it is not indicated for patients with complete LES failure or with complicated GERD. The MSA device is a small expandable bracelet- like string of consisting of 10 or more beads with a magnetic core and interlinked with independent titanic wires. The device is laparoscopically placed around the gastroesophageal junction (GEJ) with minimal dissection of the hiatus to preserve the native LES. The magnetic attraction between the beads augments the existing LES barrier function to prevent reflux, and the mobile wires connecting the beads allow the device to expand during swallowing, belching, or vomiting (Reynolds 2017, Siddiqi 2017, Zadeh 2018, Guidozzi 2019).

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The LINX® device should not be placed in patients with suspected or known allergies to titanium, stainless steel, nickel or ferrous material, or in those with pacemakers, defibrillators or metallic implants in the abdomen. In addition, it may not be appropriate for patients with a history of dysphagia, previous upper abdominal surgery, previous endoluminal anti-reflux procedures, large sliding hiatal hernia, or Barrett's esophagus. Reported adverse events and complications associated with magnetic sphincter augmentation include inability to belch or vomit, bloating, and dysphagia. The latter is the most common complication of the MSA, and severe cases may require a second surgery for dilatation, and removal of the device if endoscopic dilatation fails. Other reported adverse events include device failure, device migration, device erosion, and ring eroding into the esophageal lumen (Fass 2017, Chen 2017, Zadeh 2018, Guidozzi 2019).

The LINX® Reflux Management System received U.S. Food and Drug Administration (FDA) approval on March 22, 2012 for patients with GERD as defined by abnormal pH testing, and who continue to have chronic symptoms despite the use of a maximum medical therapy.

Medical Technology Assessment Committee (MTAC)

CR BARD's Endoscopic Suturing System (EndoCinch Therapy, Endoluminal Plication) for the Treatment of GERD

BACKGROUND

Gastroesophageal reflux disease (GERD) is a chronic disorder that affects as many as 14 million Americans. It is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001). More recently endoscopic or endoluminal approaches for treating GERD have either been FDA approved or are still under investigation. These various methods can be divided in three broad categories: 1. Methods that attempt to create a fundoplication (plicating techniques), 2. Methods that create a controlled stricture (radio frequency), and 3. Methods that bulk the gastroesophageal junction (injecting bulking agents). The ideal procedure should be safe, effective over a long term, and would not affect future surgical options. Currently, there are three plicating devices: The EndoCinch (C.R. Bard's endoscopic suturing system, the ESD, and the Full-Thickness Plicator. The first two have been approved by the FDA, and the last was not approved to date. Endoluminal plication uses mechanical techniques to hinder reflux by approximation of tissue at or below the gastroesophageal junction. The EndoCinch (CR BARD Endoscopic technologies, Massachusetts, USA) system was the first FDA approved endoscopic sewing machine method for treating GERD. It was developed by Swain CP et al in London UK, in the mid-1980s. In the Bard method, an oroesophageal tube (19.7 mm in diameter and 30 cm long) is placed to facilitate passage of the suturing device. The suture capsule, which is similar to a sewing machine, is attached to an endoscope and loaded with a suture. After placing the suture capsule, under vision, over the selected site at the gastroesophageal junction, suction through the external vacuum line is applied. This pulls a fold of tissue into the capsule cavity, and the needle driver places the suture. Suction is released, and the tissue is withdrawn from the capsule. The procedure is repeated on an adjoining site. Drawing two sutured sites together creates a plication. It is reported that the procedure is technically difficult, has a steep learning curve, and that the results are likely to be operator dependent. Conscious sedation might not be sufficient, and a general anesthesia may be needed. Adverse effects associated with the procedure include pharyngitis, vomiting, abdominal pain, chest pain, mucosal tear, hypoxia, and bleeding. The Bard's Endoscopic Suturing system was FDA approved in March 2000, for the treatment of GERD. The ESD (Wilson-Cook Medical, Winston-Salem, N.C.) another endoscopically assisted endoluminal suturing device was also approved by the FDA for soft-tissue apposition. The Full-Thickness Plicator (Ndo Surgical, Inc, Mansfield, Mass) is another plication device that had not been approved by the FDA at time the search was made.

02/13/2003: MTAC REVIEW

Endocinch Therapy in the Treatment of GERD

Evidence Conclusion: The studies reviewed show that the procedure is associated with a reduction in the frequency and severity of heartburn and regurgitation symptoms. Patients had an improved quality of life, and

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there was a significant reduction in the use of antisecretory medications in two of the studies. However, the procedure was performed on a highly selected group of patients (those with hiatal hernia >3 cm, esophageal stricture and Barrett's esophagus were excluded). Moreover, the follow-up duration of all studies was short, and insufficient to determine the recurrence rate and long term-efficacy of the procedure. Filipi's study was an RCT, yet the patients were randomized to two different suture configurations of the same procedure and not to an alternative treatment. Randomized controlled studies with long-term follow-up are needed to compare the procedure with other medical and surgical anti reflux therapies and assess the sustained effect of the procedure and the long-term relief from symptoms without using antisecretory medications.

Articles: The search yielded 12 articles, all on the Bard technique. There was one randomized controlled trial, one case-control study and one case series. The rest were reviews, tutorials, letters or dealt with the technical aspect of the procedure. There were no published studies on the Wilson-Cook ESD, or the Ndo Full-Thickness Plicator. Evidence tables were created for the three studies identified in the search:

Filipi CJ, Lehman GA, Rothstein RI, et al. Transoral flexible endoscopic suturing for treatment of GERD. A multicenter trial. Gastrintest Endosc 2001; 53:416-422. See Evidence Table. Mahmoud Z, McMahon BP, Arfin Q, et al. Endocinch therapy for gastro-esophageal reflux disease: a one-year prospective study. *Gut* 2003, 52:34-39. See Evidence Table. Velanovich V, Ben-Menachem T, and Goel S. Case-control comparison of endoscopic gastroplication, with laparoscopic fundoplication in the management of gastroesophageal reflux disease. Early symptomatic outcomes. *Surg laparosc Endosc Percutan Tech* 2002, 12:219-223. See Evidence Table.

The use of Endocinch therapy in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter for the Treatment of GERD

BACKGROUND

Gastro-esophageal reflux disease (GERD) is a chronic disorder that affects as many as fourteen million Americans. It is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmaco-therapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up ((Lafullarde, 2001). More recently endoscopic or endoluminal approaches for treating GERD have either been approved or are still under trial. These various methods can be divided in three broad categories: 1. Methods that create a controlled stricture (radiofrequency), 2. Methods that attempt to create a fundoplication, and 3. Methods that bulk the gastroesophageal junction (injecting bulking agents). The ideal procedure should be safe, effective, with long-term effects, and do not affect future surgical options. Endoscopic injection of an inert material into the submucosa of the distal esophagus has been tried with the intention to impede the reflux. The bulking effect results from both the material injected and the tissue response. Examples of the bulking agents used are bovine collagen, ethylene vinyl alcohol, polytetrafluoroethylene and others. These are injected through long catheters and small gauge needles under endoscopic guidance. In the experiments conducted the resulting improvement in reducing the LES pressure and GERD symptoms were temporary, and did not last long, either due to the biodegradation or migration of the injected material. Other non-biodegradable substances injected into the submucosa or muscle, and with the use of different application techniques are still under trial. These methods are still in the investigational stage and are not approved by the FDA.

02/13/2003: MTAC REVIEW

Bulking Material in the Treatment of GERD

Evidence Conclusion: There is insufficient evidence to determine the efficacy and safety of endoscopic injection of bulking material for the treatment of GERD.

Articles: The search did not yield any study. Two studies were revealed from review articles. Both were pilot studies with no comparison groups. One included only a series of 15 patients (10 in Brussels and 5 in Rome), and the other was a case series with only ten participants.

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The use of bulking material in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Magnetic Sphincter Augmentation – (LINX® Reflux Management System)

BACKGROUND

Gastroesophageal Reflux Disease (GERD) is an extremely common clinical manifestation of excessive reflux of acidic gastric components. Also referred to as chronic acid reflux, GERD is characterized by a chronic, often progressive dysfunction of the lower esophageal sphincter (LES) allowing acids and biles from the stomach to flow back into the esophagus. Common symptoms include heartburn, regurgitation and dysphagia and can adversely impact the quality of life by interfering with daily activities, disturbing sleep, and reducing productivity. Left untreated GERD can lead to more serious complications such as esophageal stricture, Barrett's esophagus and esophageal cancer (Gorecki 2001). Simple diet and lifestyle modifications can ease some of the symptoms associated with GERD, however, more severe or frequent cases may require pharmaceutical treatment with antacids, H2-receptor antagonists or proton pump inhibitors (PPIs). Some cases of GERD, however, will not respond to medications and may require surgical intervention. Laparoscopic fundoplication (LF), has long been considered the gold standard of antireflux surgery. The technique involves wrapping the upper part of the stomach (gastric fundus) around the lower end of the esophagus in an effort to reinforce the LES. Although LF has a high success rate, the procedure is non-reversible and has been associated with a variety of potential side-effects such as dysphagia, loss of belching and vomiting and increased flatulence and bloating. The LINX® Reflux Management System, developed by Torax® Medical (St. Paul, MN), was designed to prevent back flow into the esophagus and is suggested as an alternative to anti-reflux surgery. More specifically, the magnetic sphincter augmentation (MSA) device is a series of interlinked magnetic beads implanted laparoscopically at the junction between the esophagus and stomach that acts as a reinforcement of the LES. The device relies on small wires that allow the magnetic beads to expand and allow the flow of foods and liquids into the stomach while preventing reflux at the same time. According to the manufacturer, the LINX Reflux Management System requires less recovery time, provides immediate relief and faster return to solid foods compared with other surgical interventions. To add to this, the device can be removed if side-effects, such as dysphagia, pain and bloating, become unbearable. The LINX® Reflux Management System received US Food and Drug Administration (FDA) approval on March 22, 2012. The device is intended for use in patients with GERD who continue to have symptoms despite the use of a maximum medical therapy for the treatment of reflux. More specifically, it is intended for use in patients who would be considered candidates for anti-reflux surgery. This topic has not previously been reviewed by the Medical Technology Assessment Committee (MTAC) and is currently under consideration due to coverage decision support.

12/15/2014: MTAC REVIEW

LINK Reflux Management System

Evidence Conclusion: A feasibility trial by Lipham and colleagues, included 44 patients and aimed to assess the long-term safety and effectiveness of the LINX Reflux Management System (up to 3.7 years). In this study, patient's baseline measurements were used as the control for comparison with post-implant measurements. In all outcome measures improvements were seen with reduced esophageal acid exposure, improved GERD-HRQL scores and decreases in use of PPIs. As a result, the investigators concluded that sphincter augmentation with LINX provides long-term clinical benefits with no safety issues (Lipham, DeMeester et al. 2012). Evidence Table 1 In the second study, a pivotal trial by Ganz and colleagues, the investigators sought to evaluate the safety and effectiveness of the LINX Reflux Management System. The study included 100 patients with GERD and assessed esophageal pH as well as manometry and barium esophagography. The investigators report that 64% (95% CI, 54%-73%) of patients achieved success with normalization of esophageal acid exposure, or a ≥50% reduction in exposure at one year. Additional endpoints were also promising with 50% or more improvements seen in 92% of patients on the GERD-Health Related Quality of Life (HRQL) questionnaire. Although the authors concluded that the LINX device resulted in a decreased exposure to esophageal acid, improved reflux symptoms and allowed cessation of PPIs in the majority of patients, they also noted that additional prospective RCTs with appropriate controls are necessary for confirmation. (Ganz, Peters et al. 2013). Finally, the third study, by Riegler and colleagues, evaluated 249 patients who had undergone MSA and LF and completed one-year follow-up. With the overall goal to compare the clinical experience of each procedure, the investigators evaluated patients reflux symptoms, PPI use, side effects and complications. At one year, both groups showed improvement in total GERD-HRQL score (20 vs. 3 in the MSA group and 23 vs. 3.5 in the LF group) and discontinuation of PPIs was higher in the MSA group with 81.8% of patients abstaining and only 63% in the LF group (P=0.009). The investigators concluded that both MSA and LF were comparable but that MSA should be considered as the first-line surgical option Evidence Table 3. Adverse events and complications were documented in all three of the critically appraised publications. In addition, a recent publication from Lipham and colleagues provides a safety

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analysis of the first 1,000 patients treated with the MSA device. The analysis included safety related events collected from the published literature, FDA databases for device related complications and information provided by the manufacturer for over 1,000 patients treated worldwide between February 2007 and July 2013. This paper was not critically appraised, however, the safety data is generally summarized in table one, below. (Lipham, Taiganides et al. 2014).

Table 1. Summary of events by source

Source of data	# of events included in analysis	Breakout
Clinical literature	32	• 9 device removal • 20 esophageal dilation • 3 hospital readmissions
MAUDE database	20	• 19 device removal (includes US and OUS) • 1 device erosion
Manufacturer's database	59	• 8 device removal • 1 intra/perioperative complication • 11 hospital readmissions • 39 esophageal dilation

Generally speaking, the body of evidence is limited by small sample sizes, short-term follow-up, as well as a lack of randomization and adequate comparators. Selection bias may be an issue in the third study as the selection of intervention was ultimately made by the surgeon at the time of surgery. It should also be noted that the majority of studies assessing the LINX Reflux Management System are either funded by the device manufacturer or authored by consultants to the manufacturer. Ultimately the body of evidence provides insufficient evidence to support the safety and effectiveness of the LINX Reflux Management System. Conclusions: There is insufficient evidence to support the effectiveness of the LINX Reflux Management System in patients with refractory GERD. There is insufficient evidence to support the safety of the LINX Reflux Management System in patients with refractory GERD.

Articles: The literature search revealed just over 100 publications relating to treatment of GERD using sphincter augmentation many of which were not directly applicable to the objective at hand. No randomized controlled trials (RCTs) were revealed comparing the LINX Reflux Management System with alternative surgical interventions such as LF. The FDA's 2012 approval relied on two publications, a pivotal clinical trial and a feasibility study, which were selected for critical appraisal. Post-approval studies of the LINX Reflux Management System, required by the FDA, are currently ongoing. In addition to the pivotal and feasibility trial, two additional studies were considered. The first was a recent observational study comparing MSA to laparoscopic fundoplication (LF) and the latter, a safety analysis of the first 1,000 patients treated with MSA (this study was not critically appraised but discussed in the evidence summary). The following articles were selected for critical appraisal: Lipham JC, DeMeester TR, Ganz RA, et al. The LINX® reflux management system: confirmed safety and efficacy now at 4 years. Surgical Endoscopy. 2012; 26:2944-2949. See Evidence Table 1. Ganz RA, Peters JH, Horgan S, et al. Esophageal Sphincter Device for Gastroesophageal reflux disease. NEJM. 2013;368(8):719-72. Reigler M, Schoppman, Bonavina L, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. Surgical Endoscopy. 2014. See Evidence Table 3.

The use of LINX Reflux Management System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Stretta Procedure (Electro-Surgical Coagulation-Radiofrequency [RF] Application- Curon Medical Inc's CSM Stretta System) for the Treatment of GERD

BACKGROUND

Gastroesophageal reflux disease (GERD) is a one of the most common medical disorders in the United States. It is a chronic disorder that is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long

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treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001). More recently options include injection therapy to the lower esophageal sphincter, endoscopic sewing procedures, and radiofrequency ablation therapy. The ideal procedure should be safe, effective for a long time, and would not affect future surgical options. This review evaluates the radiofrequency techniques. Radiofrequency (RF) energy has been used for the general surgical application of tissue coagulation for more than 70 years. RF energy leads to collagen shrinkage, and in turn tissue contraction and tightening. Recently RF is being used for different clinical purposes, including its application to the gastroesophageal junction. The Stretta System (Curon Medical, Sunnyvale, CA) consists of a RF control module and a flexible Stretta catheter. The catheter has a 20F soft bougie tip and a balloon, which opens in a surrounding basket. On its widest area after balloon inflation, the catheter has four nickel-titanium needle electrodes (5.5 mm long), which can be extended in the LES muscle. The catheter is introduced transorally and positioned at the Z-line (squamocolumnar junction). It aspirates and irrigates the esophageal lumen with water to prevent surface injury. The four electrodes provide 60 to 300 J of RF energy to each needle, heating the surrounding muscle tissue to the target temperature between 65° and 85° C while cooling the mucosal with its irrigation system. 15 to 25 lesion sets are created in the region from 2 cm proximal to 1 cm distal to the Z-line by rotating the catheter 45 degrees and varying its linear position. The RF-induced burns eventually scar down and create a reflux barrier. The mechanism of action of RF is reported to be a reduction in the frequency of LES relaxations, as well as physical alteration in tissue compliance and wall thickness of the gastroesophageal junction. The Curon Medical Inc.'s CSM Stretta System was approved by the FDA on April 18, 2000. Curon recommends the device for mild or moderate cases of GERD only. The Stretta procedure is reported to be easy to learn and apply. However, there is a concern that if the scars continue to contract, at least some patients will develop a stricture that could be difficult to manage. Other adverse events that may be associated with the procedure include chest pains, fever, mucosal tear, and dysphagia.

12/10/2003: MTAC REVIEW

Electro-Surgical Coagulation (radio-frequency application) in the treatment of GERD

Evidence Conclusion: Of the studies reviewed, an RCT compared Stretta procedure to sham treatment, and a non-randomized longitudinal study compared it to laparoscopic fundoplication. The third was just a survey from a registry with no control or comparison group. Corley et al's trial was randomized and controlled however, it was a small study, with a high dropout rate, and some baseline differences between the two groups, that were not adjusted for in the analysis. Moreover, the procedure was compared to a sham treatment and not to another intervention e.g. laparoscopic fundoplication. The follow-up duration might have been insufficient to determine the long-term sustained effects, or potential late harms that could be associated with the procedure. In addition, the patients included in the study were highly selected for the trial and may not represent typical GERD patients. Richard et al's study was not randomized and patients were highly selected for each procedure. It was not blinded, not powered, and the follow-up duration was as short as 2 months for some patients, which is insufficient to determine the long-term durability of benefits or harms of the procedure. Both Corley's and Richard's studies were financially supported by Curon Medical, the manufacturer of the Stretta system. The third study reviewed was a retrospective survey of patients who underwent the Stretta procedure in several centers, with no reference to the inclusion/exclusion criteria, or techniques used for performing the procedure. Overall, the results of the studies show that radiofrequency application to the gastroesophageal junction to selected GERD patients is associated with improvement in symptoms and quality of life compared to sham treatment or laparoscopic fundoplication. The heartburn improvement associated with GERD vs. sham treatment was significant in the per protocol analysis but not with the ITT analysis in Corley's trial.

Articles: The search yielded 9 articles. There were no meta-analyses or randomized controlled trials. There were only three empirical studies all of which were case series. One had a very small sample, and only three months follow-up. The other two with relatively larger sample sizes, and longer follow-up duration were selected for critical appraisal. In December 2001, Curon Medical announced the completion of two major clinical trials, one of which is a RCT of the Stretta vs. sham treatment. To date these studies have not been published. *Evidence tables were created for the following studies:* Triadafilapoulos G, DiBaise JK, Nostrant T, et al. The Stretta procedure for the treatment of GERD: 6 and 12-month follow-up of the U.S. open label trial. *Gastrointest Endosc* 2002, 55149-156. See Evidence Table. Houston H, Khaitan L, and Richards WO. First year experience of patients undergoing the Stretta procedure. *Surg Endosc* 2002, Nov 20. See Evidence Table.

The use of electro-surgical coagulation (radio-frequency application) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/13/2003: MTAC REVIEW

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Electro-Surgical Coagulation (radio-frequency application) in the treatment of GERD

Evidence Conclusion: The two-case series reviewed show that the Stretta procedure may be a promising treatment for GERD. Patients had significant reduction in the esophageal acid exposure and use of antisecretory medication, as well as significant improvement in their quality of life scores, compared to those before the intervention. However, the studies were case series that provide the lowest grade of evidence. In the studies reviewed, participants were highly selected for the procedure. Only patients with small or no hiatal hernias, no dysphagia, stricture, or Barrett's disease as well as those whose symptoms are controlled by pharmacological treatment were included in the studies. Moreover, the interpreters of the results were not blinded to the treatment, the follow-up duration was insufficient, dropout rate was high, and there were no comparison or control groups. In conclusion, there is insufficient evidence to determine the efficacy of the Stretta procedure in the treatment of GERD. Prospective randomized studies with larger sample sizes, comparison to another intervention or treatment, and a long follow-up duration will be needed.

Articles: The search yielded seven review articles and two empirical studies: (1) An RCT comparing radiofrequency ablation to sham treatment, and (2) A longitudinal non-randomized study comparing the procedure to fundoplication. *Evidence tables were created for these two studies as well as a patient registry published prior to 2003 that was not included in the earlier review:* Corley DA, Katz P, Wo JM, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: A randomized, sham-controlled trial. *Gastroenterol* 2002; 125:668-672. See Evidence Table. Richards WO, Houston HL, Torquati A, et al. Paradigm shift in the management of gastroesophageal reflux disease. *Ann Surg* 2003; 237:638-649. See Evidence Table. Wolfsen HC, and Richards WO. The Stretta procedure for the treatment of GERD: A registry of 558 patients. *J Laparoendoscp Adv Surg Tech* 2002; 6:395-402. See Evidence Table.

The use of electro-surgical coagulation (radio-frequency application) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

EndoGastric Solutions Stomaphy X™ Endoluminal Fastener, InScope™ Tissue Apposition System, Transoral Incisionless Fundoplication

BACKGROUND

Over the last two decades, several less invasive endoluminal /endoscopic techniques have been developed for the management of GERD. These procedures include radiofrequency ablation (Stretta system), magnetic sphincter augmentation (LINX procedure), and transoral incisionless fundoplication, among others.

Transoral incisionless fundoplication (TIF) using the (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. Similar to the NF, TIF attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. It involves wrapping a portion of the stomach around the esophagus without requiring any incisions.

TIF is performed in an outpatient setting under general anesthesia, and involves inserting the EsophyX™ device transorally, under direct endoscopic visualization, into the stomach and positioning it at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The fundus of the stomach is folded up and around the distal esophagus utilizing the tissue mold and chassis of the device. Next, an integrated suction apparatus grasps the distal esophagus and positions it below the diaphragm. H-shaped fasteners, made of polypropylene, are then delivered through apposed layers of esophageal and fundus tissue to anchor the repair. This process is repeated to create a full thickness, partial circumference, and gastroesophageal fundoplication. Approximately 20 fasteners are implanted during the procedure resulting in the recreation of an omega shaped full-thickness gastroesophageal valve from inside the stomach 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are < 2 cm in size through the use of a built-in vacuum invaginator (Jafri 2009, Louis 2010, Hunter 2015, Testoni 2014, Trad 2014, Witteman 2015).

TIF 1.0 utilizing the EsophyX™ device was first performed in 2005 and received United States Food and Drug Administration (FDA) initial 510(k) clearance in 2007. The EsophyX device is indicated for endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract for the treatment of symptomatic chronic gastroesophageal reflux disease in
patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia < 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease (FDA website accessed June 2020).

The EsophyX technology underwent several modifications along the years. Currently, there are three generations of the device; the original EsophyX® device, EsophyX2®, EsophyX Z®. Over the same timeline, four different

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fundoplication procedures using the EsophyX have emerged. The initial device was used to perform the endoluminal gastro–gastric fundoplication, called "ELF". The second procedure TIF 1.0, was a longitudinally oriented plication of gastric cardia onto the distal esophagus just proximal to the gastroesophageal junction. The third procedure TIF 2.0, incorporated a rotational wrap of the cardia and fundus around the circumference of the distal esophagus in addition to providing a 2–4 cm length of the wrap over the intra-abdominal distal esophagus. This results in tightening and reinforcing the sling fibers of the proximal stomach (the lower portion of the LES), accentuating the cardiac notch, steepening the angle of His, and reestablishing the flap valve mechanism. The fourth procedure is a combined laparoscopic hiatal hernia repair with transoral incisionless fundoplication 2.0 (HH-TIF). Each of TIF procedures described is markedly different from the others and have different clinical outcomes. The TIF-2 procedure is believed to be the most similar procedure to NF morphologically and physiologically and is accomplished by using the third generation EsophyX® Z, launched in 2015 and cleared by the FDA in 2016 (Chang 2020, Ihde 2020).

Reported adverse events associated with the procedure include gastrointestinal bleeds, esophageal laceration, pleural effusion, mediastinal abscess, and potential failure of the procedure due to the pull on the fastener used to create the valve.

04/09/2008: MTAC REVIEW
Endoluminar Fasteners
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the EndoGastric Solutions StomaphyX™ endoluminar fastener for weight loss. There is insufficient published evidence to determine the efficacy and safety of the InScope™ Tissue Apposition System for endoscopic gastric sutures.
Articles: The literature search did not reveal any published studies, on the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system, or on the InScope™ Tissue Apposition System. Information about the systems was obtained from the FDA and the manufacturer's Web sites.

The use of endoluminar fasteners in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/15/2011: MTAC REVIEW
Endoluminar Fasteners
Evidence Conclusion: Two case-series were selected for review that evaluated the safety and effectiveness of transoral incisionless fundoplication (TIF) for the treatment of GERD. The first study followed 110 subjects for a median of 7 months and the second study followed 86 subjects for 12 months. The primary outcome in both of these studies was GERD Health-Related Quality of Life (GERD-HRQL). Both studies found significant reductions in GERD-HRQL compared to baseline. However, results from these studies should be interpreted with caution as both studies were case-series (lowest-quality evidence). Serious adverse events included two perforations and a post-TIF intraluminal bleeding that required a blood transfusion. Other adverse events included: left shoulder pain, abdominal pain, sore throat, nausea, and epigastric pain (Barnes 2011; Cadière 2008). **Conclusion:**
There is insufficient evidence to determine the safety and efficacy of transoral incisionless fundoplication for the treatment of GERD.
Articles: To determine the safety and efficacy of transoral incisionless fundoplication using the EsophyX system for the treatment of GERD. Screening of articles: No randomized controlled trials were identified that addressed the safety or efficacy of transoral incisionless fundoplication using the EsophyX system for the treatment of GERD. Studies were not selected for review if they included less than 25 subjects. The largest studies with the longest duration of follow-up were selected for review. The following studies were critically appraised: Barnes WE, Hoddinott KM, Mundy S, Willams M. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. *Surg Innov 2011;* 18:119-129. See Evidence Table. Cadière GB, Buset M, Muls V, et al. Antireflux transoral incisionless fundoplication using EsophyX: 12-month results of a prospective multicenter study. *World J Surg 2008;* 32:1676-1688. See Evidence Table.

The use of endoluminar fasteners in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/13/2020: MTAC REVIEW
Transoral Incisionless Fundoplication with Esophyx
Conclusion:

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- The published RCTs evaluating the safety and efficacy of TIF 2.0 using EsophyX compared the procedure versus a sham therapy or PPI and not to laparoscopic Nissen fundoplication (LNF), the most appropriate comparator.
- There is no direct published evidence, to date, to determine the safety and effectiveness of TIF 2.0 using EsophyX compared LNF, the gold standard for the management of patients with refractory GERD.
- Indirect comparison suggests the LNF is superior to TIF 2.0 in esophageal acid control, healing of esophagitis and increasing in LES pressure.
- There is insufficient published evidence to determine the effects of TIF using EsophyX on net health outcomes, and whether it will lead to protection from long-term adverse events of GERD and Barrett's esophagus.
- TIF may be superior to sham therapy (i.e. no therapy), but not PPIs in reducing percent time pH <4.
- TIF may be superior to sham therapy in improving the quality of life, but not in reducing the incidence of persistent esophagitis.
- The published studies and MAs indicate that the efficacy of TIF may decrease over time and that most patients may still need to use PPIs, but maybe at a lower dose.
- Open label trials found significant improvements with TIF 2.0 in subjective measures, but no difference in objective outcome measures of pH normalization and esophagitis when compared with PPI therapy. This may suggest a potential placebo effect of TIF 2.0.
- There is insufficient published data to determine the long-term safety of TIF 2.0 using EsophyX in patients with GERD.

Articles:
The literature search identified 6 RCTs, one non-randomized comparative study, and over 20 noncomparative observational studies published between 2011 and 2018. The search also revealed 4 meta-analyses (MAs) of exclusively RCTs or RCTs together with observational studies. One of the meta-analyses also included a network MA (NMA). Of the published RCTs, only one trial (Svoboda et al, 2011) compared TIF vs. LNF, 2 trials compared TIF to sham therapy, and two compared the procedure to different PPIs. The Svoboda trial was a small trial (N=52) that used 2 generations of the devices and different techniques for the TIF group along the study (Plicator® method for 18 patients, and the EsophyX® in16 patients). The study was thus not included in any of the published meta-analyses as combining results of studies using different procedures and generations of the device would lead to incorrect conclusions on effectiveness of the procedure in treating reflux disease.

The meta-analysis with the more valid methodology and most inclusive of published RCTs (Huang et al, 2017) as well as the Richter and colleagues' systematic review with both a direct and network meta-analysis were selected for critical appraisal. The published RCTs that compared TIF 2.0 versus LNF, sham therapy, or PPIs were summarized in a table format. See Evidence Table.

The use of Transoral Incisionless Fundoplication with Esophyx does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/08/2019: MTAC REVIEW
Magnetic Sphincter Augmentation (MSA) (LINX® Reflux Management System) for Gastroesophageal Reflux Diseases
Conclusion:

- There is no published evidence, to date, from randomized controlled trials to determine the comparative safety and effectiveness of MSA and laparoscopic Nissen fundoplication in patients with GERD refractory to maximal medical therapy.
- Low quality evidence from short-term non-randomized comparative observational studies suggest that MSA may be associated with better postoperative ability to belch and vomit and less bloating compared to fundoplication in patients with GERD.
- There is insufficient evidence to determine the long-term safety or effectiveness of MSN in patients with medically refractory GERD.

Articles: The literature search for recently published studies after the December 2017 MTAC review did not identify any randomized controlled trial that compared magnetic sphincter augmentation (LINX® Reflux Management System) versus Nissen fundoplication. The search revealed only one RCT that compared MSA versus double-dose PPIs in patients with moderate to severe GERD who failed once daily PPI therapy for 8 weeks (Bell, 2019). One qualitative systematic review (Stanak 2018) and two more recent systematic reviews with meta-analyses (Ailofi 2018, and Guidozzi 2019) that pooled the results of nonrandomized comparative observational studies, were also identified, as well as a small retrospective study (Richards 2018) of patients who underwent the procedure by a single surgeon. The RCT comparing magnetic sphincter augmentation to double-dose PPI was excluded as the aim of the review was to compare the device to Nissen fundoplication the gold standard procedure

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for patients with GERD-related symptoms despite the use of a maximum medical therapy. The most recent meta-analyses of studies comparing LINX® reflux management system with Nissen fundoplication were reviewed. No evidence tables referenced for this report.

The use of Magnetic Sphincter Augmentation (MSA) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

LINX® Reflux Management System - Considered Not Medically Necessary:

CPT® Codes	Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

Radiofrequency Energy Delivery to Gastroesophageal Junction/Transesophageal radiofrequency energy (Ex: CSM Stretta) - Considered Not Medically Necessary:

CPT® Codes	Description
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease

Transoral (Endoluminal) Gastroplication or Suturing/Transoral incisionless fundoplication (TIF) (Ex: Esophyx) - Considered Not Medically Necessary:

CPT® Codes	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed

Endoscopic placement of a bulking material at the lower esophageal sphincter - Considered Not Medically Necessary:

CPT® Codes	Description
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance

CR BARD's Endoscopic Suturing System - Considered Not Medically Necessary:

CPT® Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
02/13/2003	Initiated annual review because of Medicare criteria 05/03/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015MPC,	10/06/2020

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	02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 02/06/2018[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/21/2016	Added LINX® Medicare Coverage
10/04/2016	MPC approved to adopt Kaiser Permanente criteria for GERD when Medicare is silent
08/06/2019	Added MTAC review for Magnetic Sphincter Augmentation- LINX® management system for GERD
02/04/2020	MPC approved to adopt Transoral (Endoluminal) Gastroplication or Suturing (Esophyx) MCG A-0205 for medical necessity determinations.
06/02/2020	Removed deleted code C9737 (LINX®)
10/06/2020	Added MTAC Review for Transoral Incisionless Fundoplication with Esophyx. MPC approved to retain existing policy of non-coverage.
10/06/2020	MPC approved MCG 24th ed. guideline for Implantable Magnetic Esophageal Ring (LINX®) A-0990

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Clinical Review Criteria

Genicular Nerve Block for Knee Pain

- Coolief Cooled Radiofrequency Ablation for Knee Pain
- Genicular Nerve Ablation
- Thermal Genicular Nerve Radiofrequency Ablation (GNRFA)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457)
Local Coverage Article	Billing and Coding: Nerve Blockade for Treatment of Chronic Pain and Neuropathy (A52725)

For Non-Medicare Members

Service	Criteria
• Coolief Cooled Radiofrequency Ablation for Knee Pain • Genicular Nerve Ablation • Thermal Genicular Nerve Radiofrequency Ablation (GNRFA)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. This procedure requires review if the ablation is being done as an alternative to surgery. ***Note:** Genicular nerve ablation can also be done during surgical procedures for anesthesia, such as total knee replacement or ligament and tendon repair and does not require review for those circumstances.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Hayes Technology Assessment

A nerve block is a form of regional anesthesia. The genicular nerve is a sensory nerve that innervates the knee. Genicular nerve blocks are performed to relieve pain in patients who may not be candidates for knee surgery or in advance of total knee replacement surgery. In a genicular nerve block procedure, an anesthetic agent, (e.g.,

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lidocaine, bupivacaine, etc.), is injected on the genicular nerve. Genicular nerve blocks may be performed as a diagnostic step to ensure that blocking the nerve provides pain relief. In these cases, after a genicular nerve block demonstrates pain relief, genicular neurotomy or genicular nerve ablation may be performed as a more permanent solution.

Hayes Rating: D[2] - Insufficient Evidence: For use genicular nerve blocks combined with a corticosteroid or alone for treatment of pain and loss of function associated with osteoarthritis of the knee or persistent chronic pain following total knee arthroplasty.

This Rating reflects a very-low-quality body of evidence that does not consistently provide proof of benefit. Substantial uncertainty remains due to conflicting evidence and limited follow-up.

Hayes. Hayes Technology Assessment. *Genicular Nerve Block for the Management of Knee Pain*. Dallas, TX: Hayes; June 24, 2020. Retrieved July 13, 2020, from https://evidence.hayesinc.com/report/htb.genicular3323

Background

Osteoarthritis (OA) of the knee is a common chronic degenerative joint disorder and one of the leading causes of physical impairment and decline in the quality of life in older adults in the US and worldwide. It is a progressive condition in which the cartilage between bones in the joint wears away leaving the bones to rub more closely against one another resulting in pain, swelling, stiffness, and loss of function.

Conservative treatment for symptomatic knee OA includes physical therapy, aquatic therapy, weight loss, oral or topical non-steroidal anti-inflammatory drugs, bracing, and orthosis. Intraarticular injection of corticosteroids, hyaluronic acid, and other treatment modalities have also been used to alleviate the pain however, the analgesic effect is short-term with the steroid injection and unproven with some other therapies. Overall, conservative measures may relieve symptoms and improve function in some patients, but they do not restore the normal knee function, reverse the damage, or slow the progression of the disease. Knee joint arthroplasty is the most effective treatment for relieving pain and improving the knee function in patients with severe knee OA, but it is an invasive surgery that may be associated with medical and postsurgical complications. In addition, older individuals with comorbidities might not be good candidates for the surgery and others may be unable or unwilling to undergo the operation (El-Hakiem 2018, Jamison 2018, Erdem 2019).

Over the years, researches have been investigating alternative less invasive therapies for the treatment of patients with refractory knee OA. Several existing and new therapies have thus been or are being evaluated for the alleviation of chronic pain in patients with musculoskeletal disorders including knee OA.

Radiofrequency ablation (RFA) is one of these modalities considered for the treatment of patients with symptomatic knee. RFA is a nonsurgical, minimally invasive procedure that uses radio waves to create an electrical current through the body. The created current delivers heat to the targeted tissue resulting in its destruction, Ablation of the nerve tissues disrupts the ability of the nerve to send pain signals. RFA was first used by a German surgeon in 1931 to treat trigeminal neuralgia and three decades later, the first radiofrequency ablation commercial machine was introduced in the market. The indications of RFA have expanded over the years and is currently being used for the treatment of a variety of medical conditions including chronic low back pain, cardiac arrhythmias, tumors, varicose veins, obstructive sleep apnea, and several other disorders. More recently RFA gained popularity in alleviating pain due to musculoskeletal disorders. In 2010 Choi and colleagues investigated its use for OA knee pain based on the theory that blocking the sensory innervation for a painful structure will result in pain relief (Choi 2011, Gupta 2017).

The knee joint is innervated by the articular branches of various nerves including the femoral, common peroneal, saphenous, tibial and obturator nerves known as the genicular nerves. Several of these nerves can be approached percutaneously under fluoroscopic or ultrasound guidance to identify the anatomical landmarks around the knee and locate the targeted genicular nerves (Choi 2011, Gupta 2017).

Conventional RFA treatment uses a high temperature probe to impair/destroy the targeted nerve fibers that carry the pain signals to the brain. The high heat originating from the RF probe may potentially damage adjacent tissues as the temperature reaches 70-90°C. In addition, it has been reported that the lesion produced by the heat is limited in size and thus may not reach some target areas. To overcome these limitations, two new techniques the (pulsed RFA (p-RFA) and the cooled RFA (C-RFA) have been investigated for GNRFA (Oladeji 2019).

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

Coolief™ RFA treatment (the focus of the current review) also known as cooled radiofrequency ablation or neurotomy, follows the same method as the conventional RFA neuronal tissue damage, but uses water-cooled technology to safely impair or destroy the sensory nerves. A radiofrequency generator transmits a small current of RF thermal energy through an insulated electrode placed within the tissue. Sterile water circulates continuously inside the Coolief™ probe to cool it and regulate its temperature while it delivers the RF thermal energy. According the investigators of the technology, the circulating water modulates the thermal heat in the tissue to ≈60°C and alters the size, shape, and projection of the lesions compared to conventional RFA. It is postulated that delivering RF energy through water-cooled electrode enables more RF energy to be safely delivered to the targeted nerves creating larger spherical -shaped lesion that increases the area of denervation and minimizes the risk of excessive heating and damaging the adjacent tissues (Gupta 2017, Oladeji 2019, AVANOS report 2019).

The Cooled RFA (CRFA) procedure is performed in an outpatient setting under local anesthesia, conscious sedation and fluoroscopic or ultrasound guidance. It is performed in 2 stages (McCormick 2017, Davis 2018):

1. A diagnostic genicular nerves block procedure: After positioning the patient in a supine position on a fluoroscopy table, a 25-guage 2.5-3.5-inch Whitacre needle is placed under fluoroscopic guidance at three unique anatomic sites to block the superior lateral, superior medial, and the inferior medical genicular nerves. Accurate placement of the needle is confirmed using fluoroscopy in the AP and lateral planes, then lidocaine is injected in order to numb each genicular nerve. Patients with a positive response (≥50% reduction in pain in the 24hrs following injection) are offered radiofrequency ablation (stage 2) for a more sustained response.
2. Genicular nerve radiofrequency ablation procedure performed under fluoroscopic visualization of the anatomical landmarks for probe placement. The patient is positioned supine on the fluoroscopy table (similar to the diagnostic nerve block procedure), and given conscious sedation, and local anesthesia at each of the 3 anatomic sites for RFA. An introducer needle (50 or 70 mm 17-guage) is then placed to lesion the 3 genicular nerves after which the internally cooled RFA electrode (Coolief, 4-mm, 18-guage active tip) is inserted in the introducer needle and its positioning verified with AP and lateral fluoroscopic views. Lidocaine is then injected through the introducer needle to numb the region before the thermal ablation. Each target undergoes CRFA for 150 seconds at a set temperature of 60°C which produces tissue temperature of 77°C-80°C surrounding the electrode. The needles are then removed, and the patients allowed to recover before they are discharged to home.

Medical Technology Assessment Committee (MTAC)

Coolief Cooled Radiofrequency Ablation for Knee and Hip Pain
10/14/2019: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence to determine the safety and efficacy of cooled RFA treatment for the management of moderate to severe chronic OA knee pain that is refractory to conservative therapy in patients who are not candidates for surgery.
- There is low to moderate quality evidence from one relatively small RCT showing that genicular RFA using Coolief™ system, performed prior to total knee replacement surgery had no significant effect compared to sham ablation, on reducing post-operative pain, use of pain medications, or improving function.

Articles: The literature search for studies on cooled genicular never ablation for symptomatic knee osteoarthritis, published after the March 2018 INCT review yielded less than 10 articles including a report on the 12 months follow-up results of the pivotal RCT (Davis et al 2019). The search also identified a RCT comparing the effect of CRFA versus a sham therapy performed prior to TKA, on postoperative pain. Among the other recently published articles was a randomized trial that evaluated the utility of genicular nerve blocks to predict the outcome of genicular nerve cooled radiofrequency ablation in patients with osteoarthritis (McCormick et al, 2018); a cost-effective analysis of CRFA based on Davis et al's trial (Desai 2019); one observational study with no control or comparison group (House et al, 2019), three technical reports, and a case presentation.
See Evidence Table.

The use of Coolief Cooled Radiofrequency Ablation for Knee and Hip Pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Thermal Genicular Nerve Radiofrequency Ablation (GNRFA) for continued chronic knee pain post total knee replacement
07/13/2020: MTAC REVIEW

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Evidence Conclusion:
There is insufficient published evidence to support the use of genicular RFA for reducing postoperative pain after total knee preplacement surgery.

Articles:
There is a paucity of published literature evaluating the use of thermal genicular neve ablation for the management of persistent pain after a total knee replacement surgery. The only published randomized controlled trial identified by the literature search was a small double-blinded trial that compared the efficacy of genicular nerves RFA versus analgesic block with corticosteroids in alleviating pain and improving function and QoL in patients with pain after a TKA (Qudsi-Sinclair S et al, 2017 (Evidence Table 1).

This trial was randomized, controlled, and double-blinded, but had its limitations including the small sample size study (N=30 randomized and 28 included in the analysis), lack of power calculations, randomization method not discussed, and subjective outcomes. There were also some baseline differences between the study groups e.g. their ages, duration of a pain, knee function, QoL, and the use of medication including opioids before the intervention. The differences were not significant, but the numbers may be too small to detect statistically significant differences.

The overall results of the study show the following (details in the evidence table)

- A significant reduction in pain scores in each of the treatment arm compared to baseline values, this was more pronounced in day 1 after each of the two procedures but tended to increase during follow-up.
- At one year the NRS was almost 5 in the RFA group and >5 in the steroid group (a value of 5-10 indicates worst possible pain).,
- Knee functioning also improved vs baseline, in each of the treatment arms, but was still considered poor and unsatisfactory according to the values of the KSS and OKS.
- There were no significant differences between the 2 study groups in any of the outcome measures (pain, function, QoL, or patient satisfaction). Lack of significant difference does not necessarily indicate that the two intervention have similar results as indicated by the authors). The power of the study may have been insufficient to detect statistically significant differences.

The use of Thermal Genicular Nerve Radiofrequency Ablation (GNRFA) for continued chronic knee pain post total knee replacement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch
ICD-10 Codes	**Description**
M25.561	Pain in right knee
M25.562	Pain in left knee

Non-Medicare - Considered Not Medically Necessary:

CPT® Codes	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch

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64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MPC] Medical Policy Committee

Revision History	Description
08/07/2018	MPC approved to adopt policy of non-coverage for GNA.
12/03/2019	Added MTAC review for Coolief RFA and MPC approved a non-coverage policy for this procedure.
05/18/2020	Added comment about procedure being done for anesthesia during other surgical procedures, which does not require review.
06/23/2020	Added CPT codes 64454 and 64624
08/04/2020	Added Medicare LCD L35457, LCA A52725 and ICD-10 codes M25.561 and M25.562. Removed “hip” from non-coverage policy and added MTAC review from July 2020. MPC approved to retain policy of non-coverage for genicular nerve ablation for non-Medicare patients.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Gynecomastia

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Article (LCA)	Billing and Coding: Plastic Surgery (A57222)

For Non-Medicare Members

Kaiser Permanente has elected to use the Mastectomy for Gynecomastia (KP-0273 v2 eff 04.01.2022) MCG* Care Guideline for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from primary care provider or specialist, addressing the indications described in the medical necessity criteria

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gynecomastia is a unilateral or bilateral enlargement of the male breast due to benign proliferation of glandular elements. Pubertal gynecomastia resolves without intervention in the majority of cases. Gynecomastia in postpubertal males may be due to persistent pubertal gynecomastia, medications, liver disease, kidney disease, testicular tumors, or endocrine disorders. The cause remains undetermined in about 25% of cases. Male breast cancer is uncommon and usually presents as a discrete breast mass.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT® Codes	Description
19300	Mastectomy for gynecomastia

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Date Created	Date Reviewed	Date Last Revised
01/05/2016	01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	11/02/2021

[MPC] Medical Policy Committee

Revision History	Description
12/19/2017	Added Plastic Surgery LCD L37020
08/04/2020	Added Medicare LCA A57222
11/02/2021	MPC approved modifications to the hybrid criteria for non-Medicare members. Requires 60-day notice, effective date 04/01/2022.

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Patient Referral Guidelines
Heart/Lung Transplant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Heart Transplants (260.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Heart Transplant

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for Heart transplantation[1]. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. **GENERAL PRINCIPLES**
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection is a contraindication to transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low [2,3,4]. Exceptions may be made on a case-by- case basis.
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines and kidney) may require abstinence from tobacco products to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
      1. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
      2. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
   g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

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h. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
i. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

INDICATIONS FOR HEART TRANSPLANT

a. End-stage heart disease as evidenced by one or more of the following:
    i. Functional class III or IV
    ii. Not correctable by medical or other surgical therapies
    iii. A low VO2 maximum: [5]
        1. ≤14 ml/kg/min in patients not on a beta blocker
        2. ≤12 ml/kg/min in patients on a beta blocker [6]
        3. <19 ml/kg/min adjusted for lean body mass in patients with a BMI >30 kg/m^2
        4. Less than 50% of age predicted maximum.
    iv. A VE/VCO2 >35 in a patient with a sub-maximal cardiopulmonary exercise test (RER <1.05)[2]
    v. Cardiac index < 2 L/min/m^2
b. Unable to wean from mechanical or inotropic support.
c. Amyloid Cardiomyopathy
    i. TTR Amyloid
    ii. (AL) Amyloidosis without significant extra-cardiac involvement.
d. Refractory Life-Threatening Arrhythmias

3. The transplant should only be offered for conditions in which cardiac transplant has proven clinical benefits.
CONTRAINDICATIONS FOR HEART TRANSPLANT (In conjunction with the General Principles listed above in Section 1 of these guidelines):

a. Significant diseases such as:
    i. Severe uncontrolled or poorly controlled hypertension.
    ii. Clinically significant vascular disease not correctable by intervention.
    iii. Pulmonary hypertension not reversible by drug manipulation despite maximum tolerated medical management. [7]
        1. Adults: PVR > 4-6 Wood units or transpulmonary gradient > 15 mm Hg
        2. Children: PVR > 9 Wood units
    iv. Severe pulmonary disease after optimal treatment of severe heart failure.[8]
    v. Severe hepatic disease after optimal treatment of severe heart failure.[8]
    vi. Kidney disease with creatinine clearance <34 ml/kg/min or GFR < 30 ml/min after optimal treatment of heart failure. [8,9,10]
    vii. Active and/or progressive central nervous system disease excluding patients with embolic stroke who have recovered completely.
    viii. Evidence of cachexia or malnutrition (BMI < 19 kg/m^2 or < 80% ideal body weight).[10]
    ix. Obesity (BMI>35 kg/m^2 or > 140% ideal body weight) [11] has been associated with poor outcomes after cardiac transplant.
    x. Diabetes with complications resulting in severe end-organ damage.
    xi. Auto/acquired immune disease with multi-organ manifestation
    xii. Acute pulmonary embolus
    xiii. Active peptic ulcer disease
    xiv. Severe symptomatic osteoporosis
    xv. Age over 70 (Carefully selected patients over 70 years of age may be considered for cardiac transplantation)
    xvi. AL Amyloidosis with significant extra-cardiac manifestations
    xvii. Patients with viral hepatitis will require additional evaluation, including hepatology consultation.
    xviii. Any other co-morbid condition that would limit life expectancy or quality of life.

Footnotes

1. Note: All patients must be continuously re-evaluated for indications and contraindications. Candidates considered for re-transplantation must be evaluated using the same indications.
2. Liver Transplantation 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
3. Liver Transplant Surg., 1997, Vol. 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
4. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), TPMG New Medical Technology.

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5. Mehra MR, Canter CE, Hannan MM, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. J Heart Lung Transplant 2016; 35:1-23. 10.1016/j.healun.2015.10.023
6. Patients on Beta blockers should have a cut-off of ≤12 ml/kg/min, and patients intolerant to beta blockers a VO2 ≤14 ml/kg/min.
7. Circulation; 84 (3), 329 – 337. *Journal of Heart Transplantation* (1990): 526 – 537.
8. Selected patients for combined organ transplant will be evaluated on a case-by-case basis.
9. Must have 20mg per kilogram of creatinine in a 24-hour collection period. Creatinine clearance can also be calculated by the Cockcroft-Gault formula.
10. Mehra MR, Canter CE, Hannan MM, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. J Heart Lung Transplant 2016; 35:1-23. 10.1016/j.healun.2015.10.023
11. Body Mass Index (BMI) = (weight [kg] / height2 [m^2]). Percent Ideal Body Weight (PIBW) was calculated as follows: Men IBW = 106 pounds for the first 5 feet of height, add 6 pounds for each additional inch. Women IBW = 100 pounds for the first 5 feet of height add 5 pounds for each additional inch. Journal of Heart and Lung Transplantation, Aug 1999, page 752.

LUNG TRANSPLANT:

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for lung & heart/lung transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral, rather should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, early referral should be made.
b. Patients with a history of malignancy with moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
c. Uncontrollable active infection is a contraindication to transplant.
d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low. [4, 5, 6] Exceptions may be made on a case-by-case basis.
e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.
f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
   i. Patients must have a care giver or care givers who are physically and cognitively able to assist the patient with self- care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
   ii. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre- transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
h. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
   i. Evidence of such non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
i. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR LUNG TRANSPLANT

a. Must meet all prerequisites listed in the General Principles section
b. Any disease state in which transplantation has become an accepted mode of treatment worldwide including

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i. Chronic obstructive pulmonary disease (COPD), which may include asthma, chronic bronchitis, emphysema and/or Alpha 1 antitrypsin deficiency
ii. Idiopathic pulmonary fibrosis
iii. Sarcoidosis
iv. Connective tissue disease-related pulmonary fibrosis
v. Eosinophilic granulomatosis
vi. Bronchiectasis
vii. Cystic fibrosis (CF)
viii. Pulmonary hypertension (both primary and secondary)
ix. Lymphangiomyomatosis (LAM)
x. Interstitial lung disease not otherwise defined.

c. Patients should be referred for transplant evaluation by a pulmonologist or a cardiologist who has accumulated data defining both the disease as potentially treatable by transplantation and progression is occurring despite maximal medical therapy.
d. Early referral is strongly encouraged for progressive lung disease with a poor prognosis[7]
e. Ideally, the patient should be ambulatory with rehabilitation potential.

3. CONTRAINDICATIONS FOR LUNG TRANSPLANT

a. Must meet all prerequisites listed in the General Principles section
b. Invasive mechanical ventilator support[8].
c. Unresolved infection (except in cystic fibrosis and bronchiectasis).
d. Uncontrolled chronic infection (i.e., HIV with detectable viral load)
e. Other systemic diseases including but not limited to:
   i. Diabetes with end organ effects; i.e., renal, cardiac or uncorrectable peripheral vascular disease. Insulin use itself is not a contraindication.
   ii. Uncontrolled hypertension.
   iii. Significant neurologic disease impairing cognitive function.
   iv. Malnutrition [9]
   v. Obesity >140% ideal body weight or BMI >32 kg/m2 [10, 11](with an understanding that a BMI <30 may be necessary for transplantation).
      1. May wish to consider initiating transplant workup if patient has pulmonary fibrosis and BMI >32 (but <34) if showing willingness to lose weight.
   vi. Advanced hepatic dysfunction.
   vii. Advanced renal dysfunction (creatinine clearance < 50 ml/min. after maximum therapy). However, patients with underlying cardiopulmonary causes of low creatinine clearance can be considered for transplant on a case-by-case basis.
   viii. Evidence of clinically significant obstructive coronary artery disease and/or LVEF <40%. [12]
   ix. Active or unresolved peptic ulcer disease.
   x. Chronic opiate use: Patients should be seen by a pain management specialist for alternative forms of therapy.
   xi. Uncorrectable bleeding diathesis or clotting disorder

4. RELATIVE CONTRAINDICATIONS

a. Patients with previous thoracotomy and/or sclerosing procedures should be considered on a case by case basis.
b. Systemic corticosteroid therapy >10 mgs prednisone daily.
c. Esophageal dysmotility and reflux. Surgical repair may be necessary.[13]
d. Age >70 for lung transplant referral.
e. Symptomatic osteoporosis.
f. Major mechanical chest deformity (such as kyphoscoliosis).
g. Short stature patients (in USA 4'11" for females and 5'4" for males) are significantly disadvantaged and early consideration of multiple listing is encouraged.

PATIENT PROFILE FOR COMMON DIAGNOSES LUNG TRANSPLANT REFERRAL GUIDELINES

Any or all of the listed guidelines for each disease entity should raise consideration for lung transplantation evaluation. Clinical correlation is always of primary importance.

1. **GROUP A – Obstructive Lung Disease** [14, 15] **(See Table 1Below)**

1.1. FEV1 < 25 %

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1.2. DLCO < 40%

1.3. Hypoxemia; PO2 < 55Hypercapnia; PCO2> 51[16]

1.4. Bode Index > 5

2. **GROUP B – Pulmonary Arterial Hypertension** (See Table 1 Below)[17, 18, 19]

2.1. Patients with clinically significant PAH should be evaluated by physicians experienced in treating pulmonary hypertension and have received maximum available pharmacological treatment.

2.2. Possible indications for referral include:

2.2.1. Pericardial Effusion[20]

2.2.2. World Health Organization (WHO) (New York Heart Association) class 3 or 4

2.2.3. Lack of improvement in WHO Class 3 or 4 and/or lack of improvement in 6-minute walk test of < 350 meters, despite maximum pharmacological therapy.

2.3. Definite indications, after maximum pharmacologic treatment for referral include: [21]

2.3.1. Mean RA > 15 mmHg

2.3.2. Cardiac Index < 2L per minute. Untreated, the mean survival for patients with these criteria is 10-11 months.

3. **GROUP C – Cystic Fibrosis** [22](See table 1 Below)

3.1. FEV1 < 40%

3.2. PO2 < 55

3.3. Clinical deterioration, especially in young female patients, as characterized by increasing number of hospitalizations, including recurrent pneumothoraxes, rapid fall of FEV1, recurrent major hemoptysis uncontrolled by embolization and/or increasing cachexia should prompt consideration for transplant referral.

3.4. PCO2 > 51

3.5. Patients with *Burkholderia cepacia* have a relative contraindication.

4. **GROUP D – Restrictive Lung Disease)** [22, 23](See Table 1 Below)

4.1. Force Vital Capacity < 80%[22]

4.2. Decline in Forced Vital Capacity of ≥10% and/or decline in DLCO ≥ 15% during 6 months of follow-up[22]

4.3. Diffusing Capacity (corrected for alveolar volume) < 60%

4.4. Evidence of interstitial lung disease on HRCT in conjunction with one or more of the above.

Referral to lung transplant program should be considered when a definitive diagnosis of usual interstitial pneumonitis (UIP) or idiopathic pulmonary fibrosis (IPF) is made and may be considered for the diagnosis of fibrotic nonspecific interstitial pneumonitis (NSIP).

OTHER CONDITIONS

Other conditions for which transplant may be appropriate include the Lung diseases described in Table 1 below.[24]

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Table 1: Lung allocation score (LAS) primary diagnostic groupings for lung transplant candidates

LAS lung disease diagnosis grouping	
Group A (obstructive lung disease)	• Chronic obstructive pulmonary disease (COPD), with or without alpha-1-anti deficiency, due to chronic bronchitis and or emphysema • Lymphangioleiomyomatosis (LAM) • Bronchiectasis, including primary ciliary dyskinesia • Sarcoidosis with a mean pulmonary artery (PA) pressure ≤30 mmHg
Group B (pulmonary vascular disease)	• Idiopathic pulmonary arterial hypertension (iPAH, formerly known as primary hypertension [PPH]) • Eisenmenger's syndrome • Other pulmonary vascular diseases
Group C (cystic fibrosis or immunodeficiency disorders)	• Cystic fibrosis (CF) • Immunodeficiency disorders such as hypogammaglobulinemia
Group D (restrictive lung disease)	• Idiopathic pulmonary fibrosis (IPF) • Pulmonary fibrosis due to other causes • Sarcoidosis with mean PA pressure >30 mmHg • Obliterative bronchiolitis (nonretransplant)

Source: Revision to policy 3.7.6.1.

1

ADDENDUM

GUIDANCE FOR LUNG TRANSPLANT FOR IRREVERSIBLE PULMONARY FAILURE FROM COVID-19

Background: Transplant has been successful for other conditions, including infections, that lead to irreversible pulmonary failure, so this disease has some familiar aspects within the lung transplant community. Because of the specific conditions surrounding the effects of SARS-C0V-2, and because much of the mechanism underlying the development of lung injury and recovery are still unclear, the following elements are recommended for any consideration for referral of and authorizations for potential candidates for lung transplant. The below represent elements, *IN ADDITION TO THE USUAL CRITERIA PROVIDED IN THE CMS LUNG PATIENT REFERRAL GUIDELINES:*

1. Age under 65 if ECMO has been used as bridge to transplant
2. Disease has progressed in spite of maximal non-invasive ventilatory support
3. No other significant organ dysfunction exists
4. Sufficient time for recovery must be allowed: once on invasive mechanical support or ECMO, referral should not be considered fewer than 4-6 weeks after ventilator-dependent or ECMO-supported pulmonary failure
5. Patients on prolonged 0_2 therapy other than mechanical support or ECMO should be given sufficient time to determine irreversibility of the condition (usually three months) and should be ambulatory with good opportunity for rehabilitation.
6. Evidence of irreversible lung disease (bullae, fibrosis) must be present
7. The ability to gain patient, not surrogate, approval for transplant is an essential ethical concept in light of the relatively poor long-term outcomes from lung transplant
8. Ability to do adequate pulmonary rehabilitation while on support for respiratory failure
9. Have 2 negative SARS-COV-2 PCR tests at least 24 hours apart with one of the samples being a deep respiratory specimen.
10. Transplants should be performed only at lung transplant programs experienced in the highest risk lung transplants including familiarity with transplanting patients with ECMO bridging to transplant. Furthermore, they should have:
    a. Broad donor pool (represented by low time to transplant measures), and
    b. Low wait-list mortality

Reference: Cypel M, Keshavjee S. Comment When to consider lung transplantation for COVID-19. Lancet Respir Med. 2020;8:944–6. https://doi.org/10.1016/S2213-2600(20)30393-3 .

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ISHLT guidance https://ishlt.org/ishlt/media/documents/SARS-CoV-2_Guidance-for-Cardiothoracic-Transplant-and-VAD-center.pdf

Footnotes

1. See Addendum 1, New system for lung allocation (enclosed)
2. Orens, JB, et al, 'International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation', *Journal of Heart and Lung Transplantation*, 25(7), July 2006, 745-755.
3. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2015; 34:1–15
4. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
5. *Liver Transplant Surg,*. 1997, Vol 3, 304 – 310.The natural history of alcoholism and its relationship to liver transplantation.
6. 6. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
7. J Thorac Dis. 2019 Sep; 11(Suppl 14): S1708–S1720.
8. Under acceptable case-by-case circumstances, a patient who has been listed for a lung transplant and previously ambulatory, and now requires mechanical ventilation, may still be a potential candidate for lung transplantation. Patients who have been listed for lung transplant, and require invasive mechanical ventilation, can remain on the transplant list provided that there remains rehabilitation potential. On a carefully selected case-by-case basis, patients who are on invasive mechanical support, and are ambulatory with a potential for rehabilitation, can be listed for lung transplant. *Chest 2001; 119* (1) 224-227.
9. Any disorder of nutrition causing a lack of necessary or proper food substances in the body or improper absorption and distribution of them (Taber's Cyclopedic Medical Dictionary).
10. *Journal of Heart and Lung Transplantation Vol. 18 (8), August 1999, pg 750-761*
11. *The Journal of Heart and Lung Transplantation 2010*; 29 (9), 1026 – 1033. Impact of Recipient Body Mass Index on Survival after Lung Transplantation.
12. Potential candidate for Heart/Lung transplantation will be evaluated independently.
13. Annals of Surgery, 2006. Vol.244 (4) 491-497.
14. Lung Transplantation in Advanced COPD: Is it Worth it? Semin Respir Crit Care Med. 2010 June; 31(3): 365-372; Selecting lung transplant candidates: where do current guidelines fall short? Expert Rev Respir Med. 2012 February; 6(1): 51-61.
15. Amer *Rev Respir Dis* 140: S92 and S95 1989; Ann Int Med 99: 612: 1983; *New England Journal of Medicine*,1999 340(14), 1081-91
16. Celli BR, Cote CG, Marin JM et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. N Engl J Med 2004;350:1005-12.
17. Applicable to idiopathic pulmonary arterial hypertension, familial pulmonary arterial hypertension, collagen vascular disease limited to the lungs, pulmonary veno-occlusive disease, pulmonary capillary hemangiomatosis, and drug induced pulmonary hypertension. *CHEST, 2004*, Volume 126 (Supplement 1).
18. AJRCCM 201. 184: 159-171 - Thorough review of lung transplantation; J Heart Lung Transplant. 2006. 25(7): 745-55. - Consensus report from ISHLT Pulm Circ. 2011. April-June. 1(2): 182-191 - PH and lung transplant.
19. *Transplantation*. 2010 Aug 15. 90(3): 298-305. - Suggests that 6MWD </= 300 m and RAP >/= 14 mm Hg is better predictor of wait list mortality than LAS scoring system.
20. McGoon MD and Miller DP. Eur Respir Rev. 2012; 21(123):8-18.
21. *Ann Int Med* 115: 343 1991
22. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2015; 34:1–15
23. Nathan, SD., Lung Transplantation- Disease-Specific Considerations for Referral', CHEST 2005; 127: 1006-1016.
24. OPTN Policy 10: Allocation of Lungs, 10.1.F.i Lung Disease Diagnosis Groups, Effective Date 9/1/2016

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

This service is covered when it is medically necessary and identified as a benefit in the consumer's coverage contract. Kaiser Permanente adopted the MCG Guideline for medical necessity decision making.

Evidence and Source Documents

The scientific literature is periodically reviewed, and patient selection criteria are updated when new efficacy data becomes available.

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Kaiser Permanente Committee on Medically Emerging Technology
Transplant, Lung, Double - 7/12/91 - Double lung transplantation is efficacious for appropriately selected patients.
Transplant, Lung, Single - 7/12/91 Single lung transplantation is efficacious for appropriately selected patients.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/1996	09/07/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013 MDCRPC, 01/07/2014 MPC, 10/07/2014MPC, 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC, 03/07/2023MPC	01/10/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt KP National Criteria for Heart and Lung Transplant
09/03/2019	MPC approved to change General Principles 1.3 to *Uncontrollable infection is a contraindication to transplant* as recommended by KP National Transplant Services.
03/03/2020	MPC approved the proposed changes from KP National Transplant Services
04/06/2021	Per National Transplant Guidelines: 1.3 added “active” for Heart Transplant and changes to Lung Transplant. *Lung Transplant Guideline requires 60-day notice, effective date September 1, 2021.
01/10/2022	MPC approved the proposed changes from KP National Transplant Services. 60-day notice is not required.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
High-Frequency Chest Wall Oscillation Devices (HFCWO)

- ABI Vest® for Cystic Fibrosis
- Vest® Airway Clearance System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	High Frequency Chest Wall Oscillation Devices (L33785)
Local Coverage Article (LCA)	High Frequency Chest Wall Oscillation Devices (A52494)

For Non-Medicare Members

A. The member must have **ONE of the following**:
   1. A diagnosis of cystic fibrosis.
   2. A diagnosis of bronchiectasis:
      a) Characterized by daily productive cough for at least 6 continuous, months or, frequent (i.e. more than 2/year) exacerbations requiring antibiotic therapy, and
      b) Confirmed by high resolution, spiral, or standard CT scan
   3. Neuromuscular Disorder
      a) Acid maltase deficiency
      b) Anterior horn cell diseases, including amyotrophic lateral sclerosis
      c) Hereditary muscular dystrophy
      d) Multiple sclerosis
      e) Myotonic disorders
      f) Other myopathies
      g) Paralysis of the diaphragm
      h) Post-polio
      i) Quadriplegia regardless of underlying etiology.

B. And meet **ALL of the following** criteria:
   1. Well-documented failure of standard treatments to adequately mobilize retained secretions with all of the following:
      a) Chest physical therapy and flutter device at least twice daily (when age appropriate)
      b) A pattern of hospitalizations at least annually or more
      c) Significantly deteriorating clinical condition
   2. Be under the care of a pulmonologist
   3. Had a rental trial to confirm compliance before purchase

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Conventional chest physical therapy (CPT), also known as percussion and postural drainage (P/PD) has traditionally been the standard of care of secretion clearance methods for patients with excessive or retained lung secretions. Depending on the severity of the disease or the presence of infection, CPT is performed in 1-3 sessions per day, each lasting between 23-30 minutes. These are administered by a physical therapist or a trained caregiver. CPT is labor intensive and time consuming, which could lead to poor compliance.

A number of airway clearing devices have thus been developed for independent use with little or no assistance by others. These include the high-frequency chest wall oscillation (HFCWO), which is an external non-invasive respiratory modality that mobilizes airway secretions from the small peripheral airways. The technique typically produces compression of the chest wall via an inflatable vest linked to an air pulse generator. The generator delivers an intermittent flow to the vest which rapidly compresses and releases the chest wall at a variety of frequencies. Consequently, an oscillation of airflow within the airways is achieved. The researchers believe that the underlying mechanisms include increased airflow-mucous interaction causing a reduction in viscoelasticity, production of airflow bias that promotes a cephalad movement of the mucous, as well as the enhancement and stimulation of ciliary activity (Osman 2010).

HFCWO is most commonly used for assisting mucous secretion in patients with disorders associated with abnormally thick mucous hypersecretion but preserved muscle function such as cystic fibrosis. It has also been advocated as an adjunctive therapy to assist cough clearance in patients with neuromuscular disorders who have relatively normal mucus but weak respiratory muscles (Chaisson 2006, Osman 2010, Finder 2010).

The FDA has cleared several airway clearing systems for delivering high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage in situations where physicians recommend external manipulation of the thorax. These systems include the Vest™ Airway Clearance System (also known as the ABI Vest or the ThAIRapy Vest, or the ThAIRapy Bronchial Drainage System), Medpulse Respiratory Vest System, and the FREQUENCER which produces sound wave stimulation to oscillate and loosen mucous secretion in the chest.

HFCWO is most commonly used with cystic fibrosis patients who have abnormally thick secretions. It has also been used for other conditions such as bronchiectasis. Another proposed application is treating patients with neuromuscular disorders, who may have impaired cough and may not be able to clear their airways. An inadequate cough in these patients can lead to atelectasis or pneumonia. Other possible treatments for airway clearance in patients with neuromuscular disorders include percussion and postural drainage (P&PD), the traditional procedure, autogenic drainage, positive expiratory pressure therapy, flutter valve and intrapulmonary percussive ventilation (IPV) (Panitch et al., 2006; Langenderfer, 1998).

Neuromuscular diseases are a heterogeneous group of inherited or acquired disorders characterized by progressive irreversible weakness of functional groups of skeletal muscles including the respiratory muscles necessary for ventilation and cough. Depending on the severity of the disorder, ineffective cough and clearing of respiratory secretions can present as frequent respiratory infections, pneumonias, and atelectasis. As the disorder progresses, the patients may develop spinal deformities, gas exchange abnormalities, sleep disorders, and cardiac dysfunction. These and any concomitant pulmonary disorder can severely compromise the existent muscle weakness and precipitate respiratory failure (Chaisson 2006, Yuan 2010).

The Vest™ Airway Clearance System (Hill-Rom, ST Paul, Minnesota), consists of a 1. Non-stretching inflatable cloth-like vest that covers the entire thorax and provides high frequency chest wall oscillation; 2. Large-bore tubing connects the vest to the air-pulse generator; and 3. An air pulse generator that creates pressure to inflate and deflate the vest against the thorax. The vest is inflated to a constant pressure to maximize the surface area over which high frequency (5-20 Hertz), small volume pressure impulses are transmitted externally to the entire chest area. Pressure pulses are controlled by the patient and applied during expiration. A typical treatment may last for 20-30 minutes and consists of periods of compression separated by huff coughs (Chatburn 2007).

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Medical Technology Assessment Committee (MTAC)

ThAIRapy/ABI Vest®

12/13/2000: MTAC REVIEW

Evidence Conclusion: The scientific evidence does not permit conclusions about the effect of the ThAIRapy/ABI Vest® on health outcomes. The two randomized trials had small sample sizes and threats to validity that make their findings inconclusive. The Arens study did not find differences between patients (n=50) randomized to the ABI Vest® compared to chest physical therapy, but this may have been due to low statistical power (the authors did not discuss statistical power issues). The Kluft study included only 29 individuals, had a brief intervention (4 days total), no "wash-out" period between the ABI vest and chest physical therapy interventions (patients had a different intervention each day), gave nebulized saline to the ABI vest but not the physical therapy group, and examined sputum weight, an intermediate outcome measure. The Warwick and Hansen study, an interrupted time series design had the smallest sample size (n=16) and the validity was seriously threatened by possible selection bias. None of the available studies examined clinical outcomes such as pulmonary exacerbations or hospitalizations and no information was provided on short-term or long-term adverse health outcomes associated with the use of the ABI Vest®.

Articles: The search yielded 20 articles. 11 articles were not directly relevant or were review articles. Of the remaining 9 articles, 5 were randomized controlled trials (RCTs). The two RCTs with the largest sample sizes were selected for critical appraisal (the remaining three RCTs all had sample sizes of less than 20 patients). In addition, an interrupted time-series analysis with longer-term follow-up of patients was reviewed. Arens R, Gozal D, Omlin KJ, Vega J, Boyd KP, Keens TG, Woo MS. Comparison of high frequency chest compression and conventional chest physiotherapy in hospitalized patients with cystic fibrosis. Am J Respir Crit Care Med 1994; 150: 1154-7. See Evidence Table Kluft J, Beker L, Castaginino M, Gaiser J, Chaney H, Fink RJ. A comparison of bronchial drainage treatments in cystic fibrosis. Pediatr Pulmonol 1996; 22: 271-74. See Evidence Table .Warwick WJ, Hansen LG. The long-term effect of high-frequency chest compression therapy on pulmonary complications of cystic fibrosis. Pediatr Pulmonol 1991; 11: 265-71. See Evidence Table.

The use of ThAIRapy/ABI Vest® for treatment of cystic fibrosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

ThAIRapy/ABV Vest®

10/08/2003: MTAC REVIEW

Evidence Conclusion: There is no published empirical evidence on the use of the Vest™ Airway Clearance System for bronchiectasis. There is no new published evidence on the use of the Vest™ Airway Clearance System for cystic fibrosis. The summary of the evidence on the ABI vest from December 2000 is: "The scientific evidence does not permit conclusions about the effect of the ThAIRapy/ABI vest on health outcomes. The two randomized trials had small sample sizes and threats to validity that make their findings inconclusive. The Arens study did not find differences between patients (n=50) randomized to the ABI vest compared to chest physical therapy, but this may have been due to low statistical power (the authors did not discuss statistical power issues). The Kluft study included only 29 individuals, had a brief intervention (4 days total), no "wash-out" period between the ABI vest and chest physical therapy interventions (patients had a different intervention each day), gave nebulized saline to the ABI vest but not the physical therapy group, and examined sputum weight, an intermediate outcome measure. The Warwick and Hansen study, an interrupted time series design had the smallest sample size (n=16) and the validity was seriously threatened by possible selection bias. None of the available studies examined clinical outcomes such as pulmonary exacerbations or hospitalizations and no information was provided on short-term or long-term adverse health outcomes associated with the use of the ABI vest."

Articles: The search yielded 6 articles. There were no new empirical studies on the Vest™ Airway Clearance System for cystic fibrosis. There were no empirical studies on the Vest™ Airway Clearance System for bronchiectasis.

The use of ThAIRapy/ABI Vest® for treatment of cystic fibrosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

High Frequency Chest Wall Oscillation

02/04/2008: MTAC REVIEW

Evidence Conclusion: There is no empirical evidence on the safety and effectiveness of the Vest™ Airway Clearance System for improving health outcomes in patients with neuromuscular disease.

Articles: The search yielded 11 articles. When limited to English language publications and human populations, there were 7 articles. Only 2 of the 7 articles, both of them reviews/opinion pieces, specifically addressed the topic of interest, airway clearance for patients with neuromuscular weakness. The remaining articles were on different,

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related topics. No empirical studies were identified. One of the review articles (Panitch, 2006) stated that HFCWO has not been studied in patients with neuromuscular disease.

The use of High-frequency chest wall oscillation (HFCWO) for treatment of neuromuscular deficiency does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
High Frequency Chest Wall Oscillation
Evidence Conclusion: The evidence on the use of high-frequency chest wall oscillation (HFCWO) therapy in patients with neuromuscular disorders is very limited and insufficient to determine the safety and effectiveness of the Vest™ Airway Clearance System for improving health outcomes in these patients. The published studies to date have very small sample sizes and short follow-up durations. Those with a control group have several threats to their internal validity. Among these are unblinding, including heterogeneous groups of population, potential selection bias, insufficient power to detect significant differences between therapies, relatively high dropout rates, and/or analyses were not based on intention to treat. Additionally, the studies were funded by the manufacturer of the airway clearance systems used.
Articles: The majority of published literature on high-frequency chest wall oscillation (HFCWO) was on its use for patients with cystic fibrosis and other obstructive airway diseases. The literature search for studies published after the last MTAC review of the technology for patients with neuromuscular disorders revealed only one small RCT that compared the use of HFCWO to the standard chest physiotherapy among a small group of pediatric population with cerebral palsy or neuromuscular disease. Yuan N, Kane P, Shelton K, et al. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial. *J Child Neurol*. 2010; 25:815-821**.** See Evidence Table

The use of High-frequency chest wall oscillation (HFCWO) for treatment of neuromuscular deficiency does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
A7025	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each
E0480	Percussor, electric or pneumatic, home model
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

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Date Created	Dates Reviewed	Date Last Revised
12/13/2000	12/07/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC] ,08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	01/19/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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01/19/2016	Defined conditions for neuromuscular disorder

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Clinical Review Criteria
Home Care Services Criteria

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 7 Home Health Services.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Home Care Guidelines for medical necessity determinations. ** For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

**note - Social Work is to be considered a secondary service and not a primary service

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Background

The criteria for admission to home health services are based on the federal regulations for the Medicare home health benefit.

Evidence and Source Documents

Kaiser Permanente Home Care Services Policy HCS-06-1008.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT® or HCPC Codes	Description

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No specific codes

Date Created	Date Reviewed	Date Last Revised
02/1996	01/05/2010[MDCRPC], 11/02/2010[MDCRPC], 09/06/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC] , 10/04/2022[MPC]	12/05/17

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/07/2016	MPC approved to adopt MCG guidelines for home health services

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Clinical Review Criteria

High Intensity Focused Ultrasound (HIFU) for the Treatment of Localized Prostate Cancer

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, KPWA has elected to use ***MCG* High Intensity Focused Ultrasound (HIFU), Prostate (A-0271)*** for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* High Intensity Focused Ultrasound (HIFU), Prostate (A-0271) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (oncologist, radiologist, primary care provider)
- Most recent imaging

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Prostate cancer is the second most frequently diagnosed cancer across the globe (Wolff et al., 2015). A 2008-2010 data estimated that 15% of men in the United States will be diagnosed with prostate cancer at some point in their lives (Wolff et al., 2015). However, the mortality rate is low because it is a slow growing cancer.

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Treatment is based on a number of factors including tumor stage, prostate specific antigen (PSA) value, Gleason score (GS), patient's age, concomitant diseases, life expectancy and patient's preference (Warmuth, Johansson, & Mad, 2010). A wide range of options are available for prostate cancer and these include active surveillance, watchful waiting, radical prostatectomy, hormone therapy, radiotherapy, external beam radiotherapy (EBRT), brachytherapy and chemotherapy (Wolff et al., 2015). High Intensity Focused Ultrasound (HIFU) and cryotherapy are being considered as treatment options.

HIFU is a procedure in which beams target localized tissue without destroying the surrounding tissue and the high energy produced by HIFU leads to coagulative necrosis (Dogra, Zhang, & Bhatt, 2009). Two mechanisms including hyperthermia and acoustic cavitation cause the destruction of the tissue (Kennedy, Ter Haar, & Cranston, 2014). First, high energy is produced and converted to heat as the ultrasound wave disseminates through the tissue. This high energy leads to extreme temperatures surpassing the threshold level of protein denaturation (>43-degree C) resulting in coagulative necrosis. In the surrounding areas of the target zone, temperatures decrease suddenly keeping the outside tissues unaffected. Second, the interaction between ultrasound and micro-bubbles of water in the sonicated tissue result in cavitation. Cavitation may lead to diffusion of energy reinforcing tissue destruction (Stride & Coussios, 2010).

For this procedure, a transducer, covered by a condom through which cooled water is circulated to cool the rectal wall, is inserted into the rectum and several images are taken. The transducers generate very precise small lesions destroying the prostate partially or completely (Cordeiro et al., 2012).

HIFU is non-invasive and non-ionizing technique that is believed to have some advantages over other thermal therapy such as cryotherapy, laser ablation, and photothermal therapy and radiofrequency interstitial tumor ablation (Cordeiro et al., 2012). Two types of systems have been approved by the Food and Drug Administration (FDA). These include the Sonablate 450 (developed by SonaCare Medical) and the Ablatherm HIFU (EDAP TMS SA) both of which received FDA approval in October and November 2015 respectively. HIFU is indicated for primary treatment and salvage treatment for localized prostate cancer.

Medical Technology Assessment Committee (MTAC)

High Intensity Focused Ultrasound (HIFU) for the treatment of localized Prostate Cancer

MTAC REVIEW: 06/21/2016

Evidence Conclusion: INTC reviewed the technology in 2008 and concludes that there is insufficient evidence to determine whether the technology is medically appropriate for any patient and that the existing evidence regarding how HIFU treats prostate cancer is of insufficient quantity and quality. In April 2016, INTC conducted another review of the technology and concludes that: "the body of evidence that is available from which to assess the efficacy and safety of HIFU for localized prostate cancer (as primary and salvage therapy) is very low quality. The risk of bias in existing studies is high. Across studies, there is variation and/or lack of information regarding patient selection criteria, how HIFU was delivered, how outcomes were measured, and how long patients were followed"

INTC review can be adopted.

HIFU for Primary and Salvage therapy

Systematic Review of the Efficacy and Safety of High-Intensity Focused Ultrasound for the Primary and Salvage Treatment (Warmuth, Johansson, & Mad, 2010) (evidence table 1) The aim of this study was to assess the efficacy and safety of HIFU in the primary and salvage treatment for prostate cancer. The primary outcomes were the biochemical disease-free survival rate, the negative biopsy rate, overall survival rates, prostate cancer–specific survival rates, adverse events, and QOL. The literature search was performed from 200 to 2010 and included 20 case series (with more than 50 participants) in which 93% of patients were treated with primary therapy and 7% for salvage HIFU. For all HIFU procedures, the biochemical disease-free survival rate was between 78% and 84%, 45%- 84%, and 69% at 1, 5, and 7 years, respectively. The negative biopsy rate was 86% at 3 months and 80% at 15 months. Overall survival rate and prostate-cancer specific survival rate were reported in 1 study and were 90% and 100% at 5 years and 83% and 98% at 8 years, respectively. Adverse events were mainly related to the urinary tract (1-58%), potency (1-77%) and rectum (0-15%).
The study has several limitations including the study design lacking control group, long term follow-up was not available and the quality of evidence of included studies was low, surrogate outcomes were used and the central question is whether surrogate outcomes corroborate with overall survival, QOL, and prostate cancer specific survival, and the possibility for publication bias. The evidence is of low quality; therefore, results should be interpreted with caution.

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Ablative therapy for people with localized prostate cancer: a systematic review and economic evaluation (Ramsay et al., 2015) (evidence table 2) This systematic review indicates that the biochemical failure rate of HIFU was higher (statistically significant) than that of EBRT at 1 year but no statistically significant difference was observed at 5 years. The results also indicate statistically significant lower rate of disease free survival for HIFU compared to EBRT at 1 year. At 4 years, overall survival was better for HIFU compared to EBRT. Compared to RP, there was an increased risk of biochemical failure for HIFU at 1 and 5 years. But this difference was not significant. Also, in term of disease free survival, no statistical significant difference was noted when HIFU was compared to RP at 1 year. At 3 years, the difference was not statistically significant. For urinary incontinence, erectile dysfunction, or bowel problems (not in the table), data were insufficient to reach a conclusion. Results were not statistically significant for dysuria or urinary retention. Nonetheless, high proportion of urethral stricture was observed for HIFU. When comparing HIFU to active surveillance (AS) (not on the table), there was no difference in overall survival or erectile dysfunction. The results are mixed and due to the poor quality of case series included in the review, with the lack of long term findings, the result should be interpreted with caution.

HIFU for Salvage therapy

High intensity focused ultrasound (HIFU) for definitive treatment of prostate cancer (Cordeiro et al., 2012) The purpose of this review was to update the available literature on HFU as definitive treatment of prostate cancer and to describe the techniques extensively and give an overview of historical background. Searched was conducted from 200 to December 2011. The search included case series with more than 50 participants assessing efficacy and safety of HIFU. No RCTs were identified and only 33 uncontrolled studies were identified. HIFU as salvage therapy after EBRT was assessed in two case series. The mean age was 68 years with mean preoperative PSA ranged from 6.89 to 7.73 ng/mL and Gleason score (GS) was ≥ 8. Prostate volume preoperatively ranged from 18-21.4 mL; 34-56% received neoadjuvant androgen-deprivation therapy (NADT). Patients were followed for 15-18 months. The negative biopsy rate ranged from 73-80%; patients achieving PSA≤.5 ng/ml was 61% in one study; the mean PSA Nadir ranged from 1.97-2.38 ng/ml and disease-free survival ranged from 38-53% (30 mos-36mos). In terms of complications, urinary retention represented 7.8%, urinary tract infections (1.4- 3.5%), urinary incontinence (7-31.5%), bladder stenosis (17%), rectal urethral fistula 3 weeks after HIFU (3-6%) and erectile dysfunction was not assessed. The authors concluded that HIFU seems to control cancer on the short to medium term with less adverse events compared to established therapies.
There was heterogeneity among the studies; individual studies are case series resulting in low quality evidence. In addition, long term data was not available. Therefore, results should be interpreted with caution.

Additional studies

Subsequent studies (assessing HIFU as primary or salvage therapy) to the systematic reviews aforementioned were non-randomized controlled trial and did not compare HIFU to other treatment options. Accurate conclusions cannot be made from these studies. Summary of additional studies for HIFU as primary therapy: Nine non-RCTs (Aoun et al., 2015; Sebastien Crouzet et al., 2014; Dickinson et al., 2016; Feijoo et al., 2016; Ganzer et al., 2013; Liu & Chiang, 2016; Mearini et al., 2015; Uchida et al., 2015; van Velthoven et al., 2015) were examined and were for the most part observational studies. The sample size ranged from 50 to 1002; follow-up varied from 12 to 108 months. Of the nine studies, only two were comparative (Aoun et al., 2015; Liu & Chiang, 2016) and the findings from these two studies indicate: for Liu, 2016 (HIFU vs. cryoablation), no differences between biochemical recurrence rates were found; for Aoun, 2015 (HIFU vs. brachytherapy), similar survival outcomes were observed with greater biochemical recurrence free survival in the brachytherapy group. Summary of additional studies for HIFU as salvage therapy: Five observational studies (Baco et al., 2014; Sébastien Crouzet et al., 2012; Song et al., 2014; Uddin Ahmed et al., 2012; Yutkin et al., 2014) were examined; the sample size varied from 19 to 290; follow-up ranged from 19.8 months to 51.6 months and there was heterogeneity in the measures of outcomes. The survival rates varied as well.

Conclusion:

- No RCTs comparing HIFU to other treatment options were identified.
- The available evidence is of low quality since it is represented by non-comparative, case series/observational studies.
- The overall concerns are the lack of control group and long-term follow-up, the use of surrogate outcomes raising the question of consistency with overall survival and QOL, and the variations in patient populations and biochemical progression-free survival.
- Conclusion on efficacy and safety of HIFU for the treatment of localized prostate cancer or recurrent localized prostate cancer cannot be drawn at this time.

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Articles: No RCTs were identified. The following articles are selected for critical appraisal: Systematic Review of the Efficacy and Safety of High-Intensity Focused Ultrasound for the Primary and Salvage Treatment (Warmuth et al., 2010) (evidence table 1) Ablative therapy for people with localized prostate cancer: a systematic review and economic evaluation (Ramsay et al., 2015) (evidence table 2) High intensity focused ultrasound (HIFU) for definitive treatment of prostate cancer (Cordeiro et al., 2012)

The use of High Intensity Focused Ultrasound (HIFU) for the treatment of localized Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/05/2016	07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	01/07/2022

[MPC] Medical Policy Committee

Revision History	Description
05/02/2017	Adopted MCG A-0271
05/02/2017	Adopted Non-Medicare policy for Medicare members
03/16/2021	Added new CPT code 55880 effective 1/1/2021
01/07/2022	Removed diagnosis codes for HIFU

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Clinical Review Criteria
High-end imaging Site of Care Medical Policy

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Criteria

For Medicare Members

This policy does not apply to Medicare members.

For Non-Medicare Members

A high-tech imaging service (i.e., MRI/MRA/CT/CTA) must meet applicable medical necessity criteria for coverage. When coverage criteria are met for the requested imaging procedure, this coverage policy is used to help determine the medical necessity of the requested site of care for ambulatory, non-emergent imaging.

A high-tech imaging procedure in a *hospital-based* imaging department or facility is considered medically necessary for an individual with **ANY** of the following indications:

- Less than 13 years of age
- Requires obstetrical observation
- Requires perinatology services
- Imaging related to transplantation services at an approved transplantation facility
- Patient is enrolled in an approved clinical trial and trial protocol requires imaging to be done at this site
- Known contrast allergy and use of that contrast agent is planned
- There are no other appropriate alternative sites for the individual to undergo the imaging procedure for **ANY** of the following reasons:
  - Surgery or procedure will be performed at a specific hospital and pre-operative or pre-procedure imaging must be done at the same hospital, as it is an integral component of the procedure. This is not common. Examples would include epilepsy surgery where ablation of specific areas is planned or pre TAVR insertion in certain geographies. There must be documentation of a medically necessary reason the images cannot be performed at a freestanding facility and transmitted to the hospital and/or surgeon for pre op planning or in the OR.
  - Moderate or deep sedation or general anesthesia is required for the imaging procedure and freestanding facility providing such sedation is not available
  - Equipment for the size of the individual is only available at a hospital-based imaging facility
  - Individual has a documented diagnosis of claustrophobia requiring open magnetic resonance imaging which is not available in a freestanding facility; or
  - Imaging outside the hospital-based imaging department or facility is expected to adversely impact or delay care.
  - The patient has a pacemaker that requires coordination, monitoring, and a code team onsite during the MRI, which are not available at a nearby freestanding site*

*Kaiser Permanente can provide this at multiple sites

All other high-tech radiology (imaging) procedures at a hospital-based imaging department or facility are considered not medically necessary. In the absence of one of the above circumstances, it would be expected that non hospital-based locations would be used, such as a clinic or free-standing imaging centers. Hospital-based

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imaging departments may be authorized if there is no appropriate geographically accessible free-standing imaging center.

If requesting these *services*, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Hospital-based advanced radiologic imaging procedures are generally more appropriate for individuals whose health status necessitates the availability of more supportive care for the minimization of the risks associated adverse health events.

Certain high-risk medical conditions can necessitate the need for an anesthesiologist to be present during the advanced radiologic imaging for individuals including neonates and children. Children can require specialized pediatric equipment including smaller anesthetic tools such as endotracheal tubes and monitoring equipment. Conversely, large individuals or those with claustrophobia may also require specialized equipment which could include an open magnetic resonance imaging (MRI) as opposed to a traditional MRI scanner.

Examples of advanced radiologic imaging include computed tomography, computed tomography angiography, magnetic resonance imaging, magnetic resonance angiography.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Computed Tomography (CT) and Computed Tomographic Angiography (CTA)

CPT® or HCPC Codes	Description
70450	Computed tomography, head or brain; without contrast material
70460	Computed tomography, head or brain; with contrast material(s)
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections
70486	Computed tomography, maxillofacial area; without contrast material
70487	Computed tomography, maxillofacial area; with contrast material(s)
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections
70490	Computed tomography, soft tissue neck; without contrast material
70491	Computed tomography, soft tissue neck; with contrast material(s)
70492	Computed tomography, soft tissue neck; without contrast material followed by contrast material(s) and further sections
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing
71250	Computed tomography, thorax, diagnostic; without contrast material
71260	Computed tomography, thorax, diagnostic; with contrast material(s)

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71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing
72125	Computed tomography, cervical spine; without contrast material
72126	Computed tomography, cervical spine; with contrast material
72127	Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections
72128	Computed tomography, thoracic spine; without contrast material
72129	Computed tomography, thoracic spine; with contrast material
72130	Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections
72131	Computed tomography, lumbar spine; without contrast material
72132	Computed tomography, lumbar spine; with contrast material
72133	Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing
72192	Computed tomography, pelvis; without contrast material
72193	Computed tomography, pelvis; with contrast material(s)
72194	Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections
73200	Computed tomography, upper extremity; without contrast material
73201	Computed tomography, upper extremity; with contrast material(s)
73202	Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections
73206	Computed tomographic angiography, upper extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing
73700	Computed tomography, lower extremity; without contrast material
73701	Computed tomography, lower extremity; with contrast material(s)
73702	Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further section
73706	Computed tomographic angiography, lower extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing
74150	Computed tomography, abdomen; without contrast material
74160	Computed tomography, abdomen; with contrast material(s)
74170	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing
74176	Computed tomography, abdomen and pelvis; without contrast material
74177	Computed tomography, abdomen and pelvis; with contrast material(s)
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)

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75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)
75635	Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing
76380	Computed tomography, limited or localized follow-up study

Magnetic Resonance Angiography (MRA)

CPT® or HCPC Codes	Description
70544	Magnetic resonance angiography, head; without contrast material(s)
70545	Magnetic resonance angiography, head; with contrast material(s)
70546	Magnetic resonance angiography, head; without contrast material(s), followed by contrast material(s) and further sequences
70547	Magnetic resonance angiography, neck; without contrast material(s)
70548	Magnetic resonance angiography, neck; with contrast material(s)
70549	Magnetic resonance angiography, neck; without contrast material(s), followed by contrast material(s) and further sequences
72159	Magnetic resonance angiography, spinal canal and contents, with or without contrast material(s)
71555	Magnetic resonance angiography, chest (excluding myocardium), with or without contrast material(s)
74185	Magnetic resonance angiography, abdomen, with or without contrast material(s)
72198	Magnetic resonance angiography, pelvis, with or without contrast material(s)
73225	Magnetic resonance angiography, upper extremity, with or without contrast material(s)
73725	Magnetic resonance angiography, lower extremity, with or without contrast material(s)
C8900	Magnetic resonance angiography with contrast, abdomen
C8901	Magnetic resonance angiography without contrast, abdomen
C8902	Magnetic resonance angiography without contrast followed by with contrast, abdomen
C8909	Magnetic resonance angiography with contrast, chest (excluding myocardium)
C8910	Magnetic resonance angiography without contrast, chest (excluding myocardium)
C8911	Magnetic resonance angiography without contrast followed by with contrast, chest (excluding myocardium)
C8912	Magnetic resonance angiography with contrast, lower extremity
C8913	Magnetic resonance angiography without contrast, lower extremity
C8914	Magnetic resonance angiography without contrast followed by with contrast, lower extremity
C8918	Magnetic resonance angiography with contrast, pelvis
C8919	Magnetic resonance angiography without contrast, pelvis
C8920	Magnetic resonance angiography without contrast followed by with contrast, pelvis
C8931	Magnetic resonance angiography with contrast, spinal canal and contents
C8932	Magnetic resonance angiography without contrast, spinal canal and contents
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents
C8934	Magnetic resonance angiography with contrast, upper extremity
C8935	Magnetic resonance angiography without contrast, upper extremity
C8936	Magnetic resonance angiography without contrast followed by with contrast, upper extremity

Magnetic Resonance Imaging (MRI)

CPT® or HCPC Codes	Description
70336	Magnetic resonance (eg, proton) imaging, temporomandibular joint(s)
70540	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; without contrast material(s)
70542	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; with contrast material(s)

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70543	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences
70554	Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration
70555	Magnetic resonance imaging, brain, functional MRI; requiring physician or psychologist administration of entire neurofunctional testing
71550	Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s)
71551	Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); with contrast material(s)
71552	Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; without contrast material
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)
72148	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; without contrast material
72149	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; with contrast material(s)
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic
72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar
72195	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)
72196	Magnetic resonance (eg, proton) imaging, pelvis; with contrast material(s)
72197	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences
73218	Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; without contrast material(s)
73219	Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; with contrast material(s)
73220	Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73221	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; without contrast material(s)
73222	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; with contrast material(s)
73223	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences
73718	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; without contrast material(s)
73719	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; with contrast material(s)
73720	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73721	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material

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73722	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; with contrast material(s)
73723	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material(s), followed by contrast material(s) and further sequences
74181	Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s)
74182	Magnetic resonance (eg, proton) imaging, abdomen; with contrast material(s)
74183	Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences
76391	Magnetic resonance (eg, vibration) elastography
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
77084	Magnetic resonance (eg, proton) imaging, bone marrow blood supply
C8900	MRA with contrast, abdomen
C8901	MRA without contrast, abdomen
C8902	MRA without contrast followed by with contrast, abdomen
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral
C8909	MRA with contrast, chest (excluding myocardium)
C8910	MRA without contrast, chest (excluding myocardium)
C8911	MRA without contrast followed by with contrast, chest (excluding myocardium)
C8912	MRA with contrast, lower extremity
C8913	MRA without contrast, lower extremity
C8914	MRA without contrast followed by with contrast, lower extremity
C8918	MRA with contrast, pelvis
C8919	MRA without contrast, pelvis
C8920	MRA without contrast followed by with contrast, pelvis
C8931	MRA with contrast, spinal canal and contents
C8932	MRA without contrast, spinal canal and contents
C8933	MRA without contrast followed by with contrast, spinal canal and contents
C8934	MRA with contrast, upper extremity
C8935	MRA without contrast, upper extremity
C8936	MRA without contrast followed by with contrast, upper extremity

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/23/2020	01/05/2021[MPC], 01/03/2022[MPC], 01/10/2023[MPC]	07/14/2022

[MPC] Medical Policy Committee

Revision History	Description

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03/26/2021	Clarifying language added to specify that the policy applies to non-emergent, ambulatory high-tech imaging requests.
05/20/2021	Updated policy effective date to 08/01/2021.
07/08/2021	Updated policy effective date to 09/01/2021.
04/25/2022	Updated applicable codes to include related HCPCS codes. Requires a 60-day notice, effective date 09/01/2022.
06/07/2022	MPC approved the updates to the alternative sites section of the criteria; updated MRI codes
07/14/2022	Added clarifying language for pre TAVR insertion in certain geographies

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Clinical Review Criteria
Prometheus Lab Testing

- Anser ™ ADA for Adalimumab (Humira) Antibodies
- Anser TM IFX test for Infliximab (Remicade) Antibodies
- Anser VDZ (Vedolizumab)
- IBD SGI Diagnostic Test

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	MolDX: Prometheus IBD sgi Diagnostic Policy (L37313) This service is not covered per Noridian LCD.
Local Coverage Article	Billing and Coding: MolDX: Prometheus IBD sgi Diagnostic Policy (A57517)
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance specific to Anser antibody levels for infliximab or adalimumab, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Prometheus Testing," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Anser antibody levels for infliximab or adalimumab can be approved under **ALL of the following** conditions:

1. Ordered by a gastroenterologist
2. Is being ordered as a consideration of changing to alternate therapy in the setting of a concern for loss of response

Service	Criteria
Homogenous Mobility Shift Assay (HMSA) Anser VDZ (Vedolizumab) Prometheus IBD sgi Diagnostic Test	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Many chronic inflammatory diseases are mediated by up-regulation of the pro-inflammatory cytokine tumor necrosis factor-alpha ((TNF)-α. Protein-based drugs that block TNF-α such as Infliximab (IFX), are effective in reducing the disease activity of these inflammatory disorders. IFX is a chimeric mouse-human monoclonal antibody approved by the FDA for the treatment of patients with Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and chronic severe plaque psoriasis. IFX is highly effective in

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inducing and maintaining remission in a large proportion of these patients. However, more than 30% of cases fail to respond to anti-TNF-α therapy, and 20-60% of those who initially respond, lose their clinical response over time despite maintenance treatment. This loss of response (LOR) usually requires escalation of the dose, shortening the interval between doses, change in the anti-TNF agent to regain the clinical remission, or switching to a non-anti-TNF therapy (Wang 2012, Nanda 2013, Wang 2013, FDA web page accessed August 26, 2013).

The reason for loss of response to IFX is still debatable, but the anti-drug antibody formation is believed to play an important role. IFX is a chimeric mouse/human IgG1 molecule and thus the antibodies are primarily directed against the murine fragment. Antibodies to IFX (ATI), also frequently called human antichimeric antibodies (HACAs), are reported to develop in up to approximately 60% of patients depending on the dosing schedule, administration of concurrent steroids or immunomodulators, and the method of measuring the antibodies in the blood. The antibodies can appear as soon as after the first IFX dose and can persist in the blood for up to 4.5 years even after discontinuation of the therapy. ATI may increase the drug clearance in treated patients and/or neutralize its effect. Researchers found that a lower serum IFX levels is associated with a significantly higher risk of loss of clinical response to the drug. This loss of clinical response and remission due to immunogenicity is a potential major limitation to IFX leading to clinical relapse, impaired quality of life, and increased cost of care. Anti-drug antibodies may also cause serum sickness and hypersensitivity reactions. Despite these observed associations, some researchers dispute the clinical relevance of anti-infliximab antibodies and question whether the presence of antibodies to TNF agents is directly correlated to the decreased efficacy. To date, there is insufficient knowledge about the factors influencing the formation of the antibodies, and on whether the immune reaction to IFX can be transient. It is assumed however, that once the antibody is initiated, it cannot be overcome (Afif 2010, Kopylov 2012, Vande Casteele 2013, Nanda 2013, Wang 2013).

It is suggested that accurate monitoring of the serum drug and anti-drug antibody levels should be an important part of therapy in patients receiving anti TNF-α drugs. However, there is no gold standard technique or test for the detection and quantitative measurement of anti-infliximab antibodies (ATI). Anti-drug antibodies and drug levels in the serum are assessed by the bridging ELISA method, or less commonly by the radioimmunoassay (RIA) method. Each of these two methods has its limitations; the main limitation of the bridge ELISA method is its inability to accurately detect the antibodies in the presence of the drug in the circulation due to cross interference between the drug and the assay. This lowers the sensitivity of the test in detecting antibodies in the presence of IFX. Thus, ELISA can accurately measure the anti-drug antibodies only when there is no drug in the circulation, which limits its clinical utility. RIA method is limited by its complexity, safety concerns of handling radioactive material, and prolonged time needed to reach equilibrium for proper management (Wang 2012).

A novel Homogenous Mobility Shift Assay (HMSA) was recently developed and validated by group of researchers In San Diego (Wang and colleagues 2012) to quantitatively measure the induced ATI and IFX levels in serum samples of patients treated with infliximab. The Anser ™IFX test is not ELISA-based and is believed to be able to measure both the serum concentrations of infliximab and infliximab antibodies in the presence of serum infliximab. In the HMSA, serum samples are acidified during sample preparation to dissociate drug-anti-drug-antibody (IFX-ATI) complexes, thereby allowing the detection of ATI in the presence of IFX and overcoming the limitation of bridge ELISA (Casteele 2013).

Medical Technology Assessment Committee (MTAC)

Homogenous Mobility Shift Assay (HMSA)

10/21/2013: MTAC REVIEW

Evidence Conclusion: ***Analytic validity*** There is insufficient evidence to determine the analytic validity of the existing tests for measuring the antibodies to IFX. There is no gold standard technique for anti-infliximab antibodies (ATI) measurement and comparing the technical performance and accuracy of ATI assays in detecting ATI in the presence of IFX may be problematic. As indicated in the introduction the ELISA and RIA have their limitations, and there are no standards available for comparison. Several confounding factors can influence the measurement of these antibodies, and in turn the accuracy and reproducibility of the test. ***Clinical validity*** The results of studies that examined the association between ATI and clinical efficacy of IFX are inconsistent. While some studies showed that detectable levels of ATI using different ELISA methods or RIA were correlated with low concentrations or undetectable trough levels of IFX and higher rates of loss of response to IFX treatment, others showed no significant effect of ATI on loss of response. Two published meta-analyses (Lee et al, 2012 and Nanda et al, 2013) had conflicting results. Both had their limitations and pooled the results of randomized trials together with observational studies. In these studies, ATI was measured at one time point which may not capture its possible fluctuating, transient, or latent occurrence; different methods and assays, mainly ELISA, were used to measure ATI with no standardization; patients were on different IFX regimes (episodic or maintenance); and immunosuppressants were used among some, but not all patients. Lee et al' (2012), meta-analysis pooled the

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results of 18 studies to determine the prevalence of ATI, its effect on perfusion reactions and on disease remission rates among IBD patients treated with infliximab. The analysis included 9 RCTs, 5 cohort studies, and 4 retrospective studies with a total of 3,326 patients. The pooled results showed that patients who tested positive for ATI (using ELISA) were at increased risk of infusion reactions (RR= 2.07 [95% CI, 1.61-2.67]), but with no significant difference in the rates of remission compared to those who tested negative for ATI (RR=0.90, 95% CI 0.79-1.02). On the other hand, the pooled results of the more recent meta-analysis (Nanda et al, 2013) of 13 studies involving 1,378 patients with IBD showed that the presence of ATI was associated with lower IFX serum levels and significantly higher risk of loss of clinical response (LOR) to IFX with a pooled risk ratio for LOR = 3.2 (2.0-4.9). The ATI was measured by different methods including double antigen ELISA, antihuman chain ELISA, immunochromatography-based ELISA, fluid-phase RIA, and western blot. The results of the meta-analysis, however, have to be interpreted with caution due to the high risk of bias in the studies included, significant heterogeneity between studies, publication bias, and combining the results of randomized studies together with of observational studies. In addition, there were differences between studies in the method of assessing ATI, IFX dosing regimens, immunosuppressants use, and assessment of clinical response. The Anser IFX (HMSA) Wang and colleagues (2012) developed and validated a homogenous mobility shift assay (HMSA) to measure the serum levels of infliximab (IFX) and antibodies to IFX (ATI). They compared the performance of the newly developed IFX-HMSA to bridge ELISA and measured the ATI levels with the new test in 100 patients with ELISA positive ATI and found a high correlation between the two methods. HMSA identified five false-positive samples from the bridging ELISA method. Intra-and inter-assay precision rates for ATI were <4% and <15% respectively which, are considered high. The cutoff point of the assay was determined using sera of 100 healthy subjects who were naïve to IFX. The mean values of ATI in patient serum samples were significantly higher than those in the drug naïve health controls (mean $\pm$SD=9.57+11.43, vs. 0.73 $\pm$ 0.29, p<0.0001). The area under the curve (AUC) was 0.986, the sensitivity was 95% (95% CI, 88.72-98.36%) The authors concluded that the HMSA-IFX method showed a high assay sensitivity, precision and accuracy. However, validation was performed by using bridging ELISA methodology which can only accurately measure the anti-drug antibodies when there is no drug in the circulation.

Clinical utility- In a retrospective study, Afif and colleagues (2010) evaluated the clinical utility of measuring Human Anti-Chimeric Antibody (HACA) concentration in patients with IBD treated with infliximab. They used recorded data for 155 patients treated in one center (from 2003-2008) who had ATI and IFX concentrations measured. Testing for IFX and ATI levels was performed by ELISA at the discretion of the treating physician with no systematic strategy and was not done for all patients receiving IFX. 72% of the initial tests were ordered by a single physician, and the assay(s) used were not defined. Indications for testing were mainly due to loss of response (49%), partial response (22%) and autoimmune or delayed hypersensitivity reaction (10%). There was no control or comparison group and according to the authors, the study population represented only a subset of the total population receiving IFX at the clinic, and the clinical response was abstracted through review of patients' charts using predefined clinical criteria. The use of validated instruments as Crohn's disease Activity Index, Harvey-Bradshaw Index and endoscopic improvement could not be obtained retrospectively. 47% of the patients were on immunosuppressives, and 43 patients (29%) had the dose or frequency of IFX increased before testing. 35 patients had positive ATI based on which, the dose was increased in 6 patients, and 12 were put on a different anti-TNF. The overall results suggest that change to another anti-TNF in these ATI positive patients was associated with a significantly higher complete or partial response than those who received a dose escalation (92% vs. 17%). The authors concluded that measurement of ATI and IFX concentrations had an impact on management and was clinically useful. These results have to be interpreted with caution due to the study design and its imitations. In addition, there was no control group to determine whether any change in management in the absence of ATI measurement would have a similar or different clinical outcome. It also to be noted that 29% of the patients had the dose or frequency of IFX increased before testing. A more recent study (Vande Casteele and colleagues, 2013), used the new HMSA to retrospectively measure 1,232 consecutive frozen serum samples of 90 patients with IBD treated in one center from 1999-2011. The HMSA confirmed ATI in 59% of the patients, this was transient (disappeared by time) in 28% and was sustained in 72% of the patients. All treatment decisions to optimize and to stop therapy were based on clinical grounds and C-reactive protein level without knowledge of infliximab trough levels (TLI) or ATI status. The results of the analysis show that 68% of the patients with sustained ATI needed to discontinue IFX treatment vs. 13% with transient ATI (RR 5.1, 95% CI, 1.4-19.0). The overall results suggest, but do not provide good evidence that ATI may be transient, and that optimizing the IFX dose in patients with low-level ATI may be useful. It also indicates that sustained ATI increases the risk of loss of response to IFX. Based on these results, the authors recommended measuring IFX trough levels at week 14 and at time of loss of treatment response, and only measure ATI at consecutive time points when the trough levels of IFX are undetectable or low. These results have to be interpreted with caution due to the nature of the study and its limitations. In conclusion there is insufficient evidence to determine analytic and clinical validity of HMSA in detecting ATI to IFX. There is also inconclusive evidence to determine that ATI measurement has a significant impact on management of patients treated with infliximab or significant effect on clinical outcomes.

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Articles: The published literature on the validity and clinical utility of measuring the antibodies to infliximab (ATI) levels among patients treated with IFX agent is limited. The therapeutic effect of IFX and measuring of the drug and antibody levels were mainly studied for patients with inflammatory bowel disease (IBD). The search revealed one study on the development and validation of a HMSA test, two meta-analyses on the impact of anti-IFX among IBD patients, two observational retrospective studies on clinical utility of measuring the anti-chimeric antibody concentration (ACAC), as well two studies that compared different ELISA methods in their ability to detect ATI.The meta-analysis with more valid methodology, the validation study on the new Anser IFX (HMSA) test, and the larger observational study on the clinical utility of detecting ATI were selected for critical appraisal, Afif W, Loftus EV, Faubion WA, et al. Clinical utility of measuring infliximab and human anti-chimeric antibody concentrations in patients with inflammatory bowel disease. *Am J Gastroenterol*. 2010; 105: 1133-1139. See Evidence Table. Vande Casteele N, Gils A, Singh S, et al. Antibody response to infliximab and its impact on pharmacokinetics can be transient. *Am J Gastroenterol*. 2013; 108:962-971. See Evidence Table. Lee LY, Sanderson JD, Irving PM. Anti-infliximab antibodies in inflammatory bowel disease: prevalence, infusion reactions, immunosuppression and response, a meta-analysis. *Eur J Gastroenterol Hepatol*. 2012; 24:1078-1085. Nanda KS, Cheifetz AS, Moss AC. Impact of antibodies to infliximab on clinical outcomes and serum infliximab levels in patients with inflammatory bowel disease (IBD): a meta-analysis. *Am J Gastroenterol.* 2013; 108:40-47. See Evidence Table. Wang SL, Ohrmund L, Hauenstein S, et al. Development and validation of a homogeneous mobility shift assay for the measurement of infliximab and antibodies-to-infliximab levels in patient serum. *J Immunol Methods*. 2012; 382:177-188.

The use of Homogenous Mobility Shift Assay (HMSA) (Anser TM IFX test) for Infliximaub Antibodies does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Prometheus IBD sgi Diagnostic

10/17/2017: MTAC REVIEW

Evidence Conclusion: Analytic validity: No studies were identified **Clinical validity:** One study (Lawrence et al., 2015) with low evidence was reviewed. Fifty patients with symptoms of IBD and glycogen storage disease (GSD) type Ib were enrolled consecutively. Of 50 patients who were screened using Prometheus IBD, 11 (22%) tested positive for IBD. Of 11 patients who tested positive, 5 were Crohn's Disease, 5 were ulcerative colitis, and one was non-IBD. However, the major limitations included the sample size, lack of reference test (no test had been performed to confirm the diagnosis of IBD), non-randomized design of the study. **Clinical utility:** No studies were identified.

Conclusion:

- No studies assessing analytic validity or clinical utility were identified
- Only one study with non-randomized design and small sample size assessed clinical validity
- There is insufficient evidence to support for or against the use of Prometheus IBD sgi Diagnostic test for patients who present with symptoms of IBD

Articles: The search yielded 18 articles, none of which were relevant except one study (Lawrence, Chengsupanimit, Brown, & Weinstein, 2015) with low evidence.

The use of Prometheus IBD sgi Diagnostic does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met (Anser antibody levels for infliximab or adalimumab):

CPT® or HCPC Codes	Description
84999	Unlisted chemistry procedure

Considered Not Medically Necessary when requested/submitted as a panel (IBD sgi Diagnostic Test):

CPT® or HCPC Codes	Description
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
82397	Chemiluminescent assay

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86140	C-reactive protein;
88346	Immunofluorescence, per specimen; initial single antibody stain procedure
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
81479	Unlisted molecular pathology procedure

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Creation Date	Date Reviewed	Date Last Revised
12/03/2013	12/03/2013[MPC],1/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	02/02/2021

[MPC] Medical Policy Committee

Revision History	Description
05/02/2017	Adopted KPWA medical policy for Medicare members
06/06/2017	MPC approved medical necessity criteria for Anser Antibody testing
02/06/2018	Added MTAC review for Prometheus IBD sgi Diagnostic
02/02/2021	Added Medicare/Noridian LCD and LCA for IBD sgi Diagnostic Test

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Clinical Review Criteria
Home INR Monitoring

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11).
Local Coverage Determinations (LCD)	None
Local Coverage Article	Home PT/INR Monitoring (G0249) Billing and Coding (A55756)

For Non-Medicare Members

Kaiser Permanente has elected to use the Prothrombin Time (INR) Home Monitoring Device (A-0650) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Documentation of initial start date for warfarin
- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedics, cardiology)

Home testing is usually not recommended for a frequency of more than once a week.

Additional software or hardware required for downloading data from home prothrombin time testing systems to computers for the management of anticoagulation will not be covered because each is considered a convenience item and not medically necessary.

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Background

Oral anticoagulation (OAC) therapy is used for the prophylaxis and /or treatment of thromboembolic complications of deep vein thrombosis, embolic stroke, pulmonary embolism, cardiac valve replacement, and atrial fibrillation, as well as postmyocardial infarction. The aim of the therapy is to maintain a level of anticoagulation that will prevent thromboembolic events without increasing the risk of hemorrhagic complications. Warfarin is an oral anticoagulant that interferes with the cyclic interconversion of vitamin K which in turn leads to depletion its dependant coagulation factors including prothrombin. It is estimated that more than a million patients are treated annually with warfarin in the USA (Koerner 1998).

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In the USA, almost 40,000 mechanical heart valves are implanted annually. Mechanical valves are associated with a risk of thrombus formation and emboli. This risk is reduced by lifetime treatment with oral anticoagulants. Biologic implants on the other hand, have a lower thrombogeneity and do not require long-term anticoagulation. Thromboembolism, together with anticoagulant-induced hemorrhage, account for three fourths of all complications after mechanical heart valve replacement. These events were found to be associated with the intensity of oral anticoagulation therapy and fluctuation of international normalized ratio (INR) values. (Edmunds 1987).

Atrial fibrillation (AF), a common arrhythmia, is a leading cause of thromboembolism. It is common among the elderly, and its prevalence increases with age (1% among 60-year-old population, 5% among those aged 70-75 and >10% for 80+ years patients. (Ezekowitz 1999). The incidence of ischemic stroke among these patients may be as much as six times higher than among others with no AF. Studies show that oral anticoagulants significantly reduce the rate of stroke among AF patients (Eldor 2002). However, older patients treated with OAC have a higher rate of bleeding mainly due to the slower metabolization of the drug, and its interaction with other underlying chronic health problems. These patients should thus have better monitoring, and more rigorous regulation of the OAC to optimize their therapy, and prevent intracerebral hemorrhages, and other bleeding complications.

The intensity of anticoagulation treatment also needs to be controlled closely due to the narrow therapeutic range of warfarin, the potentially life-threatening effects of both over, and under-dosing, and its interaction with other drugs or foods like leafy green vegetables. Several other factors may affect the patients' response to warfarin control including compliance to therapy, underlying liver or kidney diseases, infections, diet, and others.

Oral anticoagulation therapy has been monitored for almost 50 years with the prothrombin time (PT) test. The test is easy to perform but its results may widely vary between institutions, and even within the same institution. In 1983 the WHO proposed the international normalized ratio (INR) in attempt to standardize PT measurements. The proposal was supported by the International Committee for Standardization in Hematology in 1985, and INR is the current standard for monitoring anticoagulation therapy. It is calculated as: INR= patient PT/mean normal PT). The recommended therapeutic INR range for oral anticoagulant therapy is 2.0-3.0 for the majority of indications. A higher range of 2.5-3.5 is recommended for patients with mechanical heart valves, and when therapy is recommended to prevent recurrent MI (Koerner 1998). Monitoring patients on OAC requires frequent testing, which in turn requires frequent venous punctures, and regular visits to a physicians' office or lab, as well as lab standardization. Patients on a stable OAC are seen every 4-6 weeks. It was found that at this rate of testing, 40-60% of the PT measurements fall in the desired therapeutic range (Hortskotte, 1998).

Patients using long-term OAC usually worry about complications, regular visits to the physician or lab, frequent venous punctures that may be difficult at times, dietary limitations, freedom at traveling, and other concerns that may affect their quality of life. There has always been an interest in developing an accurate faster and easier way to measure PT. Currently several monitors for finger stick testing of PT are available. These include CoaguChek, CoaguChek plus, ProTime Microcoagulation System, and Harmony INR Monitoring System. These monitors require only a finger stick whole blood rather than the citrated venous blood, and the patients can perform it at home. Among the other advantages of these systems is the immediate INR results, and convenience. In theory patient self-testing at home increases the duration when the patient is within the therapeutic INR range, increases compliance, and patient interaction with his physician, and allows better control of OAC, which in turn reduces morbidity and mortality.

Self-management or personal-self testing however is not suitable for everyone. Patients need to operate the machine, and self-sample blood, they have to be free from any major visual problems, tactile dysfunction, or severe tremors to be able to mechanically handle self-testing, they also have to be reliable and complying with the dosage algorithm.

After Joint Replacement Patients undergoing major orthopedic surgery; hip or knee arthroplasty, or hip fracture repair are in the highest risk category for venous thromboembolism (VTE) solely on the basis of the orthopedic procedure itself. Without prophylaxis, the rate of deep vein thrombosis or pulmonary embolism in these patients range from 40% to 84% and is the most common cause of death. It is thus recommended to use some type of prophylaxis for total knee replacement (TKR), total hip replacement (THR), and hip fracture surgery. The currently available methods of thromboprophylaxis include intermittent pneumatic calf compression, elastic compression stockings, or the use of pharmacological agents.

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Warfarin is the most commonly used pharmacological agent followed by low molecular weight heparin (LMWH). The American College of Chest Physicians (ACCP) recommends either adjusted-dose warfarin (INR range 2.0 to 3.0); started preoperatively or immediately after the hip or knee replacement, or SC LMWH therapy. The duration of thromboprophylaxis is controversial and varies widely between practices, ranging from 1-12 weeks postoperatively. Studies have shown a peak incidence of postoperative DVT two to three weeks after total hip arthroplasty. This, together with the shorter durations of hospitalization, extending the use of antithrombotic prophylaxis for up to 5 weeks is becoming more common (Schuringa 1999, Geerts 2001, Frederick 2003, He Xing 2008).

The intensity of anticoagulation treatment needs to be controlled closely due to the narrow therapeutic range of warfarin, its interaction with several other drugs and foods, and the potentially life-threatening effects of both over- and under-dosing of the drug. Monitoring patients on oral anticoagulation (OAC) therapy requires frequent testing, which in turn requires frequent venous punctures, laboratory standardization, and regular clinical visits.

There in an ongoing interest in developing a faster and easier way to accurately measure prothrombin time (PT). Currently several home testing systems have received FDA approval for use. These include CoaguChek, CoaguChek plus, ProTime Microcoagulation System, INRatio Prothrombin Time Monitoring System, Harmony INR Monitoring System, AcuSure, and Rubicon. These monitors may be used at home and only require a fingerstick whole blood rather than the citrated venous blood. They also give immediate INR results. In theory, patient self-testing at home increases the duration within the therapeutic INR range, increases compliance, patient interaction with his physician, and allows better control of OAC which reduces morbidity and mortality. Personal self-testing with or without self-management is however is not suitable for everyone. Patients have to be reliable and free from any major visual problems, tactile dysfunction, or severe tremors to be able to mechanically handle self-testing. They also have to comply with the dosage algorithm.

Medical Technology Assessment Committee (MTAC)

Home INR Monitoring

08/13/2003: MTAC REVIEW

Evidence Conclusion: Ideally the outcomes of randomized controlled studies for the effectiveness of a test should demonstrate its effect in altering treatment and improving the health outcomes. Two important health outcomes, bleeding and thromboembolism, were only studied in ESCAT (Kortke 2001), and time in the therapeutic range, an intermediate outcome, was used in all other studies. Kortke et al, in the ESCAT randomized controlled trial, followed 600 patients with mechanical heart valves for at least 2 years (25-51 months). They evaluated the event rates, as well as time in the therapeutic range. Less than 10% of the randomized sample took part in the 25-30-month follow-up. Patients in the self-management group had significantly less overall grade III complications (severe hemorrhage or thromboembolism) compared to those in the standard care group. The trial also showed that significantly more measurements were in the therapeutic range among patients in the self-management group. Sawicki's RCT in which 84% of the participants had heart valve replacement, also showed that a higher proportion of patients in the self-management group were within the INR target range compared to those in the routine care group. This difference was only statistically significant at three months of follow-up but not after six months. In Watzke's trial, 57% of the patients had mechanical heart replacement, and 24.5 % had atrial fibrillation. It also showed that a higher proportion of measurements among patients in the self-management group were in the therapeutic range vs. those in the standard care group, however the P value was not provided. Eldor's study on elderly patients with atrial fibrillation was too small, nonrandomized and had insufficient power to detect any difference between the groups. In conclusion there is some evidence that selected patients with mechanical heart valve replacement, who self-monitor their PT, and self manage their OAC therapy, have better control of their INR values, than those receiving a standard care. Only one trial with several limitations, showed some benefit in reducing the severe complications associated with OAC treatment. The other studies had insufficient sample sizes, and follow-up durations to study that outcome. It is worth noting that the studies were conducted among selected groups of patients and cannot be generalized to all patients with mechanical heart replacement. There is insufficient evidence to determine the effect of home INR monitoring on patients with atrial fibrillation.

Articles: The search yielded 28 articles. Many were reviews and tutorials. Abstracts, and studies conducted to evaluate the accuracy of the portable PT monitoring systems were not reviewed. The purpose of this review is assessing the home use of the monitors for patients with mechanical heart valves, or atrial fibrillation, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). There were three randomized controlled trials, and three non-randomized controlled studies on self-testing/home INR monitoring. Trials conducted among patients with mechanical heart valves, or atrial fibrillation were selected. *The following articles was critically appraised:* Kortke H, and Korfer R. International Normalized Ratio self-management after mechanical heart valve replacement: is an early start advantageous? *Ann Thorac Surg* 2001; 72:44-48. See

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Evidence Table Sawicki PT. A structured teaching and self-management program for patients receiving oral anticoagulation. A randomized controlled trial. *JAMA* 1999; 281:145-150. See Evidence Table Watzke H.H, Forberg E, Svolba G, et al. A Prospective Controlled Trial Comparing Weekly Self-Testing and Self-dosing with the Standard Management of Patients on Stable Oral Anticoagulation. *Thromb Haemost* 2000; 83: 661-665. See Evidence Table Eldor A, and Schwartz J. Self-management of oral anticoagulants with a whole blood prothrombin-time monitor in elderly patients with atrial fibrillation. *Pathophysiol Haemost Thromb* 2002; 99-106. See Evidence Table

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/01/2005: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: Ideally the outcomes of randomized controlled studies for the effectiveness of a test should demonstrate its effect in altering treatment and improving the health outcomes. Clinical endpoints for studies on self-management of anticoagulation therapy would be bleeding and thromboembolic complications. However, time within therapeutic INR range was used by some studies as a surrogate outcome to assess the quality of treatment based on self-management. In ESCAT I study (Koertke 2001) previously reviewed, 1,200 patients 6-11 days after a mechanical heart replacement were randomly divided into two groups: one monitored by family physicians, and the other controlling INR values at home. Patients were followed for at least 2 years (25-51 months) and the primary outcome was the rate of thromboembolic events and hemorrhage, and stability of INR values. Six hundred patients (50% of the randomized sample) were included in the analysis, dropouts and deaths were not included, and analysis was not based on intention to treat. The results of the trial showed that patients in the self-management group had significantly less overall grade III complications (severe hemorrhage or thromboembolism) compared to those in the standard care group. It also showed that significantly more measurements were in the therapeutic range among patients in the self-management group. ESCAT II study (Koertke 2003) was a large (N=3,300), multicenter RCT that randomized patients to two INR targets for self-management. The primary outcomes were the rate of thromboembolic events and hemorrhage, and the stability of INR values. It is an ongoing trial and the published articles only present the interim analysis with data on 55% of the total sample size. The investigators compared the results of the two INR targets for self-management in this trial and included data on thromboembolism and bleeding for the group controlled by general practitioner from ESCAT I study, which is not a valid comparison. ESCAT I was conducted years earlier, in a single center, and on a different group of patients. In this latter study, patients in the self-managed group had a higher mean INR value (3.0) compared ESCAT II study (2.8 for the conventional-dose INR, and 2.4 in the low-dose INR patients with aortic valve replacement). Overall, the interim results of ESCAT II study show that 72% to 74% of the patients in the low and conventional INR range, respectively, were within target range. The bleeding and thromboembolic rates were <1% in each of the two groups. There was no difference between them the in thromboembolic rates, and the difference in the bleeding rates did not reach statistical difference. There is no new evidence to determine the effect of home INR monitoring on patients with atrial fibrillation.
Articles: The search yielded 20 newer articles many of which were reviews and editorials. Studies conducted to evaluate the accuracy of the portable PT monitoring systems were excluded. The purpose of this review is to assess the home use of the monitors for patients with mechanical heart valves or atrial fibrillation, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). There were two publications on one large randomized controlled trial (ESCAT II) that compared two INR targets for self-management of anticoagulants after mechanical valve replacement, a small RCT that included patients with different indications for anticoagulation, and small case series with intermediate outcomes. SMART, a large ongoing trial on self-management of anticoagulation was also identified but no results were published to date. The ESCAT II trial was critically appraised: Kortke H, Minami K, Boethig, et al. INR self-management permits lower anticoagulation levels after mechanical heart valve replacement. *Circulation* 2003;108 II:75-78. Kortke H, Zittermann A, Minami K, et al. Low-dose International normalized ratio self-management: A promising tool to achieve low complication rates after mechanical heart valve replacement. *Ann Thorac Surg* 2005; 79:1909-1914.

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/07/2006: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: The previous MTAC reviews of home INR monitoring showed some evidence that selected patients with mechanical heart valve replacement who self-monitor and manage their OAC therapy, may have better control of their INR values, than those receiving standard care. All studies were conducted among selected groups of patients and the results might not be generalized to all patients with mechanical heart
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replacement. There was insufficient evidence to determine the safety and efficacy of home INR monitoring on clinically important outcomes as thromboembolic events, major hemorrhage, and death. There was also insufficient evidence to determine the benefit of home INR monitoring in patients with atrial fibrillation. Heneghan et al's recent meta-analysis (2006) assessed the effects of self-monitoring with/ or without or self-management of anticoagulation compared with standard monitoring. The meta-analysis had valid methodology, was well-conducted, and 10 out of the 14 studies it included were judged to be of good quality. The authors also performed a sensitivity analysis by excluding the studies with the lowest quality. However, the control groups in the trials received their routine care in different settings. The results of a recent meta-analysis (van Walraven, 2006) showed that the study setting has a major influence on anticoagulation control. Moreover, the majority of the trials included in Heneghan's meta-analysis, provided education and training sessions only to the patients randomized to self-testing, not to the entire study population. Education increases awareness, motivation, and may modify the patient's attitude and behavior. The education and training were given after randomization, and those who could not complete the training sessions or were incapable of self testing and/or self-management either left the study or were transferred to the routine care group. This resulted in a high dropout rate (20% to > 30%) in the intervention groups, and intention to treat analysis was not conducted in all the trials, which could overestimate the observed results. Ideally, training would be performed prior to randomization to eliminate those who are unable to complete it, and/or are incapable of self testing or self-management, from participating in the trial. The results of this meta-analysis indicate that the thromboembolic events, major bleeds, and death rates were significantly lower in the self-monitoring groups versus the controls who were managed by their personal physicians, anticoagulation management clinics, or managed service. Those who both self-tested and self-adjusted their therapy dose had significantly lower thromboembolic events and mortality rates but a non-significant reduction the rate of hemorrhage. The difference in thromboembolic event rates was not significant between the intervention and control groups in the pooled results of the 3 trials conducted among patients with mechanical heart valves. The authors did not report on the difference in major hemorrhage or death rate among these patients, and no subgroup analysis was provided for patients with atrial fibrillation. Kaiser Permanente INTC recalculated some of the results of Heneghan's meta-analysis using ITT analysis, and found no significant differences between the intervention and routine care group in the percent of subjects with a mean INR in the therapeutic range, and in the major hemorrhagic events in the self-management vs. those receiving care in AMS (anticoagulation management services). Fitzmaurice, et al's (2005) study was a relatively large, multicenter, randomized, and controlled trial. However, it had several limitations and potential biases. Less than 25% of the eligible patient agreed to participate in the trial and were actually randomized to the study groups. Training on self-testing was given after randomization and only to the intervention group not to the entire population, which resulted in a higher dropout rate (43%) in the self-management group compared to 11% of those in the routine care group. Those who were considered incapable of self managing withdrew from the trial or were returned to the routine care group. The study population who self-selected to enroll was younger and included more men than the eligible population. Moreover, participants in the intervention group tested their INR more frequently than those in the routine care group (mean every 12 days vs.38 days) group, and apparently received more care, which is another potential source of bias. Patients in the routine care group were managed in a variety of models including anticoagulation clinics, hospital outpatient clinics, and primary care clinics which may have an influence on their anticoagulation control, and outcomes. Overall the results of this RCT show no significant differences between the intervention and routine care groups in the percent of time spent within therapeutic INR range (primary outcome) or in the rates of serious bleeding, or serious thrombosis. Patients in a target INR of 3.5 had poorer control before and during the study compared to those with target INR of 2.5. However, patients in the intervention group with a 3.5 target INR showed a significant improvement between the pre-study and study periods. No such improvement was observed for those with a 2.5 INR target in either group, or those with a 3.5, target in the routine care group. These results of the Heneghan's meta-analysis and Fitzmaurice's RCT may not be generalizable to all patients treated with long-term oral anticoagulants. The study participants were highly motivated, mainly younger, willing to take and complete a structured training course on self-management, and capable of performing self-testing correctly and reliably.

Articles: The search revealed 7 newer randomized trials that were published after the last review, as well as a meta-analysis of RCTs that assessed the effects of self-monitoring or self-management of anticoagulation compared with standard monitoring. Only three of the recent RCTs were relevant (Fitzmaurice 2005, Voler 2005, and Menedez-Jandula 2005). The latter two were included in the meta-analysis. Studies conducted to compare two home INR monitors, or to evaluate the accuracy of the portable PT monitoring systems were excluded. The purpose of this review is to assess the home use of the monitors for patients receiving long-term anticoagulation treatment, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). Two ongoing trials were also identified: 1. Self-Management of Anticoagulation, a Randomized Trial (SMART) which is a large multicenter trial on self-management of anticoagulation and, 2. The Home INR Study (THINRS) with more than 400 patients from VA Medical Centers with atrial fibrillation and/or mechanical heart valve who are expected to be anticoagulated indefinitely. The trial compares anticoagulation (AC) management using home monitoring devices to high quality management implemented by an AC service. It will have a

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minimum of 2 years of follow-up, and the primary outcome is event rates (stroke, bleeding or death). Heneghan's (2006) meta-analysis and the RCT that was not included in the meta-analysis were critically appraised. Heneghan C, Alanzo-Coello P, Garcia-Alamino JM et al. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet 2006; 367:404-11.See Evidence Table Fitzmaurice DA, Murray ET, McCahon D, et al. Self-management of oral anticoagulation: randomized trial. BMJ 2005;331:1057- See Evidence Table

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/01/2008: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of home INR monitoring for thromboprophylaxis warfarin therapy post knee or hip replacement surgery. An ideal study would be a randomized controlled trial that compares health outcomes of home INR monitoring of the warfarin dose to routine monitoring in hospital or anticoagulation management services. The trial should address the effect of INR home monitoring on altering treatment and preventing thromboembolism without increasing bleeding risks. The only published study on home thromboprophylaxis with warfarin anticoagulation therapy after hip and knee replacement surgery was a case series that studied the efficacy of a program designed to maintain the prophylactic anticoagulant oral therapy within the target range. The patients did not monitor their own INR or adjust their own therapy. Instead it was coordinated between Home Care and community laboratory, and dose adjustments were made by the patient's family physician. Yet the program failed to achieve the target INR in almost 60% of cases during the six weeks postoperatively. Conclusion There is insufficient evidence to determine that: Home INR monitoring after joint replacement surgery increases the percentage of time spent within the therapeutic INR range, compared to routine care. Home INR monitoring, vs. routine care, after joint replacement surgery is effective in reducing the deep vein thrombosis and pulmonary embolic events rates, without increasing hemorrhagic events.
Articles: The search did not reveal any RCT that compared outcomes of monitoring of INR post joint replacement at home vs. in the hospital or anticoagulation management centers. There was only one published empirical study on the home prophylaxis with warfarin after hip and knee arthroplasty. Schuringa P, Yen D. Home prophylactic warfarin anticoagulation program after hip and knee arthroplasty. Can J Surg. 1999; 42:360-362. See Evidence Table.

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT or HCPC® Codes	Description
G0248	Demonstration, prior to initiation of home INR monitoring, for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient's ability to perform testing and report results
G0249	Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes: provision of materials for use in the home and reporting of test results to physician; testing not occurring more frequently than once a week; testing materials, billing units of service include four tests
G0250	Physician review, interpretation, and patient management of home INR testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include four tests

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/10/2002	01/05/2010 MDCRPC, 05/04/2010 MDCRPC, 03/01/2011 MDCRPC, 01/03/2012 MDCRPC, 11/06/2012 MDCRPC, 09/03/2013 MPC, 07/01/2014 MPC, 05/05/2015MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC, 09/04/2018MPC, 09/03/2019MPC, 09/01/2020MPC, 09/07/2021MPC , 09/06/2022MPC	09/01/2020

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/01/2020	Added Medicare LCA A55756

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Date Sent: 6/28/23
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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Home Pulse Oximetry – Rental for Home Use

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Oxygen and Oxygen Equipment (L33797) "Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment."
Local Coverage Article	Oxygen and Oxygen Equipment – Policy Article (A52514) "Oximeters (E0445) and replacement probes (A4606) will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the beneficiary's treatment."

For Non-Medicare Members

Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The pulse oximeter is a completely noninvasive device that provides a means of continuous and quick real-time estimates of arterial oxygen saturation (SaO_2). It has been validated relative to transcutaneous oxygen tension, and arterial blood gas measurement. (Fanconi, 1985). The device estimates arterial hemoglobin saturation by measuring the light absorbance of pulsating vascular tissue at two wavelengths. It is easy to use and interpret and does not need any special training or new skills on the part of the user. It also requires a little setup time and adds no risk to the patient.

Pulse oximetry is becoming a standard of practice during general anesthesia in the United States (Eichhorn, 1986). It is also used as an independent monitor in emergency rooms and intensive care units. Other clinical applications of the device include monitoring patients during transport, respiratory monitoring during narcotic administration, and the evaluation of home-oxygen therapy.
The pulse oximeter, however, has some limitations; it does not provide an early warning of decreasing arterial oxygen tension (PaO_2) and may fail to detect an inadvertent endobronchial intubation in the operating room. It also cannot distinguish more than two hemoglobin species in the blood; thus methemoglobin and carboxyhemoglobin will cause errors in the pulse oximeter saturation (SpO_2) if present in large amounts. Artifactual signals created by patient motion or external light may also create a technical problem and interfere with the device in estimating the oxygen saturation. It was also reported that circumstances that reduce the amplitude of finger pulsation e.g. hypothermia, hypotension, or the administration of a vasoconstrictive drug would adversely affect the accuracy of the device (Yelderman,1983).

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The home pulse oximeter is being reviewed due to several requests received by Clinical Review for coverage for adult patients with progressive pulmonary disease, pediatric patients with RVS, or patients being discharged home but requiring continued monitoring to ensure stability in the home.

Medical Technology Assessment Committee (MTAC)

Home Pulse Oximetry

10/08/2003: MTAC REVIEW

Evidence Conclusion: There are insufficient published studies to provide evidence on the home use of pulse oximeters among adults or children with respiratory failure or chronic pulmonary disease.

Articles: The search yielded 46 articles. A large number was not related to home monitoring of oxygen saturation, and a few addressed the home use of pulse oximetry for the diagnosis of sleep apnea. The search did not reveal any empirical study conducted among adults with chronic obstructive lung disease using a home pulse oximeter to monitor their oxygen saturation. The search revealed three small case series conducted among either healthy infants to assess their oxygen saturation during the first six months or among infants with bronchopulmonary dysplasia receiving home oxygen therapy. None of the studies was critically appraised.

The use of home pulse oximetry in the management of oxygen levels for adults or children with respiratory failure or chronic pulmonary disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medicare: considered not medically necessary
Non-Medicare: medical necessity review no longer required

CPT® or HCPC Codes	Description
E0445	Oximeter device for measuring blood oxygen levels noninvasively
A4606	Oxygen probe for use with oximeter device, replacement

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/08/2003	09/07/2010[MDCRPC], 07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 03/05/2013[MDCRPC], 01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC]	02/01/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Director Clinical Review and Policy Committee

Revision History	Description
02/01/2017	Medical necessity review no longer required for non-Medicare members.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Home Oxygen Therapy for Chronic Use

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Claims Processing Manual Chapter 20, Section 30.6, Oxygen and Oxygen Equipment
National Coverage Determinations (NCD)	Home Use of Oxygen (240.2) Home Use of Oxygen in Approved Clinical Trials (240.2.1)
National Coverage Analysis (NCA) – Decision Memo	Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2)
Local Coverage Determinations (LCD)	Home Use of Oxygen and Oxygen Equipment (L33797)
Local Coverage Article	Oxygen and Oxygen Equipment – Policy Article (A52514)

For Non-Medicare Members

Kaiser Permanente has elected to use the Home Oxygen (KP-0343) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider and/or specialist (palliative care, primary care, pulmonary care)
- Most recent Pulse Oximetry documentation and/or most recent at rest &/or activity log

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In 1986, Kaiser Foundation Health Plan of Washington experienced an increased use of home oxygen and could find no clinical evidence in patient charts that would support the use of oxygen. In addition, once a patient was placed on home oxygen, they were never re-tested to verify continued need of the treatment. In 1989, a task force was initiated to review use and develop clinical indications for use at Kaiser Permanente. The task force reviewed the current literature and adopted the Medicare home oxygen criteria. In addition, they defined several situations where exceptions would be appropriate. The program was initiated for review of all home oxygen requests, and to set up testing and re-testing programs. The program was submitted to Medicare for approval. Medicare not only approved it, but also adopted several of its most critical features such as the re-testing program.

Applicable Codes

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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E0447	Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 liters per minute (LPM)
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each
E1392	Portable oxygen concentrator, rental
E1405	Oxygen and water vapor enriching system with heated delivery
E1406	Oxygen and water vapor enriching system without heated delivery
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/15/1985	09/07/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 01/08/2013MDCRPC, 11/05/2013 MPC, 09/02/2014 MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC	03/01/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
03/01/2022	Updated applicable codes

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Date Sent: 6/28/23
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Hyperbaric Oxygen Therapy

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Hyperbaric Oxygen Therapy (20.29)
Local Coverage Determinations (LCD)	Oxygen and Oxygen Equipment (L33797)
Local Coverage Article	Oxygen and Oxygen Equipment (A52514)

*Note: It is clinically rare for a patient to require more than 40 hyperbaric treatments for any diagnosis. Requests for more than 40 treatments should be sent to the Medical Director for closer review.

For Non-Medicare Members

Hyperbaric oxygen may be indicated with a confirmed diagnosis of **ONE or more of the following**:

1. Chronic severe diabetic ulcer, and need for initial treatment, as indicted by **ALL of the following**:
   a. Severe wound defined by Wagner grading system, as indicated by **one or more of the following**:
      - Grade 3 Wagner ulcers are deep and involve abscess(es), osteomyelitis (bone infection) and/or joint sepsis
      - Grade 4 Wagner ulcers include gangrene (decay of body tissues) in the forefoot (anterior third of the foot) or heel region(s)
      - Grade 5 Wagner ulcers involve extensive gangrene **AND**

   b. There is a document plan for initial treatment, which includes **ALL of the following**:
      - Must have complete evaluation and treatment for any underlying peripheral vascular or neuropathic disease. To assess vascular status there must be a documented exam of femoral, popliteal, dorsalis pedis and posterior tibial pulses. If absent or reduced, must have documented ABI Scores. If questionable accuracy of ABI score, due to diabetes, a vascular surgeon consult is needed.

   c. Minimal to no healing present despite conventional wound treatment for minimum of 30 days, including **ALL of the following**:
      - Documentation of adequate diabetic control and most recent HbA1C
      - Pressure reduction or offloading for at least 8 weeks. (Must have documentation at each visit of the use (or of noncompliance) of walker boot, knee, scooter, or wheelchair)
      - Topical wound treatment. Need documentation regarding what specific products have been used, duration, and effectiveness (i.e., Apligraf, dermagraph, saline, hydrogels, hydrocolloids, alginates, or wound vac)
      - Appropriate wound debridement (practitioner must have appropriate training to perform) and

   d. Must have formal Infectious Disease consult and treatment for a minimum of 6 weeks for severe wound/bone infection

   e. Transcutaneous tissue oxygenation (PtcO2) levels of **one or more of the following**:
      1. PtcO2 of 25 mm Hg (3.3 kPa) or greater on room air
      2. PtcO2 value less than 25 mm Hg (3.3 kPa) on room air that meets **one or more of the following:**
         a. PtcO2 increase of more than 20 mm Hg (2.7 kPa) while breathing 100% oxygen via face mask at normal atmospheric pressure or

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   b. PtcO2 increase of greater than 200 mm Hg (26.6 kPa) in chamber during hyperbaric oxygen therapy
2. Chronic severe diabetic ulcer, and need for continued treatment, as indicated by **ALL of the following**:
   a. Adherent to hyperbaric oxygen therapy
   b. Documented evidence of improvement after 24 visits and need for continuing improvement after that point
   c. Plan for no more than 40 total treatments
3. Decompression illness or suspected intravascular gas embolism
4. Anemia, as indicated by **ALL** of the following
   a. Emergent anemia, as indicated by **1 or more** of the following
      - Active hemolysis with rapidly progressive anemia
      - Active massive hemorrhage
      - Severe signs or symptoms unresponsive to volume replacement (eg, tachycardia, hypotension, chest pain, cognitive impairment)
   b. Patient unable or unwilling to receive red blood cell transfusions
5. Carbon monoxide (CO) poisoning is unconscious and has a carboxyhemoglobin level over 40%
6. Cyanide poisoning, acute
7. Intracranial abscess
8. Central retinal artery occlusion
9. Gas gangrene (inpatient only)
10. Idiopathic sudden sensorineural hearing loss (will need 20 visits maximum)

    KP SSNHL GUIDELINES

    A. Patients presenting with mild to moderate HL:
       - Oral and IT steroid should be discussed with all patients.
       - Treatment should be initiated, if possible, within 2 weeks of onset.
       - Oral steroid alone should be recommended as initial therapy for mild to moderate HL within 2 weeks of onset but can be offered up to 6 weeks after onset.
       - IT steroid should be strongly recommended for salvage for oral steroid failure within 6 weeks of onset
       - Combo therapy (oral and IT steroid) should be recommended for those presenting more than 2 weeks after onset and within 6 weeks of onset.
       - HBO should not be offered unless there are medical contraindications to oral or IT steroid therapy or special situations ie only hearing ear.
       - Patients with > 25% drop in discrimination regardless of the severity of their pure tone loss should be treated as presenting with severe to profound HL patients

    B. Patients presenting with severe to profound HL:
       - HBO therapy combined with steroid treatment should be initiated within 2 weeks of onset if possible.
       - Combo therapy (oral and IT steroid) should be “strongly” considered within 6 weeks of onset.
       - IT steroid should be strongly recommended for salvage for oral steroid failure within 6 weeks of onset
       - HBO should not be considered routinely as isolated adjuvant initial or salvage therapy without steroid therapy unless there are medical contraindications to oral or IT steroid therapy or special situations ie only has one hearing ear and that is the ear which is affected by sudden hearing loss.

    C. Treatment:
       - Oral Prednisone should be 60mg for at least 7 days.
       - IT steroids should be Dexamethasone 10mg/ml up to 3 injections as needed. Treatment intervals – “weekly”
       - HBO: 100% at 2-2.5 ATA 10-20 Dives lasting 90 or 60 minutes.

    D. Audiogram:
       - Initial, after treatment start consider audiograms prior to additional interventions or if patient reports significant improvement, 6 months after last intervention.

    E. Ruling out Retro-cochlear Lesion:
       - MRI (or CT with contrast if MRI contraindicated) required to rule out retro cochlear lesion

    F. Routine Laboratory Testing:
       Not recommended
11. Clostridial and non-clostridial myonecrosis: Plan of care indicates use will be in conjunction with other medical/surgical therapies and will not interfere with or delay surgical debridement. (Provided for hospital inpatient only)
12. Necrotizing soft tissue infections (provided for hospital inpatient only)
13. Osteoradionecrosis as indicated by **ONE or more of the following**:

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a. Mandibular/maxillary osteoradionecrosis (diagnosis is typically made by a clinical exam with exposed bone, and/or by imaging). History of previous radiation therapy to the mandible or maxilla of at least 5,000-7,000 rads
b. Osteoradionecrosis in other sites, as an adjunct to conventional treatment. Osteoradionecrosis presents some months/years after radiation (sternum, long bones)
c. 30 pre/10 post treatments

14. Open or closed crush injury, compartment syndrome, or acute traumatic ischemias (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147240/)
15. Femoral necrosis (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147240/)
16. Skin grafts and flaps (compromised) (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147240/)
17. Soft tissue radionecrosis as an adjunct to conventional treatment: Typically, bowel, bladder, larynx or wounds in area of prior radiation therapy. Must wait 6 months post completion of radiation therapy. Requires visualization of the damaged area with serial exams to monitor progress (e.g., cystoscopy, laryngoscopy, sigmoidoscopy). Additional health plan review if 30 treatments are exceeded. (40 max). Total radiation dose and field must be documented. Must have **ONE of the following**:
    a. Radiation-induced proctitis diagnosed by sigmoidoscopy
    b. Radiation-induced hemorrhagic cystitis diagnosed by cystoscopy
    c. Radiation-induced head and neck soft tissue injury – soft tissue radionecrosis, typically of the larynx, or in a radiated field.
18. Dental extractions must meet **ALL of the following**:
    a. Clinical plan on file from the dentist/oral surgeon detailing planned extractions timeline
    b. History of at least 5,000-7,000 rads received to the teeth planned for the extraction
    c. Initial Request is for 20 treatments prior and 10 after the extractions. If the initial treatment of 20/10 was delivered within prior 5 years, then only 10 more treatments post extractions are required for any additional extractions done within 5 years but not pre-extraction)
19. Chronic refractory osteomyelitis, unresponsive to both conventional medical and surgical treatment. Must have a prior infectious disease consultation and at least 6 weeks of medical management and a surgical consultation regarding debridement. Any hardware should be removed if feasible. Not indicated for acute osteomyelitis. If involves a distal toe, requires physician consultation prior to auth. Any treatments beyond 30 should have physician consultation. Pelvic bone osteomyelitis from decubiti requires debridement and flap surgery and does not respond well to hyperbaric. For osteomyelitis associated with a diabetic foot ulcer, see I. above.

Hyperbaric oxygen pressurization is considered investigational in all other situations.

***Note: Topical application of oxygen (CPT A4575) does not meet the definition of HBO therapy and is considered investigational/not medically necessary in all cases. Also, its clinical efficacy has not been established.**

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multi-place chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999).

Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999).

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Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum which can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation).

Evidence and Source Documents

Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis
Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible
Hyperbaric Oxygen Therapy for Prophylaxis before Breast Surgery
Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis

Medical Technology Assessment Committee (MTAC)

Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis

BACKGROUND

Many types of cerebral cancer are treated with external beam, stereo tactically focused or implanted radiation. One of the most common and debilitating sequelae of high dose radiation is tissue destruction and necrosis. Radiation-induced necrosis (RIN) manifests itself as headache, ataxia, cranial nerve palsy, seizures, and visual loss. Necrotic tissue had historically been surgically re-sected when anatomically feasible or left untreated. One proposed method of treatment is the use of hyperbaric oxygen therapy (HBOT) which increases tissue oxygen concentration and may stimulate angiogenesis and establish a new blood supply to healthy cerebral tissue. Typically, hyperbaric oxygen is administered by placing patients into a whole-body hyperbaric chamber and exposing them to oxygen concentrations of 2 times normal atmospheric pressure for a period of 2-4 hours, once a day. Treatments are usually repeated usually 20-40 times with symptomatic improvement used as the measure of treatment success.

08/11/1999: MTAC REVIEW

Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis

Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1996-1999 using terms radiation necrosis, radiation injuries, cerebral necrosis and hyperbaric oxygenation. Dr. Kindwall, the author of a recent review, identified 2 case series (n=10, n=2) as the only published data on hyperbaric oxygen for treating **cerebral** radiation-induced necrosis. The Kaiser Permanente New Technology hotline staff was also unable to identify any additional literature reporting original data. Data from the case series of 10 patients, 8 of whom had biopsy-proven RIN, demonstrated that, with a median follow up of 7 months post HBOT, symptoms completely resolved in 1 patient, improved in 4 patients, did not get worse in 1 patient, and ended up worse in 4 patients. One patient developed ear pain from HBOT and had ear tubes placed and one developed sinusitis and discontinued treatment. Because this study was a case series rather than a randomized trial, it is not possible to determine whether hyperbaric oxygen therapy improves the clinical outcome of patients with radiation-induced cerebral necrosis beyond what would be expected with corticosteroid therapy alone. The best published scientific evidence on treating radiation induced cerebral necrosis with hyperbaric consists of a case series of 10 patients, 8 of whom had biopsy-proven RIN, demonstrated that, with a median follow up of 7 months post HBOT, symptoms completely resolved in 1 patient, improved in 4 patients, did not get worse in 1 patient, and ended up worse in 4 patients. One patient developed ear pain from HBOT and had ear tubes placed and one developed sinusitis and discontinued treatment. Because this study was a case series rather than a randomized trial, it is not possible to determine whether hyperbaric oxygen therapy improves the clinical outcome of patients with radiation-induced cerebral necrosis beyond what would be expected with corticosteroid therapy alone.
Articles: Chuba, PJ, et al, Cancer 1997;80:2005-2012

The use of hyperbaric oxygen does not meet *Kaiser Permanente Medical Technology Assessment Criteria.*

Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible

BACKGROUND

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multiplace chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999). Hyperbaric

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oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999). Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum that can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation). Osteoradionecrosis (ORN) of the mandible is a potential complication of head and neck irradiation. It is defined as a nonhealing, nonseptic lesion of bone (Clayman, 1997). The underlying cause of ORN is believed to be progressive vascular occlusion and tissue hypoxia after radiation treatment (Porter & Brian, 1999). Three types of ORN have been described. Type 1 occurs when a patient receives radiation therapy within 21 days of tooth extraction or mandibulotomy. Type 2 is induced by trauma. It generally occurs 3-6 years after radiation therapy, usually following a tooth extraction. Type 3 occurs spontaneously 6 months to 2 years after radiation therapy and is associated with higher radiation doses, neutron beam therapy and brachytherapy (Cronje, 1998). Hyperbaric oxygen therapy is generally accepted as a treatment for patients who have ORN. The use of hyperbaric oxygen therapy is also proposed as a prophylactic treatment before dental work to prevent ORN in patients who have had irradiation of the head and neck.

04/09/2003: MTAC REVIEW
Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible
Evidence Conclusion: There is weak evidence from one randomized controlled trial (Marx), published in 1985, that prophylactic hyperbaric oxygen treatment of patients with previous head and neck irradiation before tooth removal lowers the incidence of osteoradionecrosis of the mandible compared to patients treated prophylactically with penicillin. The Marx study had a small sample size (n=74) and the methodology was not well described, leaving open the possibility of threats to validity such as selection bias, inadequate randomization and biased assessment of outcomes. The results of the Marx study have not been replicated. Many factors may have changed since 1985 making the findings less relevant including different radiation protocols that alter the likelihood of developing ORN, better alternative prophylactic treatments and better treatments for patients with ORN. Recent authors have questioned the need for prophylactic hyperbaric oxygen treatment before dental surgery for all patients who have received head and neck radiation before dental surgery because the incidence of post-extraction ORN is relatively low and over half of the patients who do develop ORN heal after conservative treatment. The Marx study has also been criticized as including a particularly high-risk group of patients. The incidence of ORN in the Marx study was 30% in the penicillin-treated group compared to a 5.8% incidence in the general population of post-radiation tooth extraction patients and a lower incidence, 2.1% in studies conducted in the 1990s (Clayman, 1997).
Articles: The search yielded 35 articles. Many of the articles were reviews or opinion pieces, dealt with technical aspects of the intervention or addressed the treatment of osteoradionecrosis with hyperbaric oxygen rather than prophylaxis. No randomized controlled trials on prophylactic use of hyperbaric oxygen to prevent osteoradionecrosis were included in the search findings. However, an RCT published in 1985 was identified from the reference list of a review article. In addition to the RCT, there were several case reports and small case series (n<30 patients). The RCT was critically appraised: Marx RE, Johnson RP, Kline SN. Prevention of osteoradionecrosis: a randomized prospective clinical trial of hyperbaric oxygen versus penicillin. JADA 1985; 111: 49-54. See Evidence Table.

The use of hyperbaric oxygen in the prevention of osteoradionecrosis of the mandible does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hyperbaric Oxygen Therapy for Prophylaxis Before Breast Surgery
BACKGROUND
Breast cancer is the most common cancer in women, other than skin cancer, and the second leading cause of cancer death among them. According to the American cancer society, a woman has a 1 in 7 chance of having invasive breast cancer some time during her life. As of the 2004, there are slightly over 2 million women living in the USA who have been treated for breast cancer. Conservative therapy with lumpectomy, axillary dissection, and irradiation, is a frequently used option for treating early breast cancer. This allows the patient to keep her breast and reduce the physical and psychological trauma associated with the modified radical mastectomy. Radiation therapy is also indicated with mastectomy under certain conditions. In both cases, radiotherapy is given in a moderate to high dose and may be associated with mild to severe complications that might have negative influence on the health and quality of life. Among these complications are arm lymphedema, subcutaneous fibrosis, painful hardening of the breast, shoulder pain rib fracture, damage to the lungs and heart and others
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(Gothard 2003, Feldmeier 1995). These complications may be due to early reactions to radiation, or late effects that occur after at least 90 days after the start of treatment (Pasquier, 2004). Late injuries are irreversible and progressive in the majority of cases. These may cause cellular depletion, reduction in vascular density, fibrosis and atrophy all of which may result in hypoxia, and in turn delayed healing of the wounds. Conservative measures may be adequate for managing moderate cases with minimal necrosis, but cases of extensive necrosis are more challenging. Hyperbaric oxygen (HBO) was first used for the treatment of radiotherapy patients in the 1950s (Pasquier, 2004). It is defined as the breathing of pure oxygen at pressure exceeding the normal atmospheric pressure of 100 kPa that increases the solubility of oxygen in the blood. HBO treatment is administered within hyperbaric chambers, which are compressed by air (Plafki, 1998) Researchers indicate that hyperbaric oxygen therapy stimulates angiogenesis, osteogenesis, fibroblast activity, and collagen formation in irradiated tissues, which would increase the cellular level of oxygen. It has been reported that HBO therapy is associated with a low complication rate, but that there is uncertainty about the best time to start the treatment, and the number of sessions needed (Plafki, 1998). There is also uncertainty on the efficacy of the treatment for the different complications, what are its side effects, who would respond to treatment, and for which symptoms**.**

12/08/2004: MTAC REVIEW
Hyperbaric Oxygen Therapy for Prophylaxis Before Breast Surgery
Evidence Conclusion: There is no evidence to date on the prophylactic use of hyperbaric oxygen therapy before breast surgery in patients with prior radiation therapy. There is also insufficient evidence on the efficacy of HBO therapy in the treatment of late sequelae in women receiving radiation after breast-conserving surgery. The study reviewed was a case series that provide the least grade of evidence. It was small nonrandomized, and with potential selection and observation bias. The results of the study show that patients who received a hyperbaric oxygen therapy had a significant reduction of pain, edema, and erythema compared to those who refused the therapy. There was no significant difference between the groups in the improvement of fibrosis or telangiectasia.
Articles: The search yielded 35 articles. Many were review articles, dealt with technical aspects of the therapy, or the use of hyperbaric oxygen for the treatment of radio-induced lesions in different tissues and organs other than the breast. The search did not reveal any study on the use of Hyperbaric Oxygen Therapy for prophylaxis in breast surgery in patients with prior radiation therapy. There was one prospective case series with a control group on the use of hyperbaric oxygen for the treatment of late sequelae of radiation therapy after breast surgery, a smaller series of 21 patients and control group, and a retrospective review of 23 cases.
The case series with a control group was selected for critical appraisal. Carl UM, Feldmeier JJ, Schmitt, et al. Hyperbaric oxygen therapy for late sequelae in women receiving radiation after breast-conserving surgery. *Int J Radiat Oncol Biol Phys.* 2001; 49:1029-31. See Evidence Table.

The use of hyperbaric oxygen for prophylaxis before breast surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis
BACKGROUND
Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multiplace chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999). Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999). Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum which can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation). The treatment of gastrointestinal bleeding related to radiation enteritis is one possible application of hyperbaric oxygen therapy.

04/09/2003: MTAC REVIEW
Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis
Evidence Conclusion*:* There is no published evidence on the effectiveness of hyperbaric oxygen therapy for the treatment of gastrointestinal bleeding related to radiation enteritis.

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Articles: There were no published empirical studies. An abstract of a small case series (n=19) was identified in a review article. The abstract was presented at a professional meeting in 1998 and the study was not subsequently published.

The use of hyperbaric oxygen in the treatment of gastrointestinal bleeding related to radiation enteritis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session
HCPC Codes	**Description**
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval

Considered Not Medically Necessary - experimental, investigational or unproven:

HCPC Codes	Description
A4575	Topical hyperbaric oxygen chamber, disposable

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
09/1998	01/05/2010[MDCRPC], 11/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012 [MDCRPC], 06/04/2013 [MDCRPC], 04/01/2014[MPC], 09/02/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 01/09/2018[MPC], 07/10/2018[MPC], 11/06/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	03/08/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Director Clinical Review and Policy Committee

Revision History	Description
12/01/2015	Added one additional indication: treatment of central retinal artery occlusion
03/07/2017	Revised indication to dental extractions (part c)
08/06/2019	Revised criteria to include indications for open or closed crush injury, compartment syndrome, or acute traumatic ischemia's; femoral necrosis; skin grafts and flaps and added indication for dental extractions: Initial Request is for 20 treatments prior and 10 after the extractions. If the initial treatment of 20/10 was delivered within prior 5 years, then only 10 more treatments post extractions are required for any additional extractions done within 5 yrs. but not pre extraction
09/03/2019	MPC approved to adopt clinical indications for sudden hearing loss
07/07/2020	Removed Revenue code 413; Added Infectious Disease consult and treatment and medical management 6-week requirements
08/04/2020	MPC approved to adopt updates to clinical criteria for Non-Medicare-additional indications for anemia, cyanide poisoning and intracranial abscess. Requires 60-day notice, effective date 01/01/2021. Added Medicare LCA A52514.

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03/08/2021	Added clarifying language around Wagner grading system; also clarified requests will be limited to no more than 40 treatments, as well as sudden hearing sensorineural hearing loss

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Clinical Review Criteria
Intradiscal Electrothermal Therapy (IDET)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Thermal Intradiscal Procedures (150.11) This service is not covered per Medicare criteria.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Thermal Intradiscal Procedures (A-0217) MCG* for medical necessity determinations. This is not covered per MCG. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (neurosurgeon, neurologist, physiatrist, pain specialists, orthopedic spine surgeon)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Intradiscal Electrothermal Therapy (IDET) is a minimally invasive procedure that was developed as a treatment for lumbar discogenic pain. It aims to reduce the symptoms of the disrupted disc by thermocoagulating annular tissue and contracting collagen fibrils. The SpineCATH™ Intradiscal Catheter delivers thermal energy to the posterior annulus via a resistive heater coil. The annulus is comprised of Type I and II collagen fibers, which are held together by hydrogen bonds in a triple helix formation. It has been shown that these bonds break when heated to 60°C to 75°C is applied to the tissue. After being heated to the optimum temperature the collagen fibers contract and thicken. Following thermal contraction, collagen tissue undergoes a remodeling or regeneration process. Remodeling includes fibroblast in-growth and proliferation as well as new collagen formation in the treatment areas. The treatment is performed on an outpatient basis, under fluoroscopy.

IDET (SpineCath, Smith and Nephew) received FDA approval for the “coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs” (DHHS, letter 8/17/2001). It does not appear to be approved for other types of low back pain.

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Medical Technology Assessment Committee (MTAC)

Intradiscal Electrothermal Therapy (IDET)

10/11/2000: MTAC REVIEW

Evidence Conclusion: The study reviewed has a number of limitations including a small sample size, lack of a control group, potential selection bias, potential placebo effects, and the absence of significant improvements in outcomes after 6 months. Given the lack of peer-review studies and the limitation of this case series, the effectiveness of IDET for chronic back pain cannot be determined at this time.
Articles: Articles were selected based on study type. The only article found was a case series. A review article was reviewed, but no evidence table was created. *The articles selected for critical appraisal include:* Saal et al. Management of chronic discogenic low back pain with a thermal intradiscal catheter: A Preliminary Report. Spine 2000; 25:382-388. See Evidence Table
The use of Intradiscal Electrothermal Therapy (IDET) in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* (fails criteria 2 for effectiveness).

07/14/2004: MTAC REVIEW
Intradiscal Electrothermal Therapy (IDET)
Evidence Conclusion: The only published RCT on the effectiveness of IDET for discogenic low back pain (Pauza) does not provide strong evidence that IDET provides a clear clinical benefit to patients. In the *per protocol* analysis of 6-month follow-up data, the difference in the pain scores between the IDET and sham treatment groups just reached statistical significance (p=.045). Physical functioning measured by the SF-36 did not differ significantly between groups and the difference in the Oswestry disability scale did not attain statistical significance (p=.050). In the intention to treat analysis, there was a significant difference between groups in the proportion of patients who experienced >75% pain relief. The NNT=7 with a wide confidence interval, 95% CI=3 to 138 and there was no significant difference in the proportion of patients experiencing >50% pain relief. The sample size and length of follow-up were insufficient for quantifying any adverse effects of the treatment.
Articles: The search yielded 29 articles. There was one randomized controlled trial (Pauza) and this was critically appraised. There were also three case series with longer follow-up than the RCT and a cohort study. The other studies were not critically appraised because higher-grade evidence was available. The RCT reference was: Pauza KJ, Howell S, Dreyfuss P et al. A randomized placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. *The Spine Journal* 2004; 4: 27-35**.** See Evidence Table.

The use of Intradiscal Electrothermal Therapy (IDET) in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* (fails criteria 2 for effectiveness).

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/17/2000	05/3/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013MDCRPC,	05/05/2020

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	03/04/2014[MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/17/2016	Added NCD
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
05/05/2020	Removed non-applicable code S2348

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
I MIBG Imaging for Heart Failure

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"**IMIBG Imaging for Heart Failure**"** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Heart failure (HF) is a complex clinical syndrome responsible for high morbidity and mortality in the world. The prognosis of HF remains poor and its burden on mortality, reduced quality of life, and healthcare cost is increasing across the world. The goals of HF treatment are to improve symptoms, slow the progression of the disease, and prolong survival (Martins da Silva 2013, Perrone-Filardi 2011, Nakou 2013, Jain 2014).

Treatment options for HF include medications, devices, and nonpharmacological interventions. Drug therapy for chronic heart failure including B-adrenergic blockade, vasodilators, angiotensin converting enzyme (ACE), inhibitors, mineralocorticoid receptor antagonists, and diuretics can relieve symptoms and/or improve survival. Devices as cardiac resynchronization therapy may improve outcomes in some patients with NYHA class II-IV heart failure, and implantable cardioverter defibrillators (ICDs) can reduce the risk of sudden cardiac death in patients with HF and reduced left ventricular ejection fraction (LVEF). However, these devices are not beneficial to all patients, are costly, and have potential significant complications. It is thus essential to identify the patients who are more likely to benefit from intensive therapies, and those among whom devices such as ICD are not indicated (Nakou 2013, Gupta 2014, Nakajima 2014).

Heart failure is characterized by sympathetic nerve hyperactivity (up to 50 times more active than normal), which serves as a compensatory mechanism for the cardiac dysfunction associated with HF. The increased sympathetic response is initially favorable to maintain the systemic hemodynamics and peripheral circulation. However, long-lasting and excess stimulation of sympathetic nerve function leads to deleterious consequences including

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myocardial remodeling, reduced LVEF, and electrical instability which increase the likelihood of arrhythmia and sudden cardiac death (SCD) (Martins da Silva 2013, Jacobson 2010, Nakata 2013, Treglia 2013).

Researchers found that persistent stimulation of sympathetic nerve function in failing hearts impairs the efficiency of reuptake, turnover, and storage of norepinephrine (NE) at presynaptic nerve endings, resulting in spill-over and deficiency in NE stores leading to a decline in the myocardial sympathetic innervation. On this pathophysiological basis, it was suggested that the assessment of the degree of sympathetic activation of the heart can potentially be an indicator of the severity of the disease process and provide an insight to the prognosis of a patient with HF. This has led to the development of radiotracers for single-photon computed tomography (SPECT) and positron emission tomography (PET) (Martins da Silva 2013, Nakata 2013, Gupta 2014).

Guanethidine is a false neurotransmitter that is taken up by the uptake pathway for NE into presynaptic terminal. Chemical modification and labeling with radioactive iodine produce metaiodobenzylguanidine (123I-MIBG), an analog of NE that permits the visualization of adrenergic innervation in vivo. After depolarization MIBG is released into the synaptic cleft similar to NE, but unlike NE it is not metabolized by monoamine oxidase (MAO) or catechol-o-methyl-transferase (COMT), leading to higher cytoplasmic concentration that permits scintigraphic imaging in early and delayed phases (Treglia 2013, Gupta 2014).

The conventional protocol for scintigraphic myocardial imaging involves the injection of 123I-MIBG intravenously at rest after which early (from 10-30 minutes after administration) and delayed (3-4 hours after administration) images are obtained. The planar images with anterior view are adequate for evaluating cardiac sympathetic function. Tomographic images (SPECT) are often acquired to evaluate the regional myocardial uptake pattern. The most common semi-quantitative indices used for interpreting the images are the heart to mediastinum ratio (H/M) and washout rate (WR) obtained from the anterior planar images. Regions of interest are set in the heart (H: target region) and the mediastinum (M: background region) to obtain a mean count at each region. H/M ratio is calculated, and the degree of accumulation evaluated based on the resulting ratio. The WR is an index that indicates the rate at which MIBG is washed out between the early and delayed images through comparison with the cardiac count in the early image. This may reflect turnover of catecholamines attributable to the sympathetic drives and measures the ability of the myocardium to retain. MIBG normal values for these are derived from control patients and may differ between institutions (Treglia 2013).

Medical Technology Assessment Committee (MTAC)

I MIBG Imaging for Heart Failure

10/20/2014: MTAC REVIEW

Evidence Conclusion: AdreView Myocardial imaging for Risk Evaluation in Heart Failure (ADMIRE-HF., Evidence table 1), was the pivotal study that led to the recent FDA approval of 123I-MIBG use in HF patients) was a large, observational, multicenter study that evaluated the prognostic value of123I-MIBG in HF patients. 961 participants with NYHA class II/III HF and LVEF <35% underwent 123I-MIBG myocardial perfusion imaging and were followed for a maximum of 2 years to assess the primary composite endpoint of HF progression necessitating hospital admission, life-threatening arrhythmic event, and cardiac death. During a median of 17 months of follow-up (range 2 days-30.4 months), 237 first cardiac events were observed. The analysis of the results suggests that H/M ratio <1.6 was most discriminative for identifying patients at higher risk of the composite endpoint and each of its components. Patients with H/M >1.60 had a significantly lower risk of cardiac events (HR 0.40; 95% CI, 0.25-0.64), lower rate of HF progression, lower rate of arrhythmic events, and higher 2-year survival rates. The incidence of cardiac death was <1% per year in patients with H/M >1.6 and 9.6% per year among those with H/M <1.6. The results also showed that late H/M ratio provided additional information to that of plasma BNP and LVEF for identifying patients at greater risk of cardiac events. The other parameters of the 123I-MIBG imaging (early H/M and washout rate (WR) were also associated with risk for cardiac events, but late H/M ratio was the only one with independent prognostic value. A subsequent retrospective analysis of the ADMIRE-HF (Shah 2012) suggests that 123I MIBG has prognostic value across the spectrum of LVEFs. Verschure D et al, 2014 (Evidence table 2) conducted a meta-analysis of individual patient data from 6 studies incorporating 636 chronic HF patients (599 from Europe and 37 from the USA) to determine the most appropriate prognostic endpoint for 123I-MIBG scintigraphy in patients with chronic heart failure. The primary outcomes were all-cause mortality, cardiac mortality, arrhythmic events, heart transplantation, and a composite outcome of all listed events. Overall, the results of the pooled analysis indicate that late H/M was an independent predictor for all outcomes studies except for arrhythmias. The lower late H/M is associated with higher risk. LVEF was also found to be an independent predictor for these events. The analysis did not examine whether MIBG has an incremental prognostic value over other independent variables. The etiology of HF i.e. ischemic vs. non-ischemic was not an independent predictor in the multivariate analysis for any of the outcome events. The meta-analysis had the advantage of including patient data from longitudinal studies, however, the authors did not evaluate the quality of

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the studies included, did not test for homogeneity or publication bias, or do a sensitivity analysis. The analysis did not include the Japanese studies or the ADMIRE-HF study. In addition, there were variations between the studies included in the technical aspects of the procedure as regards the collimator selection, and method used to measure the myocardial uptake.
Nakata T, Nakajima K. and colleagues (2013, Evidence table 3) pooled data from six prospective cohort studies conducted in Japan from 1990 to 2009. The studies enrolled a total 1,322 patients with chronic HF, the mean follow-up duration was 78 months, and the five-year outcomes were available for 933 patients. The five-year cardiac deaths were determined by the original study investigators. Multivariate analysis was performed using the variables age, gender, early H/M, late H/M, MIBG washout rate, NYHA functional class, LVEF, history of diabetes, hypertension, dyslipidemia, atrial fibrillation, sustained ventricular tachycardia, and medications used. BNP data was available for only 512 patients. The results of the analysis indicate that survival rates decreased with decreasing H/M independent of other markers as NYHA class, BNP, and LVEF. All-cause mortality progressively decreased with increasing H/M ratio. Based on the ROC curve, a late H/M ratio threshold of 1.68 identified patients at a significantly higher mortality. This analysis only included data from studies conducted in Japan, and the H/M values as well as the results may not be generalized to other geographic areas using other methodologies or in populations with different characteristics. Pooled results of two earlier meta-analyses (Verberne H et al, 2008 et al and Kuwabara Y et al, 2011) also suggest that HF patients with reduced late H/M ratio or increased 123I-MIBG washout rate (WR) have a higher incidence of cardiac events compared to those with normal or relatively preserved uptake and washout rates. Incremental value of myocardial sympathetic innervation imaging with 123I-MIBG in heart failure patients Jain K and colleagues (2014) used data from ADMIRE-HF to assess the performance of four HF risk models (EFFECT, CARE-HF, MADIT-II and PACE) for predicting the composite clinical endpoint of cardiac death, progressive HF, or life-threatening arrhythmia. They then quantified the incremental prognostic utility of H/M ratio 123I-MBG imaging when added to each of the individual models. The results of the analysis suggest that H/M ratio >1.6 was consistent with the other models in identifying patient at lower risk of cardiac events, and that the addition of H/M to EFFECT, CARE-HF, MADIT-II and PACE models improved their discrimination by 33%, 59%, 49% and 37% respectively. These results, however, have to be interpreted with caution as it was derived from post-hoc evaluation of risk factors in ADMIRE-HF study. It may be limited to the characteristics of the participants included as well as the limitations in the observational study design.
Ketchum E, et al (2012) also used survival data from 961 NYHA II-III subjects in the ADMIRE-HF trial to investigate the incremental value of MIBG cardiac imaging when added to the Seattle Heart Failure Model (SHFM) for prediction of all-cause mortality. The results of the analysis showed that the addition of H/M to the SHFM in a Cox model significantly improved risk prediction (P<0.0001), with a greater utility in higher risk SHFM patients. The net reclassification improvement (NRI) was 22.7% (P<0.001), with 14.9% of subjects who died reclassified into a higher risk category than suggested by SHFM score alone (P=0.01) and 7.9% of subjects who survived reclassified into a lower risk category (P<0.0001). The 1-year area under the receiver-operator curve showed significant improvement for the combined model with H/M compared to the SHFM alone. Nakajima K, Nakata T, and colleagues (2014) used the same database (created By Nakata et al, 2013) to create a model for predicting fatal cardiac events by adding information from MIBG imaging. Nakata et al's pooled analysis included data for 1,322 chronic HF patients enrolled in cohort studies performed in Japan from 1990 to 2009. Prediction models were created with single and multiple variables to calculate cardiac mortality. Net reclassification improvement (NRI) analysis was based on prediction models with and without H/M ratio. The five-year risk levels were defined as low (<5%, corresponding to 1% mortality /year), intermediate (5-25%) and high (>25% corresponding to 5% mortality /year). For 5 years 205/933 patients (22%) died of a cardiac event. A multivariate analysis showed that age, gender, NYHA functional class (highest OR and X2 values), LVEF, and late MIBG H/M were significant predictors for 5-year cardiac mortality. The calculated ROC AUC (area under receiver operator curve) was 0.749 with the first 4 variables, and 0.780 after the addition of H/M (p=0.0015 for difference). The authors performed NRI analysis by the combination of age, gender, NYHA functional class and LVEF (model 1) and with the addition of late H/M (model 2). Patients who died with cardiac events were classified into the 3 risk levels according to the 2 models. The results indicate that classification was improved in 23 patients and made worse among 13 in model 2 vs. model 1. The net gain in classification was 4.9% (p=0.096). Of those who did not die of a cardiac event 38 were classified upwards and 103 downward with a net gain in classification of -9.0% (p<0.0001). This indicates that the addition of H/M is significantly improved the identification of patients at lower risk of cardiac death, i.e. it is more useful for reclassifying patients downwards to lower risk groups. This latter finding is contradictory to that observed in ADMIRE-HF study and the Ketchum and colleagues' analysis where MIBG was more effective in reclassifying patients upwards. The authors explained that this might be due to the differences between the Japanese trials and the ADMIRE-HF (USA and Europe) study. Participants in the Japanese trials were overall healthier as regards their NYHA functional class, LVEF level, higher prevalence of non-ischemic HF, and lower overall mortality. The mean H/M values were 1.71 in ADMIRE-HF, and 1.44 in the Japanese trials, which as the authors explained may be related to the technical differences between the imaging equipment in Japan vs. gamma cameras in the US and Europe. The study had its limitations as data were
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compiled from a number of studies conducted as early as 1990, with some variations in the population included, medication used, and MIBG imaging techniques. Its results need to be validated in prospective large studies. Clinical Utility of myocardial sympathetic innervation imaging with 123I-MIBG in heart failure patients. There are no published randomized controlled trials to date that directly evaluated the benefit of 123I-MIBG imaging as an aid to clinical management of HF patients. A number of published studies evaluated the use of MIBG scintigraphy in monitoring improvement in sympathetic activity in HF patients treated with vasodilators and beta-blockers. Treatment decisions and selection therapy were not based on the results of MIBG imaging and thus may not be the right study design to evaluate the effect of the test on the management decisions and/or patient outcomes. Conclusion: There is fair evidence from a number of observational studies and pooled analyses that 123I imaging of patients with heart failure and low LVEF may have an independent predictive value for estimating their risk of fatal cardiac events. There is some evidence from three analyses that H/M may have an additive (incremental) value to other risk models used for predicting cardiac mortality in patients with HF and low LVEF. There is insufficient evidence, to date, to determine that 123I-MIBG imaging of patients with heart failure and low LVEF impacts the management plan and/or improves patient outcomes. The review of the technology conducted Blue Cross Blue Shield Association, Kaiser Permanente. TEC program in April 2014 came to similar conclusions that there is evidence that myocardial MIBG innervation imaging provides prognostic information for cardiac events, and that there is a lack of evidence that the prognostic information will lead to improved health outcomes.
Articles: The literature search revealed over 200 articles on 123I-MIBG sympathetic imaging, many of which were unrelated to the current review. There were a number of published studies that examined the prognostic value of 123I-MIBG imaging of patients with HF. The studies include the pivotal ADMIRE-HF study that led to the FDA approval of using 123I-MIBG sympathetic imaging for patients with HF. The results of many of these published studies were pooled in four systematic reviews (Verberne et al, 2008, Kuwabara et al, 2011 [Japanese studies only], Nakata et al. 2013, and Verschure et al 2014 [European and USA studies]). Two subanalyses from the ADMIRE-HF study examined the ability of 123I MIBG in predicting the arrhythmic events and hospitalization in subpopulations were recently published (Sood et al 2013, and Parker et al, 2014). The search also identified the recent assessment of 123I-MIBG sympathetic imaging by Blue Cross Blue Shield Association, Kaiser Permanente. Technology Evaluation Center (TEC) Assessment Program. The literature search did not identify any trial that evaluated the clinical utility of the 123I-MIBG sympathetic imaging in heart failure patients, i.e. the impact of the test results on the management of patients. Treglia and colleagues 2013, reviewed studies that used the 123I MIBG to evaluate the effectiveness of different pharmaceutical agents in patients with HF. These studies did not actually examine the clinical utility of the test as the title of the review implies, as the management of the patients or selection of pharmaceutical agents were not based on the test results. The most recent pooled analyses (published after the TEC review) as well as the ADMIRE-HF study were selected for critical appraisal. Jacobson AF, Senior R, Cerqueira MD, et al. Myocardial iodine-123 meta-iodobenzylguanidine imaging and cardiac events in heart failure. Results of the prospective ADMIRE-HF (AdreView Myocardial Imaging for Risk Evaluation in Heart Failure) study. J Am Coll Cardiol. 2010;55 (20): 2212-2221. See Evidence Table 1 Verschure DO, Veltman CE, Manrique A, et al. For what endpoint does myocardial 123 I-MIBG scintigraphy have the greatest prognostic value in patients with chronic heart failure? Results of a pooled individual patient data meta-analysis. Eur Heart J Cardiovasc Imaging. 2014 Sep;15 (9): 996-1003. See Evidence Table 2. Nakata T, Nakajima K, Yamashina S, et al. A pooled analysis of multicenter cohort studies of (123) I-mIBG imaging of sympathetic innervation for assessment of long-term prognosis in heart failure. JACC Cardiovasc Imaging. 2013;6 (7):772-784. See Evidence Table 3.

The use of I MIBG Imaging for Heart Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/28/2014	11/04/2014 [MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC]	09/08/2015

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008

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Clinical Review Criteria
Implanted Infusion Pumps

For Insulin Pumps See Separate Criteria

- Intra-Arterial Infusion Pump
- Intraspinal Pump
- Intrathecal Pump

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Infusion Pumps (280.14)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Implanted Infusion Pump for Chronic Pain (A55323)

For Non-Medicare Members

The following criteria must be met for each specific type of treatment:

1. Chemotherapy for Liver Cancer must meet **ALL of the following**:
   a. Is receiving intra-arterial infusion of 5-FUdR for the treatment of liver cancer.
   b. Must meet **ONE of the following**:
      - Liver cancer for patients with primary hepatocellular carcinoma.
      - Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) the patient refuses surgical excision of the tumor.

2. Anti-Spasmodic Drugs for Severe Spasticity must meet **ALL of the following**:
   a. Use to administer anti-spasmodic drugs intrathecally (e.g., baclofen).
   b. The patient has chronic intractable spasticity with a baseline average Ashworth Scale* score of at least 3 (or a Modified Ashworth Scale* score of 2), and a Spasm Frequency score** of at least 2.
   c. The spasticity is unresponsive to less invasive medical therapy as determined by the following criteria:
      - A 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects.
      - The patient has responded favorably to a trial intrathecal dose of the anti-spasmodic drug, e.g., demonstrates at least a 2-point reduction in the Ashworth Scale or Spasm Frequency score for 4 hours following an intrathecal bolus of baclofen.

   *Ashworth and Modified Ashworth Scale (scale appears in middle of document)
   **Spasm Frequency Score

3. Opioid Drugs for Treatment of Chronic Intractable Pain must meet **ALL of the following**:
   a. Used to administer opioid drugs intrathecally or epidurally.
   b. Patient has severe chronic intractable pain of malignant or nonmalignant origin with a life expectancy of at least 3 months.
   c. Patient agrees to a 50% reduction in systemic opiates prior to undergoing an intrathecal opiate trial.
   d. Are proven unresponsive to one or more of the following less invasive medical therapies:

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- Trial of neuropathic pain medication
- Trial of nonsteroidal anti-inflammatory drugs (NSAIDs)
- Trial of physical therapy
- Trial of behavioral health treatments (e.g., CBT, ACT)
- The patient's history indicates that he/she would not respond adequately to non-invasive methods of pain control, such as systemic opioids (documentation should include attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain)

e. No acute psychiatric instability or uncontrolled suicide risk
f. No diagnosed substance-related disorder (other than nicotine) or patient currently receiving active treatment for disorder
g. A preliminary trial of intraspinal opioid drug administration has been undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (i.e. patient has experienced > 50% reduction in pain and concomitant increase in function) and patient acceptance.

In addition to meeting the appropriate above criteria the patient does not have one of the following contraindications:
1. A known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
2. An infection;
3. Body size at the implant site is insufficient to support the weight and bulk of the device;
4. Other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

If requesting this service, please send the following documentation to support medical necessity:
- Last 3 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Implantable pumps are designed to provide a continuous infusion of medication to a specific body site. The pumps are used with morphine for malignant pain management, and the drug 5-FUdR for liver cancer chemotherapy and Baclofen for intractable spasticity.

About two-thirds of metastatic cancer patients experience moderate-to-severe pain (Smith et al., 2002). Chronic non-malignant pain is also common. One type of non-malignant pain, chronic low back pain, is the second most frequent cause of hospital admissions in the United States (Deer et al., 2004).

Options for initial treatment of chronic pain include exercise, physical therapy, individual counseling, pain education classes, medications such as NSAIDS and complementary/alternative treatments such as massage or acupuncture. Opioids are an option as part of a comprehensive treatment plan if patients fail other therapies (GHC chronic non-malignant pain guideline). A meta-analysis of studies on oral morphine by the Cochrane Collaboration found it to be an effective analgesic for cancer pain (Wiffen et al., 2003). Another Cochrane review on chronic low-back pain found a lack of high-quality evidence and concluded that the benefits of opioids for this type of pain remain uncertain (Deshpande et al., 2007). Disadvantages of opioid analgesics include potential side effects such as nausea and vomiting, constipation, itching and respiratory depression. Moreover, during long-term opioid therapy patients may develop a tolerance leading to a need for higher doses, and patients may become physically dependent on opioids, and experience withdrawal symptoms if the medication is suddenly stopped (Wiffen et al., 2003).

The delivery of pain medication in directly into the fluid that surrounds the spinal cord (intrathecal analgesia) began in the 1970s following the discovery of opioid receptors in the central nervous system. Potential advantages of intrathecal analgesia include the ability to relieve pain in patients with previously intractable pain; the need for a lower milligram dose of opioids compared to systemic administration which may result in fewer side effects; and the ability to easily adjust the dose of opioids. Spinal analgesia was first used to treat chronic cancer-related pain. The use of intrathecal pain pumps for non-malignant pain is more controversial due to the limited

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evidence on the ability of opioids to relieve non-malignant pain over the long-term. As with oral opioids, there are concerns about tolerance, dependence and addiction (Williams et al., 2000; Cohen & Dragovich, 2007). Side effects that have been associated with long-term intrathecal morphine therapy include nausea, vomiting, itching urinary retention, constipation, sexual dysfunction and edema (Ruan, 2007).

Chronic pain is a major public health problem in the United States and across the world. It has significant negative effects on patients' functional capacity and quality of life, as well as high direct and indirect costs for the health care system. In a Gallup Survey of "Pain in America" more than 4 out of 10 adults indicated that they experience pain on a daily basis. Chronic pain is a complex phenomenon that is difficult to define. The American Society of Interventional Pain Physicians (ASIPP) defined it as:

1. Pain that persists beyond the usual course of an acute disease or a reasonable time for any injury to heal that is associated with chronic pathologic processes that cause continuous pain or pain at intervals for months or years.
2. Persistent pain that is not amenable to routine pain control methods, and
3. Pain where healing may never occur (Boswell 2007).

Chronic non-cancer pain (CNCP) has also been defined as ongoing pain that lasts over six months, that is due to non-life-threatening causes, and does not respond to available treatment methods (Ghafoor 2007).

A key to successful management of chronic pain is a multidisciplinary approach that optimizes medication use in conjunction with other nonpharmacological therapies including exercise, physical therapy, individual counseling, pain education classes, and complementary/alternative treatments such as massage or acupuncture. When conservative treatments fail, surgery to correct underlying causes is considered. These conservative and surgical therapies provide adequate pain relief for most but not all CNCP patients (Ghafoor 2007).

Intrathecal (IT) analgesia was introduced in the 1970s following the discovery of opioid receptors in the central nervous system and was initially used for malignant pain in patients who have failed to obtain adequate pain relief, or those with adequate analgesia but with intolerable side effects to drug therapy. Currently, it is being used for other indications such as chronic back pain, neuropathy, mixed neuropathic-nociceptive pain, and radicular pain from failed back syndrome. IT analgesia involves the delivery of pain medication directly into the fluid that surrounds the spinal cord to target the pre- and post-synaptic receptors in the dorsal horn of the cord (Koulousakis 2007, Smith 2008, Patel 2009).

There are two types of implantable intrathecal drug delivery systems (IDDS) available in the US. The fixed rate pump allows continuous infusion and bolus dose administration but does not have the option of changing the flow rate. The other, and most common implantable pump is a programmable infusion system which is available in different reservoir sizes. The infusion pumps are typically implanted in the lower abdomen, just beneath the skin. A catheter is inserted into the intrathecal space of the spine, tunneled under the skin and connected to the implanted pump for medication delivery, and to an external programmer that controls infusion rate and records medication concentration, volume, and dosage. A drug is infused over an extended period and may be delivered at a constant or variable rate by calibrating the infusion pump according to the physicians' specification. The pump requires refilling regularly via subcutaneous port injections. A variety of analgesic/co-analgesic agents have been utilized to provide spinal analgesia however, morphine remains the gold standard and is the only opioid approved by the FDA for intrathecal delivery to treat chronic pain. The FDA approved the use of ziconotide, for patients unresponsive to intrathecally delivered morphine. It also approved the use baclofen with the use of implantable infusion pumps for patients with severe spasticity of spinal origin. However, off-label use of other drugs in IT pumps is common (Ghafoor 2007, Koulousakis 2007, Turner 2007).

The implantable infusion pump is an invasive alternative for medication delivery and requires ongoing maintenance and surgeries to periodically replace the pump. It has the potential benefit of providing more effective pain control by administering the analgesic drug directly to the target area, using lower doses of opioids compared to systemic administration, and the ability to adjust the dose of opioids. However, there are many risks and potential harms associated with IT drug therapy. These involve the problems related to the intrathecal drug delivery systems (IDDS), and the adverse events of the medications used. Serious complications that may occur after the intrathecal catheter placement include postoperative subarachnoid hemorrhage, meningitis, catheter tip inflammatory masses, infection, root irritation, reactive arachnoiditis, catheter dislocation, and pump failure. Drug-related side effects consist of dose-independent effects as urinary retention, pruritis, pain due to bolus injection, perspiration, and sedation; and dose-dependent side effects as nausea, constipation, dysphoria, euphoria, sedation, respiratory depression, hypotension, central depression, and tachyphylaxis. As with oral opioids, there are concerns about tolerance, dependence, and addiction. Drug overdose could take place if the pump is
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inappropriately used or monitored; and drug withdrawal symptoms may occur with mechanical problems as pump failure or catheter blockage and kinking. There are also reports that patients with CNCP treated with intrathecal opioid therapy experience increased mortality compared to others with similar conditions treated with other therapies. It is thus recommended that pumps for chronic IT opioid application should only be implanted in specialized center. Before implantation the therapeutic effect of IT application should be assessed by a bolus trial or continuous injection via an external pump, connected to the intrathecal catheter through an implanted port (Cohen 2007, Koulousakis 2007, Smith 2008, Pasutharnchat 2009, Rathmell 2009, Coffey 2009).

In 1991, the Medtronic SynchroMed infusion system was approved by the FDA for the intrathecal delivery of morphine to treat malignant and non-malignant pain. The system consists of a pump that is generally implanted subcutaneously in the lower abdominal wall, a spinal catheter implanted into the lumbar intrathecal space between L1 and L4 and a programmer. The pump can be programmed via telemetry to control infusion modes and flow rates. SynchroMed is the only commercially available pump system that can be programmed outside the body. There are various models that differ in the size of the reservoir and the presence of a side catheter access port. Other implantable infusion pumps that have received FDA premarket approval include the Codman 3000 (Codman), Model 300 Constant Flow Implantable Infusion Pump (Arrow international) and the infused implantable Infusion Pump (Strato/infusaid).

Assessment objectives:

- To determine whether implanted infusion pumps for delivering intrathecal opioids are effective for the control of chronic noncancer pain (CNCP).
- To determine whether the use of implanted infusion pumps for delivering intrathecal opioids improves the quality of life and functioning in patients with CNCP.
- To determine whether the use of implanted infusion pumps for delivering intrathecal opioids are more effective than other non-invasive alternative therapies for pain control in patients with CNCP.
- To determine whether the technology is safe for use in patients with CNCP.

Medical Technology Assessment Committee (MTAC)

Implanted Pain Pumps for the Intrathecal Delivery of Opioids

08/06/2007: MTAC REVIEW

Evidence Conclusion: Cancer pain: The best evidence on the safety and effectiveness of implanted intrathecal pain pumps is an RCT with 200 patients. Of the 74% of patients with follow-up data at 4 weeks, there was a significantly greater reduction in toxicity, marginally significant reduction in pain and marginally significant increase in clinical success in the group assigned to receive a SynchroMed implantable pain pump in addition to comprehensive medical management (CMM) compared to CMM alone. Estimated survival at 6 months was higher in the group assigned to pain pumps, but the difference did not reach statistical significance. Limitations of the study include lack of blinding which could lead to biased estimates of self-report pain outcomes, funding by the device manufacturer and substantial cross-over (only 70% of the patients evaluated at 4 weeks in the pain pump group actually received implants and 5% of patients in the non-implant group received implants). Non-malignant pain: The evidence on safety and effectiveness is insufficient. There were case series and a cohort study that only compared pre- to post-implant changes, not between-group differences. The studies tended to find a reduction in self-reported pain after pump implantation and a reduction in oral morphine use (1 or 2 year follow-up). There were no comparison interventions and sample sizes were small. Device-related complications were relatively common.

Articles: The Medline search yielded one systematic review. This was published by the British Health Technology Assessment (HTA) group in 2000 and they did not identify any high-grade evidence. One randomized controlled trial was identified on malignant pain. Several articles were published based on this trial, the first on study outcomes in 2002. The article presenting the primary study outcomes (Smith et al., 2002) was critically appraised. No randomized controlled trials on non-malignant were identified. There was one non-randomized comparative trial which was critically appraised. (Thimineur et al., 2004). Two uncontrolled studies were also reviewed. Deer et al. (2004) reported data from the National Outcomes Registry for Low Back Pain. This registry was set up to prospectively collect data on patients with chronic low-back pain who underwent screening or a trial or an implanted pain pump. The other study was a prospective series using the Medtronic SynchroMed device (Anderson and Burchiel, 1999). There were other case series that had small sample sizes and/or did not mention whether a commercially available device was used. *Studies selected for critical appraisal were:*
Smith TJ, Staats PS, Deer T et al. for the Implantable Drug Delivery Systems (IDDS) study. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain. J Clin Oncol 2002; 20: 4040-4049. See Evidence Table. Thimineur MA, Kravitz E, Vodapally MS. Intrathecal opioid treatment for chronic non-malignant pain: a 3-year prospective study. Pain 2004; 109: 242-249. See Evidence Table. Deer T, Chapple I, Classen A et al. Intrathecal drug delivery for treatment of chronic low

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back pain. Am Acad Pain Med 2004; 5: 6-13. See Evidence Table. Anderson VC, Burchiel KJ. A prospective study of long-term intrathecal morphine in the management of chronic nonmalignant pain. Neurosurg 1999; 44: 289-300 See Evidence Table.

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of malignant pain meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of non-malignant pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
Implanted Pain Pumps for the Intrathecal Delivery of Opioids
Evidence Conclusion: This re-review of the implantable infusion pumps for delivering intrathecal opioids did not identify any studies that would change the conclusion from the 2007 MTAC review of the technology for the control of chronic noncancer pain (CNCP). There is still insufficient published evidence on the safety and effectiveness of the infusion pump for the control of CNCP and/or improving the QoL of the patients. The published studies for this indication were small case series and observational studies with no control groups. Comparisons were made between pre- and post-implant changes, not between differences among groups receiving different therapies or interventions. The studies had multiple threats to validity and may only provide low quality evidence; they are subject to selection and observation bias and did not take into account the placebo effect of the treatment or assess outcome for patients who had not received the therapy. Moreover, the studies did not compare characteristics of patients who completed the study to those who dropped out, did not adjust for the use of additional therapies or other confounding factors, and were funded by the manufacturer. Overall, the results of the published studies indicate a reduction in self-reported pain, reduction in oral morphine use, and /or improvement in quality of life and psychological function. However, there was a significant proportion of side effects associated with the implanted pump, the catheter, and the IT opioid use.

The Washington State Health Technology Assessment (HTA) program reviewed the implantable infusion pump for drug administration to treat chronic non-cancer pain, in August 2008. After reviewing the evidence, the Health Technology Clinical Committee (HTCC) concluded, “The evidence on infusion pumps did not demonstrate net health benefit because weak or unproven evidence of some effectiveness for certain patients was undermined by significant evidence of serious harms and adverse events associated with the implantation of infusion pumps. The committee found that infusion pumps were not proven to be equally or more safe or effective, and the cost, while not a significant factor for this decision was likely equivalent. Based on these evidentiary findings, the committee voted 8 to 2 for non-coverage.” Conclusion: There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is effective for the control of chronic non-cancer pain (CNCP).There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids improves quality of life and functioning in patients with CNCP. There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is more effective than other non-invasive alternative therapies for pain control in patients with CNCP. There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is safe for use in patients with CNCP.
Articles: The available published literature on intrathecal (IT) opioid therapy delivered through implanted pumps for chronic noncancer pain is limited and consists of systematic reviews that did not pool the results in meta-analyses, small case series, and observational cohort studies with no control or comparison groups. The literature search did not identify any meta-analyses or randomized controlled trials that compared IT opioid therapy with other non-invasive therapies published since the 2007 MTAC review. There was one retrospective cohort study (Atli 2010) reporting on 3-years outcome of chronic pain patients receiving IT treatment through implanted pumps, one case series (Shaladi 2007) of 24 patients with osteoporotic vertebral fractures treated with intrathecal morphine infusion, and another series (Duse 2009) reporting on psychological functionality of 30 patients with CNCP. The larger cohort study with a long-term follow-up was selected for critical appraisal: Atli A, Theodore BR, Turk DC, et al. Intrathecal opioid therapy for chronic nonmalignant pain: a retrospective cohort study with 3-year follow-up. *Pain Medicine* 2010; 11:1010-1016. See Evidence Table.

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of non-malignant pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT® Codes	Description
36260	Insertion of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
HCPC Codes	**Description**
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, nonprogrammable, permanent (implantable)
C2626	Infusion pump, nonprogrammable, temporary (implantable)
E0782	Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/23/1999	02/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013 [MDCRPC], 04/01/2014 [MPC], 02/03/2015 [MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC] , 07/07/2020[MPC] , 07/06/2021[MPC], 07/05/2022[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/10/2017	Added Coverage Article A55323
07/07/2020	Removed CPT code 36563 and added 36260
09/01/2020	MPC approved to adopt updates to clinical criteria for non-Medicare. Indications added under spasticity and chronic pain sections. Requires 60-day notice, effective 02/01/2021.

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Clinical Review Criteria
Intensity Modulated Radiation Therapy (IMRT)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Intensity Modulated Radiation Therapy (IMRT) (L34080) – **RETIRED** 08/01/2020 Noridian Intensity Modulated Radiation Therapy (IMRT) (L34080). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34080 for determining medical necessity.
Local Coverage Article	Billing and Coding: Intensity Modulated Radiation Therapy (IMRT) (A58245)

For Non-Medicare Members

Kaiser Permanente has elected to use the Intensity Modulated Radiation Therapy (IMRT) (KP-0455 v2) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from oncologist and radiation oncologist

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

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Evidence and Source Documents

Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer
Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer

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Background

The aim of radical radiotherapy is to deliver a homogenous radiation dose to a tumor target with a minimal dose to surrounding normal tissue. Conventional external beam irradiation (EBRT) has been used to treat prostate cancer for more than thirty years. It partly achieves its goal but leads to irradiation of unnecessarily large volumes of normal tissue. The proximity to the rectum and the bladder has limited the ability to deliver doses > 70Gy to the prostate. This dose may be sufficient for many, but not all prostate cancer cases. The frequent persistence of local residual tumor after EBRT has been a matter of concern. The inability to eradicate some prostate cancers may be related to the lack of tumoricidal doses of radiotherapy on certain resistant clones of tumor cells.

Conformal radiotherapy (CRT) aims at minimizing the volume of normal tissue irradiated by shaping the dose distribution to conform tightly to the shape of the tumor, thus reducing the dose to the normal tissue surrounding it. The three-dimension conformal radiotherapy (3D-CRT) is a further advancement to the 2D dose planning system. It entails direction of multiple beams conformed to the shape of the target from each beam's eye view (BEV). It thus enables a higher degree of certainty of target localization and permits the use of narrow margins around it. Its ultimate goal is to escalate the radiation dose to the target, while maximally excluding the adjacent normal tissue. However, there are situations in which 3D-CRT cannot produce a satisfactory treatment plan because of complex target volume shapes, or close proximity of sensitive normal tissue.

Most recently, an advanced form of 3D-CRT, called intensity modulated radiation therapy (IMRT) was developed to overcome these limitations by adding modulation of beam intensity to beam shaping. In this method intensity modulators, such as multiple leaf collimators (MLC), or beam modifiers are used to divide the treatment beam into a set of small beamlets, the intensity of which vary from 0-100%, independent of all other beamlets. IMRT can achieve any dose distribution, notably an abrupt decrease in the dose at the limit between the tumor volume and the adjacent normal tissue.

The benefits of IMRT will be greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important. Examples of these are the larynx, pharynx, and thyroid. The main focus for IMRT in the United States has been the prostate, which forms the largest single tumor site treated with IMRT. It is hoped that it will reduce the rectal and bladder doses of irradiation, allow further dose escalation and increase the cure rates.

Special software and computer control systems are necessary to implement IMRT. The planner has to define the anatomical contour of the target volume, the desired dose and the degree of inhomogeneity in the tumor volume. Several target volumes can be distinguished e.g. primary tumor and lymph nodes. The total dose or the dose per session to each target volume can be modulated. IMRT could be used for the whole duration of a radiotherapy treatment, or simply as a boost after more conventional treatment.

Medical Technology Assessment Committee (MTAC)

Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer

BACKGROUND

Intensity-modulated radiation therapy (IMRT) is a type of external beam radiation therapy that permits complex three-dimensional shaping of the radiation beams to precisely target the tumor. This allows for a larger dose of radiation to be applied to the tumor site, while minimizing exposure of the surrounding healthy tissue. Instead of a single, uniform beam as in traditional external beam radiation, IMRT involves the delivery of many small beams of varying intensity. Computer algorithms are used to coordinate the beams and plan the delivery of the radiation dose. Compared to other types of external beam radiation, IMRT is best able to generate concave dose distributions. Head and neck cancers may be particularly suited to treatment with IMRT because these tumors often have concave volumes and because head and neck tumors generally require relatively high doses (i.e. 60-70 Gy) of radiation and are in close proximity to critical tissues and organs that are radiation-sensitive (such as the salivary glands, inner and middle ears, temporomandibular joints, temporal brain and optic nerve). Head and neck cancers may also be good candidates for IMRT because of the relative lack of organ motion compared to other areas of the body. Due to the highly focused radiation dose, lack of motion is important. The most prevalent long-term adverse effect with radiation therapy for head and neck cancers is xerostomia (dry mouth) caused by damage to the salivary glands. This adverse effect may be reduced with IMRT. To date, several thousand patients worldwide have received IMRT treatment; so far, most of this has been for the treatment of prostate cancer. Several centers in the U.S. have been providing IMRT for head and neck cancer, most notably Washington University in St. Louis, the University of California, San Francisco (UCSF) and the University of Michigan (Cozzi & Fogliata, 2002). IMRT is a rapidly evolving technology that experienced clinicians believe will continue to evolve in the near future (Eisbruch, 2002).

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04/09/2003: MTAC REVIEW
Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer
Evidence Conclusion: There is insufficient evidence to determine the effect of IMRT on health outcomes in patients with head and neck cancer compared to other types of radiation therapy. There is only one published comparative study with clinical outcomes, a retrospective cohort study. This study is limited because only 26 patients received IMRT (14 had post-operative IMRT and 12 had definitive IMRT). Although the findings suggest that there is a higher survival rate and lower rate toxicity rate with IMRT compared to other forms of radiation therapy, the statistics are unreliable due to the small number in the IMRT group. (Percentages are generally considered unstable when the sample size is less than 100). In the Lee case series, actuarial 4-year survival estimates were 98% for local-regional progression-free survival and 66% for distant metastasis-free survival. Two years after IMRT, 32% of patients had Grade I xerostomia and only 1 patient had Grade 2 xerostomia. In the Chao case series, the 2-year actuarial survival estimates was 85% for loco-regional control, (89% after salvage surgery). The case series were limited by lack of comparison groups, variable length of follow-up and inconsistent interventions (e.g. three different IMRT techniques were used over time in the Lee study, and in both case series, some patients had chemotherapy). In addition, each included a heterogeneous patient population in terms of cancer location and stage.
Articles: The search yielded 120 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the procedure or addressed treatment planning only. There were no randomized controlled trials comparing clinical outcomes after IMRT versus other forms of radiation therapy. There was one non-randomized comparative clinical study, a retrospective cohort study. The other empirical studies were all case series. The most recent case series from the three major institutions performing IMRT for head and neck cancer (Washington University, UCSF and the University of Michigan) were identified. Two of these institutions had published series of over 50 patients with head and neck cancer who had received IMRT. The comparative study and the two largest case series were critically appraised: Chao KSC, Majhail N, Huang C et al. Intensity-modulated radiation therapy reduces late salivary toxicity without compromising tumor control in patients with oropharyngeal carcinoma: A comparison with conventional techniques. *Radiother Oncol* 2001; 61: 275-280. See Evidence Table

The use of IMRT in the treatment of head and neck cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/01/2004: MTAC REVIEW
Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer
Evidence Conclusion: No new randomized or non-randomized comparative studies were identified. There were updates of earlier case series from two of the major institutions performing IMRT for head and neck cancer, UCSF and Washington University. There were also several new small case series. The new literature does not substantially change the conclusions of the April 2003 MTAC review.
Articles: Medline was searched from 2003 to May 2004 using the terms, “intensity-modulated radiation therapy”, “IMRT”, and “head and neck cancer”, with variations. The search was limited to English language publication and human populations. No new randomized or non-randomized comparative studies were identified. There were updates of earlier case series from two of the major institutions performing IMRT for head and neck cancer, UCSF and Washington University. There were also several new small case series. Lee N, Xia P, Quivey JM. Intensity-modulated radiotherapy in the treatment of nasopharyngeal carcinoma: An update of the UCSF experience. *Int J. Radiation Oncology Biol Phys* 2002; 53: 12-22. See Evidence Table Chao KSC, Ozyigit G, Tran BN et al. Patterns of failure in patients receiving definitive and postoperative IMRT for head-and-neck cancer. *Int J Radiation Oncology Biol Phys* 2003; 55: 312-321. See Evidence Table

The use of IMRT in the treatment of head and neck cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer
BACKGROUND
The aim of radical radiotherapy is to deliver a homogenous radiation dose to a tumor target with a minimal dose to surrounding normal tissue. Conventional external beam irradiation (EBRT) has been used to treat prostate cancer for more than thirty years. It partly achieves this goal but may lead to irradiation of unnecessarily large volumes of normal tissue. The proximity to the rectum and the bladder has limited the ability to deliver doses > 70 Gy to the prostate. This dose may be sufficient for many but not all prostate cancer cases. The frequent persistence of local residual tumor after EBRT has been a matter of concern. The inability to eradicate some prostate cancers may be related to the lack of tumoricidal doses of radiotherapy on certain resistant clones of tumor cells. Conformal radiotherapy (CRT) aims at minimizing the volume of normal tissue irradiated by shaping the dose distribution to conform tightly to the shape of the tumor, thus reducing the dose to the normal tissue surrounding it. The three-

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dimension conformal radiotherapy (3D-CRT), is a further advancement to the 2D dose planning system. It entails direction of multiple beams conformed to the shape of the target from each beam's eye view (BEV). It thus enables a higher degree of certainty of target localization and permits the use of narrow margins around it. Its ultimate goal is to escalate the radiation dose to the target, while maximally excluding the adjacent normal tissue. However, there are situations in which 3D-CRT cannot produce a satisfactory treatment plan because of complex target volume shapes, or close proximity of sensitive normal tissue. Most recently, an advanced form of 3D-CRT, called intensity modulated radiation therapy (IMRT) was developed to overcome these limitations by adding modulation of beam intensity to beam shaping. In this method intensity modulators, such as multiple leaf collimators (MLC), or beam modifiers are used to divide the treatment beam into a set of small beamlets, the intensity of which vary from 0-100%, independent of all other beamlets. IMRT can achieve any dose distribution, notably an abrupt decrease in the dose at the limit between the tumor volume and the adjacent normal tissue. The benefits of IMRT will be greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important. Examples of these are the larynx, pharynx, and thyroid. The main focus for IMRT in the United States has been the prostate, which forms the largest single tumor site treated with IMRT. It is hoped that it will reduce the rectal and bladder doses of irradiation, allow further dose escalation and increase the cure rates. Special software and computer control systems are necessary to implement IMRT. The planner has to define the anatomical contour of the target volume, the desired dose and the degree of homogeneity in the tumor volume. Several target volumes can be distinguished e.g. primary tumor and lymph nodes. The total dose or the dose per session to each target volume can be modulated. IMRT could be used for the whole duration of a radiotherapy treatment, or simply as a boost after more conventional treatment. IMRT for prostate cancer was previously reviewed by MTAC in April, 2002. At that time, the evidence consisted of case series on the toxicity of IMRT and the item failed MTAC evaluation criteria.

4/10/02: MTAC REVIEW
Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer
Evidence Conclusion: The studies reviewed aimed at determining the toxicity of the high-dose radiation delivered by IMRT. In both studies IMRT was not compared to a low dose conventional treatment, instead it was compared to 3D-CRT, which also uses a high dose irradiation, yet not modulated. Compared to 3D-CRT, IMRT was found to cause significantly lower acute, and late rectal toxicity in Zelefsky's study, and significantly higher acute rectal toxicity in the Shu study. In the two studies reviewed, there was no significant difference between the two treatments in the acute or late bladder toxicity. Both studies were not randomized and non-blinded, there were some variations in the base-line characteristics in the treatment groups, and no adjustments were made for confounding factors. Randomized controlled studies with long-term follow-up are needed to study the effect of IMRT on the outcome of the cancer, as well as the morbidity from the radiation.
Articles: The search yielded 55 articles most of which were reviews, case reports, editorials, and letters. The literature did not reveal any randomized controlled studies or meta-analyses.
It also did not reveal any study on the effect of IMRT on the outcome of the prostate cancer. There were 2 articles on studies made to determine the toxicity of IMRT, and compare it to 3D-CRT. *The following articles were critically appraised:* Zelefsky MJ, et al. Clinical experience with intensity modulated radiation therapy (IMRT) in prostate cancer. *Radiotherapy and Oncology* 2000;55:241-9. See Evidence Table Shu H G, et al. Toxicity following high-dose three-dimensional conformal and intensity modulated radiation therapy for clinically localized prostate cancer. *Urology* 2001;57:102-7. See Evidence Table

The use of intensity modulated radiation in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

2/11/04: MTAC REVIEW
Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer
Evidence Conclusion: The evidence is limited by the lack of randomized controlled trials, comparison only to 3D-CRT rather than lower-dose standard radiotherapy, inconsistent length of follow-up, lack of actual survival data and potential confounding by androgen deprivation therapy in a substantial proportion of patients. Both studies reported on biochemical survival rates. Three-year actuarial PSA relapse-free survival varied from 81-92% in the Zelefsky study and thirty-month actuarial PSA relapse-free survival was 94% for IMRT and 88% for 3D-CRT (non-significant difference) in the Kuplian study. Change in PSA level is an intermediate outcome and may not be an accurate measure of prognosis. There appeared to be relatively low rates of serious late toxicity, but many patients were not followed up long enough to contribute to this analysis. In the Zelefsky study, 9 of the patients followed for a sufficiently long time (1%) developed grade 3 late toxicity. In the Kuplian study, actuarial grade 3 late rectal toxicity at 30 months was 2% in the IMRT group and 8% in the 3D-CRT group. The evidence is limited by the lack of randomized controlled trials, comparison only to 3D-CRT rather than lower-dose standard radiotherapy, inconsistent length of follow-up, lack of actual survival data and potential confounding by androgen deprivation therapy in a substantial proportion of patients. Both studies reported on biochemical survival rates.
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Three-year actuarial PSA relapse-free survival varied from 81-92% in the Zelefsky study and thirty-month actuarial PSA relapse-free survival was 94% for IMRT and 88% for 3D-CRT (non-significant difference) in the Kuplian study. Change in PSA level is an intermediate outcome and may not be an accurate measure of prognosis. There appeared to be relatively low rates of serious late toxicity, but many patients were not followed up long enough to contribute to this analysis. In the Zelefsky study, 9 of the patients followed for a sufficiently long time (1%) developed grade 3 late toxicity. In the Kuplian study, actuarial grade 3 late rectal toxicity at 30 months was 2% in the IMRT group and 8% in the 3D-CRT group.

Articles: The search yielded 102 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the procedures or were on related procedures. There were no randomized controlled trials. There were three new case series publications by the Memorial Sloan-Kettering Cancer Center research group (led by Zelefsky). The patients included in the three publications overlapped. Two of the articles also included patients who were treated with 3D-CRT, but IMRT and 3D-CRT were not compared in analysis. The Zelefsky case series with the largest number of IMRT cases was critically appraised. In addition, there was a study conducted at the Cleveland Clinic which compared series of patients treated with short-course IMRT and 3D-CRT. There were no studies comparing IMRT to lower dose conventional radiotherapy. *The studies reviewed were:* Zelefsky MJ, Fuks Z, Hunt M et al. High-dose intensity modulated radiation therapy for prostate cancer: Early toxicity and biochemical outcome in 772 patients. *Int J Radiation Oncology Biol Phys* 2002; 53: 1111-1116. See Evidence Table Kuplian PA, Reddy CA, Carlson TP. et al. Preliminary observations on biochemical relapse-free survival rates after short-course intensity-modulated radiotherapy (70Gy at 2.5Gy/Fraction) for localized prostate cancer. *Int J Radiation Oncology Biol Phys* 2002; 53: 904-912. See Evidence Table.

The use of intensity modulated radiation in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
HCPC Codes	**Description**
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised

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05/22/2003	07/02/2013[MPC] 05/06/2014[MPC], 03/03/2015[MPC], 07/07/2015[MPC], 01/05/2016[MPC],11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	03/02/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/07/2015	MPC approved to reinstate IMRT criteria for medical necessity review. New criteria effective date 11/2015.
09/08/2015	Revised LCD Intensity Modulated Radiation Therapy (IMRT) L34251 and L34080
03/01/2016	Added indication to policy
11/01/2016	MPC approved revised indication for lung cancer
12/05/2017	MPC approved new indication for esophageal cancer
07/07/2020	Added Medicare LCA (A57231); removed deleted CPT code 77418
03/02/2021	MPC approved to expand coverage to the IMRT criteria by including additional indications for coverage which include Cholangiocarcinoma, Gallbladder carcinoma, Gastric cancer, Hepatocellular carcinoma, Liver metastases, Lymphoma with mediastinal involvement, in proximity to lung and heart, Pancreatic cancer; Breast Cancer will still require MD review. Requires 60-day notice, effective date 08/01/2021.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Infertility Services

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare Members

For baseline policy for all plans, click here to view the criteria. *(Internal use only)*
*Individual groups may provide additional benefits or exclusions – see current coverage agreement or contact member services for specific exceptions and limitations.

Based on Kaiser Permanente policy, a member is considered infertile if they are unable to conceive or produce conception:

- After 1 year of frequent, unprotected heterosexual sexual intercourse for members 35 and under
- After 6 months of frequent, unprotected heterosexual sexual intercourse if the female partner is over age 35 years.
- Alternately, a woman without a male partner may be considered infertile if she is unable to conceive or produce conception after at least 12 trials of medically supervised donor insemination (6 cycles for women aged 35 or older).
  - The initial 12 trials of medically supervised donor insemination (6 cycles for women aged 35 or older) to establish an infertility diagnosis, are not covered under the infertility benefit.
- A member is not considered “infertile” if they have had a voluntary sterilization (e.g. tubal ligation, vasectomy). Infertility treatment post-voluntary sterilization is not covered, even if the plan has an SI rider.

As of 1/1/2022, the following plans waived the requirement for a diagnosis of infertility but may still require prior authorization or clinical review based on individual benefits and plan riders.
Association of Washington Cities (AWC)
Boeing
City of Seattle
Meta (Facebook) – for cryopreservation only
SEIU

For *only* Kaiser Permanente Individual & Family (I&F) and Small Business Group (SBG) contracts

In addition to base infertility/sterility services listed in the Infertility and Sterility policy, member is eligible for:

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- Tubal patency/uterine irregularities- HSG (radiology)
- TSH, prolactin (lab)
- Testing for Ovarian reserve –Day 3 FSH. (lab)
- Semen analysis (if member has Kaiser coverage) (lab)
- Member must use in-network lab

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Infertility is a common problem. According to the Centers for Disease Control and Prevention (CDC), about 10 percent of U.S. women ages 15 through 44 years have difficulty getting pregnant or staying pregnant.[1]

Both women and men can have problems that cause infertility. About one-third of infertility cases can be connected to the woman. Another third of the cases of infertility can be connected to the man. In the remainder of instances, a cause can't be found.

Applicable Codes

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Creation Date	Review Date	Date Last Revised
1/25/2019	02/05/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	12/16/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt coverage for KP I&F and SBG plans
06/04/2019	Added SEIU has no requirements regarding: age, duration of time, or gender per SEIU contract
05/05/2020	Information regarding the SI-AO rider for SIEU cryopreservation (Effective 8/1/2020) was added
01/04/2022	Added definition of infertility from KP policy document. Listed groups that are no longer requiring a diagnosis of infertility for members to access benefit as of 01/01/2022.
12/16/2022	Updated criteria to include indication for, *"A member is not considered "infertile" if they have had a voluntary sterilization."*

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Clinical Review Criteria
Infrared Thermography

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Thermography (220.11). *This service is not covered per Medicare criteria*.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Infrared thermography is a non-invasive imaging procedure. It produces representations of variation in temperature on the surface of the human skin. Distribution of skin temperature depends on complex relationships between the skin tissue, inner tissue, local vasculature and metabolic and hormonal activity. Use of thermography as a diagnostic tool is based on the premise that the abnormal issue, such as a tumor, would raise the temperature on the skin surface due to increased metabolic activity. In the 1950s and 60s, researchers found that local skin temperatures over a breast tumor were about 2-3 degrees higher than normal skin temperature.

Although, over the past several decades, there has been experimentation with protocols for obtaining and interpreting thermograms, to date there no established procedures for using thermography to enhance diagnosis of breast cancer or other abnormalities (Mital & Scott, 2007; Ohashi & Uchida, 2000). Among the conditions for which thermography has been proposed are Raynaud's phenomenon, gastric cancer, headaches, deep vein thrombosis, and impaired spermatogenesis in infertile men.

Several thermography devices have been approved by the FDA, including the Mark I Thermal Imager (IX-DR; Howell, MI) in 2002 and EMD Thermography System in 2006. The EMD Thermography system includes an infrared sensor that is placed in contact with the skin to measure temperature. In addition, special software is used to analyze and display the temperature measurements.

Both recently approved devices were considered to be substantially equivalent to predicate devices. Approval was based on the technology's ability to measure skin temperature, rather than their proven ability to improve diagnosis of any disease. According to FDA documents, thermography is indicated for use as an adjunctive medical imaging modality in situations where a physician chooses to use it.

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Medical Technology Assessment Committee (MTAC)

Infrared Thermography

06/04/2008: MTAC REVIEW

Evidence Conclusion: There is no empirical evidence that adjunctive infrared thermography improves the diagnosis of any disease or abnormality.

Articles: No technology assessments conducted by other organizations were identified. The Medline search did not yield any empirical studies that evaluated the diagnostic accuracy of thermography as an adjunctive diagnostic modality for any indication. Several articles were identified that proposed methods for analyzing thermograms or discussed technical aspects of using thermography.

The use of infrared thermography does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
93740	Temperature gradient studies

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
07/17/2008	05/03/2011 MDCRPC, 03/06/2012 MDCRPC ,01/08/2013 MDCRPC ,11/05/2013 MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC,12/07/2021MPC,12/06/2022MPC	05/03/2011

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
InFUSE™ Bone Graft
Bone Graft Substitutes & Adjuncts

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**InFUSE™ Bone Graft**," for medical necessity determinations. Use the Non-Medicare criteria below.

See reference: Technology Assessment for Spinal Fusion for Treatment of Degenerative Disease Affecting the Lumbar Spine

For Non-Medicare Members

Service	Criteria
InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device (Bone Morphogenetic Protein-2)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.
Bone Graft Substitutes & Adjuncts	The following Bone Graft Substitutes & Adjuncts are considered experimental and investigation, therefore are not covered: • Celling Biosciences Solum IV allograft • Cerament® • ChronOS bone graft substitute • Equivabone® Graft • Healos Sponge • Healos® bone graft replacement • i-FACTOR™ Peptide-enhanced bone graft • InterGro® DBM Fibers • Optium® DBM putty • OsteoAmp® • Osteofuse® • Vivex (Amendia)

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	• OSTEOMATRIX+ Arthrex Quickset™ • OsteoVive® • TrueFuse • Vivigen Formable® • Vivigen®

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Background

Degenerative disc disease (DDD) resulting from wear and tear of the discs between vertebrae can lead to a painful condition that may require spinal fusion (arthrodesis) of the vertebrae on both sides of the degenerative disc. Spinal arthrodesis was introduced over a century ago for treating vertebral fractures, spinal tuberculosis, tumors and severe scoliosis. These indications were later expanded to include spondylolisthesis, spondylosis, intervertebral disc disorders, and discogenic low back pain. Spinal interbody fusion restricts the unstable spinal motion segment and may provide relief from the pain associated with DDD, when all other methods have failed. It involves the removal of the degenerated intervertebral disc and fusion of the adjacent vertebral bodies. This can be achieved through an anterior approach (anterior lumbar interbody fusion or ALIF), posterior fusion (PLIF), or transforaminal approach (TLIF) (Blumenthal 1988, Baskin 2003, Glassman 2005, Papakostidis 2008, Fu 2013, Skovrlj 2014, Noshchenko 2014, Bodalia 2016, Hofstetter 2016).

Vertebral fusions usually use graft material to stimulate the fusion. For decades autogenous iliac crest bone (ICB) has been, and is still considered, the gold standard bone grafting material for its superior osteoinductive and osteogenic properties. However, its harvest may be associated with postoperative complications including persistent pain from the donor site, deep infection, scarring, and other donor site morbidity. Another limitation of using iliac crest bone graft (ICBG) is the relative inadequate supply of graft tissue for multilevel fusions. Spine surgeons have thus been looking for alternative methods to promote spinal fusion. A variety of bone graft materials and substitutes such as local bone, bones from bone banks, demineralized bone matrix, synthetic grafts, platelet gels, and other materials have been introduced into clinical practice, but did not prove to be as effective as ICBG (Blumenthal 1988, Baskin 2003, Glassman 2005,papakostidis 2008, Fu 2013, Skovrlj 2014, Noshchenko 2014, Bodalia 2016, Hofstetter 2016).

Bone morphogenetic protein (BMP), a prototypical osteoinductive protein, was first described by Marshall Urist in 1965. BMPs are members of the superfamily of transforming growth factor-beta and play an important role in embryonic development including bone formation. In the late 1990s recombinant human bone morphogenetic protein type 2, a genetically engineered osteoinductive protein, was tested for use in lumbar fusion among humans in preclinical and clinical studies (Zhang 2014, Hofstetter 2016).
InFUSE® Bone Graft (Medtronic Sofamor Danek, Memphis, TN) is a recombinant human bone morphogenetic protein type-2 (rhBMP-2) applied to an absorbable collagen sponge (ACS) carrier that localizes the protein at the site of implantation and provides a scaffold for the formation of the new bone. The sponge is manufactured from bovine Type I collagen and is designed to resorb over time. InFUSE® Bone Graft is used in conjunction with a proprietary small thimble like titanium lordotic tapered cage (LT-Cage) implant, which is intended to restore the degenerated disc space to its original height. The LT-Cage Devices come in multiple sizes (from XX Small to Large II) to match various patient anatomies. The InFUSE® Bone Graft/LT-Cage® Lumbar Tapered Fusion Device is implanted through an open or laparoscopic anterior surgical approach. The bone graft is prepared immediately prior to its use during surgery*; the protein solution is soaked into the sponge, which is then inserted into the LT-Cage. After removing the contents of the disc space, two devices are implanted side by side in the prepared intervertebral disc space. The fusion cage maintains the spacing and temporarily stabilizes the diseases region of the spine while the InFUSE® Bone Graft induces new bone tissue at the site of implantation to fuse this portion of the spine. The fusion process requires several months to complete (Baskin 2003, Glassman 2005, Medtronic website accessed 2017)

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*Once prepared, the INFUSE® Bone Graft contains rhBMP-2 at a concentration of 1.5 mg/mL

In 2002, the US Food and Drug Administration (FDA) approved the use of InFUSE® Bone Graft for anterior interbody fusion as an alternative to the iliac crest bone graft for use in conjunction with lordotic tapered cages (LT-CAGE) lumbar fusion device. According to the FDA, the device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at a single level from L4-S1. Patients should have had at least six months of nonoperative treatment prior to treatment with the Infuse Bone Graft. Later the FDA approved rhBMP-2 with other interbody fusion devices (INTER FIX™ Threaded Spinal Fusion Device and INTER FIX™ RP Threaded Fusion Device) also manufactured by Medtronic.

InFUSE® Bone Graft is contraindicated in patients who are pregnant, who may be allergic to any of the materials contained in the device, have in infection in the area of the incision, are skeletally immature, or with an existing or removed tumor in the area.

Medical Technology Assessment Committee (MTAC)

InFuse Bone Graft

10/08/2003: MTAC REVIEW

Evidence Conclusion: The trial reviewed does not provide sufficient evidence to conclude that InFUSE Bone Graft is equivalent or superior to the standard treatment. It was randomized and controlled; yet the authors compared improvements associated with the InFUSE Bone Graft with the preoperative condition, and not with the standard treatment. The trial shows that both treatments led to significant improvement in the back pain, leg pain, as well as pain associated with activity when compared to the preoperative scores. The two procedures were also associated with post-operative vs. baseline, high neurological success, patient satisfaction and bone fusion. The authors noted that the success rates and pain scores were similar between the two groups, based on the values observed and not on statistical tests of significance. It seems unlikely that there are any significant differences between the two groups, as the numbers, and scores are close. This may suggest that the effect of the two treatments may be similar, but the study isn't conclusive as it may have been underpowered to detect a difference and was not designed as an equivalence trial that requires a larger sample size, and a different method of analysis than superiority trials.

Articles: The search revealed 4 randomized controlled studies and one case series. Three of the RCTs were conducted by the same principle investigator and included patients from the same center: one large trial with 279 patients, and two smaller RCTs with 46, and 42 patients. The other trial revealed included only 14 patients. The search also revealed an article where the same principle investigator of the three RCTs pooled data form his trial as well as other 3 unpublished studies, two of which were non-randomized. It had a poor methodology and cannot be categorized as a meta-analysis. The largest of the three RCTs conducted by the same investigator group was selected for critical appraisal. *The following study was critically appraised:* Burkus JK, Gornet MF, Dickman CA, et al. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. J Spinal Disord Tech. 2002; 15:337-49. See Evidence Table.

The use of recombinant human bone morphogenetic protein (rhBMP-2) placed on an absorbable collagen sponge (ACS) in the treatment of degenerative disc disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/07/2009: MTAC REVIEW

InFuse Bone Graft

Evidence Conclusion: There is a lack published material on the use of InFUSE Bone Graft for anterior lumbar interbody fusion, the indication for which the technology received the FDA approval. Glassman and colleagues' trial (2008) had the advantage of comparing rhBMP-2 to iliac crest bone graft in a randomized controlled trial with 2-year follow-up duration. However, the technology was used off-label for a posterolateral lumbar fusion among patients older than 60 years of age. Moreover, the trial was not blinded, and the authors did not discuss the method of randomization, or clearly describe the inclusion/ exclusion criteria. Non-blinding may be a source of observation bias, especially with the subjective primary outcomes of the trial. The investigators tried to partially overcome this limitation by blinding the orthopedic surgeons who evaluated the radiological outcomes. The authors also did not discuss any power analysis for determining the sample size, and analysis was not based on intention to treat. Overall, the results of the trial show significant improvements in health-related

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quality of life, as well as the leg, and back pains at one and two years of follow-up among the patients in the two treatment groups, when compared to the preoperative status. There were no significant differences in the primary outcomes between the two interventions. The outcomes may appear similar, but the lack of significant statistical significance does not necessarily imply equivalence. The study was relatively small and might have been unpowered to detect significant differences between the study groups. It was not designed as an equivalence trial that requires a larger sample size and different method of analysis than a superiority trial. Radiographic evaluations at two years showed higher fusion rate with rhBMP-2 vs. ICBG (86.3% and 70.8%, respectively). In conclusion there is insufficient published evidence to conclude that InFUSE Bone Graft is equivalent, noninferior, or superior to the standard iliac crest bone graft in improving functional ability and quality of life of patients with symptomatic degenerative disc disease.
Articles: The search revealed over 30 articles on rhBMP-2 /InFUSE Bone Graft. Many were unrelated to the current reviews; others used rhBMP-2 in different formulations or in combination with other elements e.g. ceramic granules. Two articles (Glassman, et al 2005 and 2008) reporting on one- and two-years results of a randomized controlled study comparing the use of rhBMP-2 versus iliac crest bone graft (ICGB) for lumbar spine fusion, were identified as well as a small nonrandomized trial and two case series studies on the use of InFUSE Bone Graft. The RCT with the 2-year follow-up was selected for critical appraisal. Glassman SD, Carreon LY, Djurasovic M, et al. RhBMP-2 versus iliac crest bone graft for lumbar spine fusion: A randomized, controlled trial in patients over sixty years of age. Spine. 2008; 33:2843-9. See Evidence Table.

The use of recombinant human bone morphogenetic protein (rhBMP-2) placed on an absorbable collagen sponge (ACS) in the treatment of degenerative disc disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/21/2017: MTAC REVIEW
InFuse Bone Graft
Evidence Conclusion: As indicated in the previous section, the literature search did not identify any more recent RCTs evaluating InFUSE® Bone Graft for ALIF, but a number of qualitative reviews and quantitative meta-analyses of the published trials. All trials were open-label, the great majority was industry sponsored, and the principal authors had financial ties with the industry.
Efficacy and safety of InFUSE® Bone Graft compared to the gold standard autogenous iliac crest bone graft (ICBG) Carragee and colleagues (2011) conducted a systematic review and critical analysis of the original peer reviewed industry-sponsored publications and compared their results and conclusions versus the available FDA summaries, follow-up publications, and administrative and organizational database analyses. According to the authors, the systematic review was prompted by complaints to the editorial board of the *Spine Journal* including allegations of research bias, failure to report adverse event recorded by the study surgeons, and discrepancies between FDA summaries and published data. The authors reviewed the results of 13 original industry-sponsored rhBMP-2 publications regarding safety and efficacy, including reports and analyses of 780 patients receiving rhBMP-2 within prospective controlled study protocols. These included studies using anterior, posterior and posterolateral interbody fusion. The estimated rate of adverse events associated with rhBMP-2 use in spinal interbody fusion ranged from 10% to 50% depending on the approach and spinal level of fusion.

- Anterior interbody lumbar with rhBMP-2 was associated with higher rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation versus the controls.
- Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.
- In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events. Higher doses of rhBMP-2 were associated with a greater apparent risk of new malignancy.
- Anterior cervical fusion with rhBMP-2 had an estimated 40% greater risk of adverse events in the early postoperative period including life-threatening events.

The authors provided evidence showing discrepancy between the FDA documents and the published results of industry-sponsored trials on rhBMP-2. He noted that while the authors of the industry sponsored trials on ALIF, reported no adverse events, the FDA concluded that the original data form the trials indicate that “The incidence of adverse events that were considered device related, including implant displacement/loosening, implant malposition and subsidence were all greater in the investigational [rhBMP-2] groups compared to the control

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group" (Carragee 2011). Carragee and colleagues summarized the areas of concern regarding the safety and efficacy reported by the industry sponsored trials as follows:

1. Underestimation of adverse events and serious harms associated with rhBMP-2.
2. Presence and magnitude of conflict of interest and potential for reporting bias.
3. Invalid assumption and methodology used for estimating adverse events associated with iliac crest bone grafts, which led to exaggeration of the benefits underestimating the morbidity of rhBMP-2.
4. Significant bias against the selection of the control and techniques used in the PLIF and PLF.

The reviewers concluded that Level I and Level II evidence from original FDA summaries, original published data, and subsequent studies suggest possible study design bias in the original trials, as well as a clear increased risk of complications and adverse events to patients receiving rhBMP-2 in spinal fusion. This risk of adverse events associated with rhBMP-2 is 10 to 50 times the original estimates reported in the industry-sponsored peer-reviewed publications. Fu and colleagues, 2013 (Evidence Table 1) performed a meta-analysis to evaluate the effectiveness and harms of rhBMP-2 in spinal fusion and to assess the reporting bias in industry sponsored journal publications. The authors used data from the literature and individual patient level data of the rhBMP-2 trials (including unpublished data from the trials) provided by the manufacturer through the Yale Open Data Aces (YODA) Project. The latter project was sponsored by the manufacturer for an independent review of all published and unpublished data. The analysis included=13 RCTs (12 sponsored by Medtronic) and 31 cohort studies, 47 intervention series, and 35 case series or reports. The primary outcome was the overall success and fusion. The meta-analysis had generally valid methodology, and the studies included were rated by the authors to be of moderate quality. However, all were unblinded; industry sponsored, and according to the authors, had poor ascertainment of harm. The authors analyzed anterior and posterior fusion separately as well as cervical and lumbar fusion. The pooled results of studies comparing rhBMP-2 versus ICBG for ALIF, showed no significant differences in overall success except for very slight improvement in leg pain at 6 weeks with rhBMP-2. There were higher rates to urogenital complications and retrograde ejaculation with rhBMP-2, the difference was not significant but could be due to insufficient power. The cancer risk was significantly higher with rh-BMP-2. The authors of the meta-analysis noted that early journal publications misrepresented the effectiveness and harms through selective reporting, under-reporting, and duplicate publications. They concluded that their technology had no proven advantage over bone graft and may be associated with important harms. Simmonds et al, 2013 meta-analysis (Evidence Table 2) also used data from the YODA project to evaluate the safety and effectiveness of rhBMP-2 compared to ICBG. The analysis included 12 RCTs (11 Medtronic sponsored) for effectiveness plus 35 additional controlled adverse events studies for safety analysis. The primary outcomes were patient centered pain and function, fusion and adverse events. The results of the analysis showed that from 6 months after surgery up to 2-years, rhBMP-2 led to greater pain reduction compared to ICBG. The authors noted however; the difference may not be clinically significant as patients in both treatment groups experienced considerable reduction in pain. Successful fusion rates were found to be higher with rhBMP-2 but there was significant heterogeneity between studies in the relative risk of fusion, and the authors noted that Medtronic definitions of fusion may have been stringent as only 69% of ICBG recipients achieved fusion in 24 months. The authors found no correlation between successful fusion with rhBMP-2 and pain reduction. As regards safety, the analysis showed that pain (which was reported as an outcome and as an adverse effect) was significantly higher with rhBMP-2 shortly after surgery and lower at 24 months, compared to ICBG. Other adverse events including Implant-related events, neurologic events, retrograde ejaculation, vascular events, wound complications, and cancer, all occurred at a higher rate with rh-BMP-2, but the difference did not reach a significant level, which could be attributed to the small number of events. Zhang and colleagues, 2014 (Evidence table 3) conducted a meta-analysis of randomized controlled trials to compare the effectiveness and safety of fusion with BMPs (-2 or -7) versus ICBG for the treatment of degenerative lumbar conditions. The analysis included 19 RCTs involving 1,852 patients. The studies recruited patients with a variety of spinal disorders and different approaches were used for the fusion. In 14 of the 19 trials rhBMP was used off-label. The co-primary outcomes of the analysis were solid fusion rate, clinical outcomes, complications, and reoperation rate. The pooled results showed that the rate of fusion was significantly higher among patients in BMPs group; however, this difference was no longer significant with the sensitivity analysis that excluded 7 studies with high risk of bias. There were statistically significant differences in the overall success of clinical outcomes, complication rate, blood loss, hospital stay, patient satisfaction, or work status. Significant reductions in the operating time and reoperation rate were found in BMPs. This was a high-quality meta-analysis as regards its methodology, analysis and grading the evidence for each outcome. However, the quality of the results of a meta-analysis relies heavily on the quality of the studies it includes. Due

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to the nature of the intervention, all published trials evaluating rh-BMP-2 were unblinded, which is a source of bias, especially with subjective outcomes. In addition, there were other limitations to the published studies regarding methods of randomization and allocation procedures. There were variations between the trials in BMP used and the approach for fusion as well the methods and standards used for assessing the bone fusion which. The studies included in the meta-analysis used plain radiography, CT scan, or surgical exploration for evaluating the fusion rate. The authors explained that imaging was used to assess the status of spinal fusion, and that it provides less accurate data compared to direct operative exploration. In addition, the majority of the studies were industry sponsored and some of the authors reported conflict of interest. Overall, the authors concluded that the limited evidence does not show that BMP is superior to ICBG for the treatment of lumbar DDD and that more high-quality trials with long-term outcomes are needed. Other published meta-analyses (Chen, 2012 and Noshchenko, 2014) included the same industry sponsored RCTs, and had similar results showing that rhBMP-2 may lead to slightly higher fusion rates compared to ICBG, but with possible harm and no significant clinical improvement. **Impact of patient characteristics on the effectiveness and harms of rhBMP-2 compared with ICBG.** Laurie and colleagues' (2016) meta-analysis used the data from the YODA project to examine the impact of patient characteristics on the effectiveness and harms of rhBMP-2 as compared with ICBG. The analysis included 10 industry sponsored RCTs involving 1,255 participants. 5 trials used the anterior lumbar approach, 4 used the posterior lumbar, and one used the posterolateral lumbar approach for the interbody fusion with rhBMP-2. The population sizes of the individual trials varied from 10 to 463 participants. The results of the analysis suggest that there may be a differential treatment effect between rhBMP-2 and ICBG according to some patient characteristics. Fusion success was found to be higher with rhBMP-2 vs. ICBG in patients under the age of 60 at 6 months after the surgery and among smokers and normal weight individuals at 24 months postoperatively. No significant differences were observed between the two procedures for overweight or obese patients. The analysis also showed that the rate of device-related adverse events with rhBMP-2 was lower in individuals with no previous back surgery. **Impact of rh-BMP-2 dosing on outcomes** The BMP dose varied widely among the published studies which may indicate that is uncertainty regarding the optimal dose for the spinal fusion procedures. Hofstetter and colleagues' meta-analysis (2016) examined the effect of BMP dosing on successful fusion and morbidity with the common fusion procedures. The analysis included 48 articles involving 5,890 patients. 9 trials were on ALIF, 17 on transforaminal or posterior lumbar interbody fusion (TLIF/PLIF), 7 on anterior cervical discectomy and fusion (ACDF), and 9 trials on posterior lumbar fusion (PLF) supplemented with BMP. The authors performed separate meta-analyses for each procedure. The results of the analyses suggest that there is a wide range in the BMP dosing used for specific spinal fusion procedures (from 2.5mg/level for posterior cervical fusion [PCF] to 10.5mg/level in ACDF). The meta-analysis of studies on ALIF showed a trend toward an association between the likelihood of complications and the dose of BMP. In reports of ALIF supplemented with high doses of BMP (4.3-12.0 mg/level) the rates of endplate resorption and graft subsidence were high. More studies are needed to determine the safe and effective BMP dosing for the different applications.

Conclusion:

- The published literature does not provide sufficient evidence to determine that rh-BMP-2 has superior or equivalent effectiveness and safety compared standard iliac crest bone graft for adult patients with symptomatic lumbar degenerative disc disease referred to anterior interbody lumbar fusion.
- A number of meta-analyses and systematic reviews, including those using data from the Yale University Open Database Project, suggest that spinal interbody fusion using InFUSE® Bone Graft had a small or no advantage when compared to the standard use of iliac crest bone graft (ICBG), and may be associated with more serious adverse events.

Articles: The updated literature search did not reveal any recent trials that examined the efficacy and safety of using InFUSE® Bone Graft for anterior lumbar interbody fusion (ALIF) in patients with symptomatic single level degenerative disc disease from L1-L4. There was a number of systematic reviews with or without meta-analyses as well as several retrospective analyses on the effectiveness and safety of rhBMP-2 for spinal fusion. There were more publications and studies on the use of InFUSE® Bone Graft for cervical interbody fusion, or using the posterior, lateral, or posterolateral approaches for lumbar interbody fusion, all of which are off-label use of InFUSE® and out of scope for the current review. Two meta-analyses that included individual patient data of the rhBMP-2 trials provided by the manufacturer through the Yale Open Data Access (YODA) project, as well as another meta-analysis of published trials were selected for critical appraisal. Fu R, Selph S, McDonagh M, et al. Effectiveness and harms of recombinant human bone morphogenetic protein-2 in spine fusion: a systematic review and meta-analysis. *Ann Intern Med*. 2013 Jun 18; 158(12):890-902. Simmonds MC, Brown JV, Heirs MK,

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et al. Safety and effectiveness of recombinant human bone morphogenetic protein-2 for spinal fusion: a meta-analysis of individual-participant data. *Ann Intern Med.* 2013 Jun 18; 158(12):877-889. Zhang H, Wang F, Ding L, Zhang Z, et al. A meta-analysis of lumbar spinal fusion surgery using bone morphogenetic proteins and autologous iliac crest bone graft. *PLoS One.* 2014 Jun 2; 9(6): e97049.

The use of the InFUSE® Bone Graft/LT-Cage® Lumbar Tapered Fusion Device for Anterior Lumbar Interbody Fusion (Recombinant Bone Morphogenetic Protein Type 2 [rhBMP-2]) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary for InFUSE™:

CPT® Codes	Description
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/08/2003	10/08/2003 MPC, 12/07/2009 MPC, 07/07/2015MPC, 05/03/2016MPC, 06/07/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC , 10/05/2021MPC	12/06/2022

MPC Medical Policy Committee

Revision History	Description
08/01/2017	Added MTAC second review
07/24/2020	Added code 20930 to criteria
12/06/202	MPC approved to adopt a non-covered list of bone grafts substitutes and adjuncts. No 60-day notice required.

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Clinical Review Criteria
Inhaled Nitric Oxide (iNO) Therapy

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Criteria

For Non-Medicare Members

A. Treatment of pulmonary hypertension (PHN) to reduce risk of chronic lung disease, and respiratory failure in infants born or at near term (>34 weeks)
   1. Neonate does not have congenital diaphragmatic hernia, and
   2. Conventional therapies such as administration of high concentrations of oxygen, hyperventilation, high-frequency ventilation, the induction of alkalosis, neuromuscular blockade, and sedation have failed or are expected to fail.
   3. Treatment of Congenital Diaphragmatic Hernia (CDH)
      a. iNO is required to stabilize a patient during transition to ECMO (Usually required for a few hours before)
      b. iNO is required during transition off of ECMO when pulmonary arterial pressures are high (this can be a period of time ranging from hours to several days)

B. Treatment of pulmonary hypertension in pre-term newborns (≤34 weeks)
   There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

C. Treatment of acute respiratory distress syndrome (ARDS) in adults and children
   There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

D. Treatment of Cyanotic Congenital Heart Disease with pulmonary hypertensive crisis (all pediatric patients)
   1. The patient is being managed for acute pulmonary hypertension crisis and acute right heart failure with a predisposition to unrestricted over-circulation. OR
   2. The patient requires a surgical intervention with increased risk of pulmonary hypertension crisis and is receiving pulmonary vascular therapy AND
      a. Typical course of treatment 3 days (this may be longer on a case by case basis) to transition to oral medications and wean-off iNO OR
      b. The patient needs transplant for right heart failure and requires iNO for 1 week to several months.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Treatment of persistent pulmonary hypertension (PPHN) and respiratory failure in infants born or at near term.

Persistent pulmonary hypertension of the newborn (PPHN) is an important cause of cardiorespiratory failure in the near-term neonate (>34 weeks). It occurs when normal cardiopulmonary transition fails to take place after birth; the newborn's arteries to the lungs remain constricted limiting the amount of blood flow to the lungs and therefore

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the amount of oxygen into the blood stream. PPHN can occur either as a primary condition of neonatal maladaptation or secondary to other conditions such as pneumonia, sepsis, hyaline membrane disease, meconium aspiration, congenital diaphragmatic hernia, or pulmonary hyperplasia. Causes of PPHN may be variable, but all lead to same physiologic changes; a persistently raised pulmonary vascular resistance that leads to severe hypoxemia due to extra pulmonary shunting. Even with appropriate therapy, the mortality for PPHN remains between 5 and 10% (Gonzales 2009, Finer 2009, Steinhorn 2010).

The goal of therapy of PPHN is to maximize the amount of oxygen transported to the lungs and in turn to the systemic circulation. Conventional therapies include supplemental oxygen with often requires intubation and mechanical ventilation, induction of alkalosis, paralysis, sedation, as well as maintenance of temperature, electrolytes, glucose, and intravascular volume. Infants who fail conventional therapies may require treatment with extracorporeal membrane oxygenation (ECMO). During ECMO, the jugular vein and/or carotid artery is surgically bisected and connected to a heart-lung machine with a cannula to oxygenate the infant's blood. ECMO therapy can be lifesaving, but is highly invasive, labor intensive, and has potential side-effects such as intracranial hemorrhage and ligation of the right common carotid artery (Steinhorn 2010).

Inhaled nitric oxide (iNO) has been investigated for the treatment of PPHN to improve oxidation, reduce the need for ECMO, and decrease mortality. Nitric oxide is a colorless, almost odorless gas that is naturally produced by various human tissues and is involved in several physiologic functions. It is a rapid and potent vasodilator, and because of its small gas molecule, it can be delivered as inhalation therapy to airspaces in close proximity to the pulmonary vascular bed. Once in the blood stream NO binds to hemoglobin and is rapidly inactivated with an estimated half-life of 3-5 seconds. The effect of iNO is limited to the lungs making it a selective pulmonary vasodilator without adverse systemic hemodynamic effect (DiBlasi 2010, Steinhorn 2010).

iNO therapy is not without harmful side effects. When oxygen and nitric oxide mix together, they chemically react to form nitrogen dioxide (NO2), which is toxic to the lungs. Nitrogen dioxide concentrations greater than 10 parts per million (ppm) have been known to induce pulmonary edema, alveolar hemorrhage, changes in the surface tension properties of surfactant, and death. NO2 is dose- dependent and its concentrations should be maintained below 3 ppm by decreasing the iNO concentration if its level increases. Methemoglobinemia (MetHb), which impairs the ability of the hemoglobin molecule to bind with oxygen, is another harmful side effect of iNO therapy. MetHb is dose-dependent and its levels must be carefully monitored. Significant methemoglobinemia has been reported after accidental overdose of iNO, and a level >10% may cause cyanosis, headaches, muscle weakness, and tissue hypoxia. Laboratory and clinical studies have suggested that high doses of inhaled nitric oxide may increase the risk of bleeding, which is a serious concern because of the predisposition of premature newborns to intracranial hemorrhage (Kinsella 2006, Finer 2009, Henry 2012).

The recommended initial dose of iNO is 20 ppm, and the duration of its use is normally less than 5 days but may be maintained for up to 14 days, or until the underlying oxygen desaturation has been resolved. Abrupt discontinuation of the therapy can lead to worsening of PaO2 and increasing pulmonary artery pressure. The use of iNO was approved by the Food and Drug Administration (FDA) in 1999 for the treatment of term and near-term neonates (>34 weeks) with hypoxic respiratory failure with clinical or echocardiographic evidence of pulmonary hypertension. Using iNO for other medical conditions is considered "off label" usage.

iNO therapy is provided through a delivery system used in conjunction with a ventilator or other breathing gas administration system. Nitric oxide delivery system consists of a nitric oxide administration apparatus, a nitric oxide gas analyzer, and a nitrogen dioxide gas analyzer. INOmax® (INO Therapeutics Inc., Clinton NJ) is a commercially available brand of iNO that received initial Food and Drug Administration approval in 1999 to be used as a vasodilator in conjunction with ventilatory support and other appropriate agents. In 2009, the FDA updated the INOmax safety labeling indicating that in patients with pre-existing left ventricular dysfunction, iNO may increase pulmonary capillary wedge pressure leading to pulmonary edema, even when used for a short time (FDA webpage accessed July 20, 2012).

Treatment of pulmonary hypertension in pre-term newborns
Approximately 8-13% of all babies are born preterm (<37 weeks of gestation) across developed countries. Although survival rates have improved markedly in recent decades, preterm delivery still accounts for more than 75% of all perinatal complications and death. It is estimated that three fourths of preterm infants with birth weight <1000g develop respiratory distress syndrome (RDS), and 30- 40% are still oxygen dependent at a postmenstrual age (gestational age plus chronological age) of 36 weeks. Breathing failure in premature newborns may be complicated by raised pressure within the vessels that carry blood to the lungs (pulmonary hypertension). Those who require assisted ventilation are at high risk of developing long-term medical and neurocognitive impairment including bronchopulmonary dysplasia (BPD), which is characterized by arrested lung growth, reduced
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alveolarisation, and dysmorphic vasculature (i.e. the infants' lungs are not fully formed or are not able to make enough surfactant, which is a liquid that coats the inside of the lungs and helps keep them open so an infant can breathe in air once he or she is born). Without surfactant, the lungs collapse, and the infant may not be able to breathe in enough oxygen to support the body's organs. This may lead to neurodevelopmental impairment and damage to other organs (Barrington 2006, Askie 2010, 2011).

Conventional therapy of respiratory failure complicated by pulmonary hypertension in preterm newborn involves respiratory support, which includes assisted ventilation and continued distending pressure, the administration of surfactant, and sedation or muscle relaxation if needed.

iNO has been investigated as a treatment to prevent lung injury in preterm infants based on the findings from experimental studies performed on a variety of fetal animals and/ or premature animal models with hyaline membrane disease and elevated pulmonary artery pressure. These experiments showed that iNO therapy may enhance pulmonary angiogenesis and lung alveolarisation, reduce the pulmonary vascular resistance and improve oxygenation. Studies in full-term infants also showed that iNO may cause selective pulmonary vasodilatation to reduce pulmonary artery pressure and improve ventilation /perfusion mismatch. However, the results of studies conducted among term or near-term infants cannot be extrapolated to the preterm babies because of the difference in pathophysiology of respiratory failure, and the difference in the potential risks of iNO in preterm infants. If iNO therapy leads to a decrease in required ventilation support, it may also lead to a reduction in lung injury and bronchopulmonary dysplasia. However, it is still uncertain which subpopulation of premature infants may profit most from iNO. There is also opposing data on whether exogenous NO is protective or destructive in the presence of hyperoxia. Inhaled nitric oxide has pro-oxidation and antioxidants activities and can potentially worsen lung injury. Preterm infants are also at higher risk of developing intracranial hemorrhage, and there is a concern about the effect of iNO in increasing the bleeding time (Barrington 2006, Love 2012).

Inhaled nitric oxide is provided through a delivery system used in conjunction with a ventilator or other breathing gas administration system. iNO delivery system consists of a nitric oxide administration apparatus, a nitric oxide gas analyzer, and a nitrogen dioxide gas analyzer. INOmax® (INO Therapeutics Inc., Clinton NJ) is a commercially available brand of iNO that received initial Food and Drug Administration approval in 1999 to be used as a vasodilator in conjunction with ventilatory support and other appropriate agents for the treatment of term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The use of iNO for other neonatal medical conditions is considered "off label" use.

Treatment of acute respiratory distress syndrome (ARDS) in adults and children
Acute respiratory distress syndrome (ARDS) is a major source of morbidity and mortality, with a case fatality rate exceeding 30%. ARDS is defined by acute non-cardiogenic pulmonary edema, acute severe hypoxemia irrespective of positive end expiratory pressure, bilateral infiltrates on chest radiography, and a pulmonary artery occlusion pressure ≤18 in any adult or child more than one month old. Acute lung injury (ALI) is a milder form of the syndrome and both conditions are often referred to as acute hypoxemic respiratory failure (AHRF). They are characterized by an inflammatory process of the alveolar-capillary membrane that may result from a primary lung disease or is secondary to a number of systemic diseases. AHRF results in intrapulmonary shunting with hypoxemia and pulmonary hypertension. Hypoxemia in ARDS is mainly caused by ventilation perfusion mismatch leading to increased pulmonary shunting due to pulmonary vasodilatation in non-ventilated lung regions and vasoconstriction in ventilated areas (Milberg 1995, Afshari 2011, 2012).

Treatment of ARDS/ALI is mainly supportive and aims at improving gas exchange, control of infection, and preventing complications. The optimal therapy involves judicious fluid management, protective mechanical lung ventilation with low tidal volumes and moderate positive end expiratory pressure, multi-organ support, and treatment of the underlying cause, when possible. Pharmacotherapies have a very limited role in the management of ARDS, and to-date there is no effective medical treatment that improves survival for adult patients with the syndrome, although exogenous surfactant is beneficial in the pediatric population (Dushianthan 2011).

In 1991, inhaled nitric oxide (iNO) was shown to be a selective pulmonary vasodilator in patients with pulmonary hypertension, as well as in animals with pulmonary hypertension induced by drugs or hypoxia. Two years later, inhaled nitric oxide was introduced as a potential therapy for ARDS. Nitric oxide is a colorless, odorless gas that rapidly diffuses from alveoli through epithelial cells to gain direct access to the vasculature. Once in the blood stream it binds to hemoglobin and is rapidly inactivated with an estimated half-life of 3-5 seconds. The effect of iNO is limited to the lungs making it a selective pulmonary vasodilator without adverse systemic hemodynamic effects. iNO causes vasodilatation of ventilated lung units and redistribution of pulmonary blood flow away from non-ventilated lung areas. It decreases pulmonary vascular resistance, improves the ventilation perfusion
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mismatch, and subsequently reduces the elevated vascular resistance and pulmonary hypertension. It is also believed that iNO may also regulate both the immune and inflammatory responses (oxygenation by redistributing pulmonary blood flow toward ventilated lung units in patients with this condition (Griffiths 2005. DiBlasi 2010, Dushianthan 2011, Pierrakos 2011).

iNO therapy is also associated with harmful side effects. Nitric oxide is unstable in air and when inhaled with high concentrations of oxygen, the gaseous NO slowly forms nitrogen dioxide which is potentially cytotoxic. A NO_2 concentrations higher than 10 parts per million (ppm) has been known to induce pulmonary edema, alveolar hemorrhage, changes in the surface tension properties of surfactant, and death. NO_2 is dose-dependent and its concentration should be maintained at a level below 3 ppm by decreasing the iNO concentration if it goes any higher. Methemoglobinemia (MetHb), which impairs the ability of the hemoglobin molecule to bind with oxygen, is another harmful side effect of iNO therapy. MetHb is dose-dependent and must be carefully monitored as significant methemoglobinemia has been reported after accidental overdose of iNO. A MetHb level >10% may cause cyanosis, headaches, muscle weakness, and tissue. Renal failure has also been reported with iNO use (Kinsella 2006, Finer 2009, Dushianthan 2011, Henry 2012).

Inhaled nitric oxide is provided through a delivery system used in conjunction with a ventilator or other breathing gas administration system. The delivery system consists of a nitric oxide administration apparatus, a nitric oxide gas analyzer, and a nitrogen dioxide gas analyzer. INOmax® (INO Therapeutics Inc., Clinton NJ) is a commercially available brand of iNO that received initial Food and Drug Administration approval in 1999. It was approved for use as a vasodilator, in conjunction with ventilatory support and other appropriate agents for the treatment of term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The use of iNO for other neonatal medical conditions and for treatment in the adult patient population is considered "off label" usage.

Medical Technology Assessment Committee (MTAC)

iNO for Treatment of Persistent Pulmonary Hypertension

08/20/2012: MTAC REVIEW

Evidence Conclusion:

There is fair evidence that inhaled nitric oxide therapy for adult patients with acute respiratory distress syndrome or acute lung injury does not improve survival or other clinical outcomes and may increase the risk of renal impairment. There are insufficient published pediatric trials to determine any benefit or harm of iNO therapy in children with ARDS or ALI.

Articles: Treatment of persistent pulmonary hypertension (PPHN) and respiratory failure in infants born or at near term: The literature search revealed a number of randomized controlled studies and a Cochrane review with a meta-analysis that pooled the results of 12 RCTs. The Cochrane review and the RCT published after the meta-analyses were selected for critical appraisal. Finer N and Barrington KJ. Nitric Oxide for respiratory failure in infants born at or near term. *Cochrane Database Syst Rev.* 2006 (updated 2009) Issue 4. Art No. CD000399. See Evidence Table . Gonzalez A, Fabres J, D'Apremont I, et al. Randomized controlled trails of early compared with delayed use of inhaled nitric oxide in newborns with a moderate respiratory failure and pulmonary hypertension. *J Perinatol* 2010; 30:420-424. See Evidence Table . Treatment of pulmonary hypertension in pre-term newborns. The literature search revealed a number of randomized controlled studies published between the late 1990s and 2010 and four meta-analyses that pooled the results of all, or some of these trials including a Cochrane review (Burrington and Finer) first published in 2006 and last updated in 2010, an earlier meta-analysis (Hoehn 2000 updated in 2006) and two more recent meta-analysis (Askie 2011, and Donahue 2011). The Cochrane review and Askie and colleagues' meta-analysis of individual patient data from the same trials included in the Cochrane review were selected for critical appraisal. Askie LM, Ballard RA, Cutter GR, Dani C, et al for the Meta-analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPiNO) Collaboration. Inhaled nitric oxide in preterm infants: An individual -patient data meta-analysis of randomized trials. *Pediatrics*. 2011; 128:729-739. See Evidence Table . Barrington KJ, Finer N. Inhaled nitric oxide for respiratory failure in preterm infants. *Cochrane Database Syst Rev.* 2010 Dec 8;(12):CD000509. See Evidence Table . Treatment of acute respiratory distress syndrome (ARDS) in adults and children. The literature search revealed a number of randomized controlled studies and two meta-analyses of RCTs (Adhikari 2007, and Afshari (described in 2 publications 2010 and 2011). No trials published after the last meta-analysis were identified by the search. The more recent meta-analysis was selected for critical appraisal. Afshari A, Brok J, Moller AM et al. Inhaled nitric oxide for acute respiratory distress syndrome (ARDS) and acute lung injury in children and adults. Cochrane Database of Systematic Reviews 2010, Issue 7. Art. No.: CD002787.pub2. See Evidence Table **.** Afshari A, Brok J, Moller AM et al. Inhaled nitric oxide for acute respiratory distress syndrome (ARDS) and acute lung injury in children and adults. A systematic review with meta-analysis and trial sequential analysis. Anesth Analg 2011; 112:1411-1421. See Evidence Table.

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The use of iNO for Treatment of persistent pulmonary hypertension (PPHN) and respiratory failure in infants born or at near term does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of iNO for treatment of pulmonary hypertension pre- term newborns does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of iNO for treatment of ARDS in adults and children does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No Specific Codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Review Dates	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012 [MDCRPC], 08/06/2013 [MPC], 11/05/2013 [MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	08/06/2013

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dermal Fillers for Facial Lipoatrophy

- Sculptra
- Radiesse

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Dermal filler injections are covered when **ALL** of the following criteria are met:

1) The member has **ALL** of the following:

   a) a diagnosis of human immunodeficiency virus (HIV), and

   b) a diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4*, related to HIV or highly active antiretroviral therapy (HAART), and

AND

2) The dermal filler is approved by the Food and Drug Administration for Facial Lipodystrophy Syndrome (LDS), e.g. Sculptra® and Radiesse®.

Multiple sessions may be necessary to complete the therapy, depending upon the severity of the lipodystrophy. The following link provides examples of the Carruthers grading system*: www.facialwasting.org.

If the patient has:

1) Grade 3 lipodystrophy, up to 4 sessions may be required
2) Grade 4 lipodystrophy, up to 8 sessions may be required

*If additional treatments are desired, the treating provider will need to reevaluate the patient or repeat photos of the patient's face will be required to determine if further treatments are warranted.

Repeat treatment is typically necessary one to two years after the initial therapy, when the patient has regressed to Grade 2 or greater lipoatrophy.

CONTRAINDICATIONS

Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function as determined by HIV provider.

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If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

HIV-associated lipodystrophy has been reported in the literature starting in the late 1990s. This condition involves loss of subcutaneous fat or fat accumulations in particular regions of the body. It can include fat accumulation around the abdomen, dorsocervical area (buffalo hump) and breast hypertrophy. Regions affected by fat loss (lipoatrophy) include the limbs, buttocks and face, especially the nasolabial regions, the temples and the eye sockets. The condition is different from HIV wasting syndrome that is mainly due to loss of muscle mass. HIV-associated lipodystrophy is also associated with insulin resistance, hyperglycemia and low levels of high-density lipoprotein (HDL) (James et al., 2002).

Although the cause of HIV-associated lipodystrophy is not well understood, some investigators believe there is a link with HIV protease inhibitors (PI). The condition started being reported in the literature around the time that protease inhibitors were introduced and prescribed to HIV-infected patients. In addition, the prevalence of lipodystrophy is higher in HIV-infected patients who received PIs compared to PI-naïve patients (James et al., 2002). Lipoatrophy may be associated with the use of specific nucleosides such as stavudine and didanosine in treatment while lipoaccumulation may be associated with protease inhibitors, especially ritonavir (Dr. Wayne Dodge, personal communication).

The treatment of facial lipoatrophy is the subject of the current MTAC review. There is little published literature on this topic, but anecdotal information suggests that facial lipoatrophy negatively affects HIV-infected individuals' body image and self-esteem and can lead to social and sexual problems. The long-term natural history of lipoatrophy is also not well known. Lipoatrophy does not appear to resolve on its own, or after discontinuation of PIs and other medication (James et al., 2002; Huff, 2004).

Sculptra, an injectable form of poly-L-lactic acid (PLA) is the first FDA-approved treatment for HIV-associated facial lipoatrophy. PLA is a biocompatible, biodegradable substance that is synthetically derived from natural components. It was been used in surgical products such as dissolvable stitches and bone screws. PLA was approved in Europe in 1999 for cosmetic treatment of scars and wrinkles, under the brand name New-Fill. The FDA did not approve Sculptra for the treatment of wrinkles. FDA approval of Sculptra for facial lipoatrophy was based on unpublished data submitted by the manufacturer Dermik Laboratories. A condition of FDA approval was that Dermik agreed to conduct a registry study for five years to evaluate Sculptra's long-term safety (FDA press release; James et al., 2002). Potential limitations of injectable PLA for severe cases of facial lipoatrophy are that large quantities of material are needed to fill the defects and there may be high maintenance costs (Binder & Bloom, 2004).

Medical Technology Assessment Committee (MTAC)

Injectable Poly-L-Lactic Acid (PLA)

12/08/2004: MTAC REVIEW

Evidence Conclusion: There was one randomized controlled trial with 30 patients (Moyle, 2004) and this compared immediate treatment with PLA to delayed treatment after 12 weeks. The 12-week follow-up is the appropriate point in the study to compare treatment with no treatment. At 12 weeks, there were no significant differences between groups in depression or anxiety scores. A significantly greater proportion of patients in the immediate treatment group perceived "less thinness" in the face. The study was limited by the short follow-up period, small sample size with no statistical power analysis and lack of clear primary outcomes. The other empirical study reviewed was a case series with 50 patients (Valentin, 2003). Although there was no comparison group, advantages of the Valentin study were that there was objective measurement of changes in facial thickness and follow-up was longer, 96 weeks. There was a significant increase in total cutaneous thickness (TCT) of the face after a series of treatments with PLA and the increase in TCT persisted until the 96-week follow-up. There was a significant increase in the quality of life score compared to baseline at the 24- and 48 weeks follow-ups, but not at the 72- or 96-week follow-ups. No serious adverse effects were reported in either study. Safety and efficacy beyond 96 weeks is not known. The generalizability of Valentin study has been criticized because one dermatologist performed all of the injections; it is not known whether there would be similar results

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with other dermatologists. In summary, there is some evidence from an uncontrolled case series that treatment with Sculptra can reduce facial lipoatrophy for up to 96 weeks and has no serious adverse effects, when used by a trained dermatologist. There are no good data from controlled studies. The impact on quality of life is less clear. There are no published data on safety and efficacy of Sculptra beyond 96 weeks.

Articles: The search yielded 10 articles. Several were reviews or opinion pieces. Three empirical studies were identified. The ideal study would have the following characteristics: Randomized controlled trial, Comparison of Sculptra to alternative treatment, or placebo, Long-term follow-up, sufficiently large sample size, Important outcomes include whether treatment with Sculptra is effective at increasing facial fat and reduces any adverse psychosocial effects. In this case, there is no standard alternate treatment and no other FDA-approved new treatments for HIV-associated facial lipoatrophy. No placebo-controlled studies were identified. There was one randomized controlled trial that compared immediate treatment with PLA to delayed treatment. There was also a case series with 96 weeks' follow-up. Case series can provide important long-term safety data. The RCT and case series were critically appraised. Both used New-Fill, the European version of PLA. The third empirical study was a case report presenting data on 4 patients and was excluded from review. The following studies were critically appraised: Valantin M-A Aubron-Olivier C, Ghosn J et al. Polylactic acid implants (New-Fill) to correct facial lipoatrophy in HIV-infected patients: results of the open-label study VEGA. AIDS 2003; 17: 2471-2477. **See** Evidence Table. Moyle GJ, Lysakova L, Brown S et al. A randomized open-label study of immediate versus delayed polylactic acid injections for the cosmetic management of facial lipoatrophy in persons with HIV infection. *HIV Medicine* 2004; 5: 82-87. See Evidence Table.

The use of injectable poly-L-lactic acid (PLA) in the treatment of facial lipoatrophy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, Sculptra, 0.5 mg

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Date Created	Date Reviewed	Date Last Revised
12/08/2004	12/08/2004, 07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 01/08/2013MDCRPC, 11/05/2013MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC, 12/07/2021MPC,12/06/2022MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved coverage criteria for non-Medicare members. Requires 60-day notice, effective date 10/01/2021.

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Clinical Review Criteria
Injectable Bulking Agents for Fecal Incontinence

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Injectable Bulking Agents for the Treatment of Fecal Incontinence (A52923) Noridian ***retired*** Local Coverage Article (LCA A52923). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on Kaiser Permanente commercial criteria or literature search.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Fecal incontinence occurs when a person loses the ability to control his/her bowel movements and is unable to retain feces in the rectum. It can be caused by a wide variety of conditions that affect either the anatomy or function of the anal sphincter. Perineal injury during childbirth is a common cause of fecal incontinence in women. It can also be caused by neurological disorders such as spinal injury and multiple sclerosis, or it can result from anorectal surgery. In any case, fecal incontinence is common and, due to its association with considerable physical and social disability, is often under-reported (Tjandra, Chan et al. 2009).

First line treatment for fecal incontinence is usually conservative and includes antidiarrheal medication and pelvic floor muscle training. In patients for whom conservative treatment fails, alternative treatments include surgery to tighten the anal sphincter, sacral nerve stimulation, creation of a new sphincter from other suitable muscles,

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implantation of an artificial sphincter or a permanent colostomy. Injectable bulking agents offer an additional, less invasive, second line treatment for fecal incontinence. The concept is to inject a biocompatible material to close the anal canal to avoid fecal incontinence (Siproudhis, Morcet et al. 2007; Maeda, Vaizey et al. 2008; Graf, Mellgren et al. 2011).

At least ten different materials have been used as bulking agents for fecal incontinence including autologous fat, Teflon, bovine glutaraldehyde, cross-linked collagen, carbon coated zirconium beads, polydimethylsiloxane elastomer, dextranomer in nonanimal stabilized hyaluronic acid, hydrogel cross-linked with polyacrylamide, porcine dermal collagen, synthetic calcium hydroxylapatite ceramic microspheres and polyacrylonitrile in cylinder form (Maeda, Laurberg et al. 2013). The material can be injected either via the perianal skin or via the anal mucosa. The procedure may be performed under local, regional or general anesthesia and the injection may be guided by the surgeon's finger in the anal canal or by ultrasound. This treatment is potentially attractive in its simplicity and minimal invasiveness and can be performed in an outpatient setting.

Several injectable bulking agents have been approved by the U.S. Food and Drug Administration (FDA) in recent years for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy.

The Medical Technology Assessment Committee (MTAC) previously reviewed and failed bulking agents for the treatment of GERD in 2003. Currently, the committee has been asked to review the literature on the safety and efficacy of injectable bulking agents for the treatment of fecal incontinence compared to standard treatment for fecal incontinence. This is the first time that bulking agents have been reviewed for this indication. The topic is being reviewed for decision making guidance.

Medical Technology Assessment Committee (MTAC)

Injectable Bulking Agents for Fecal Incontinence

10/21/2013: MTAC REVIEW

Evidence Conclusion: ***EFFICACY THE*** Cochrane Collaboration identified five randomized trials for inclusion in their review to determine if the injection of bulking agents is better than currently available treatments or no treatments for fecal incontinence in adults. Only two of the trials compared a bulking agent to sham treatment and none of the studies made a comparison of bulking agents versus other therapies. On the whole, the studies were of poor quality with only two providing adequate information to reliably assess bias. In addition, most of the studies were small and limited to short-term follow up. Two of the trials reported on the short-term benefit from injections as outcome measures improved with time but neither trial had follow up beyond 12 months (Siproudhis, Morcet et al. 2007; Graf, Mellgren et al. 2011). In addition, there appeared to be some short-term benefits from injections given with ultrasound guidance compared with digital guidance (Tjandra, Han et al. 2004). Two of the studies compared different types of bulking agents with the larger trial reporting that silicone material was better than the carbon coated beads in terms of fecal incontinence at six and 12 months (Tjandra, Chan et al. 2009). The smaller trial, which was not included in this critical appraisal, compared the injection of Bulkamid™ with Permacol™ and showed some improvement in outcomes in both groups but ultimately was too small to detect differences between groups (Maeda, Vaizey et al. 2008). Currently the literature addressing the efficacy of injectable bulking agents is limited for a variety of reasons. First and foremost, outcome measures and the definition of response to treatment are varied, and as a result, problematic for this indication. Furthermore, it is unclear how severity of incontinence at baseline affects outcomes data. Finally, there is a lack of information regarding the volume, the precise location where the agent should be placed, and the choice of guidance of the needle track. Several different techniques were employed with various bulking agents used across all studies making comparisons complicated. **SAFETY** Four of the five studies reported on adverse effects (Tjandra, Han et al. 2004; Siproudhis, Morcet et al. 2007; Tjandra, Chan et al. 2009; Graf, Mellgren et al. 2011). Overall, the observed adverse events were similar across all the studies with few complications reported and the most commonly reported complication being pain at injection site. Safety data collected from these trials is limited as it is not clear if complications were recorded systematically. The severity and duration were not always mentioned, and in many cases, adverse events were recorded with no information on the number of patients reporting these events. (For example, Graf and colleagues reported 128 adverse events in patients treated with NASHA Dx and 29 events in the sham treatment group but do not detail the number of patients reporting these adverse events.) Furthermore, the safety of injectable bulking agents has not been studied past 12 months. Other studies not included in this review also reported experiencing pain or minor ulceration at the injection site or in the anal canal for up to 10 weeks after the procedure (Malouf, Vaizey et al. 2001). Further complications included leakage of the bulking agent in 1 of 10 patients and, in a different study, passing of the bulking agent in 2 of 18 patients (Davis, Kumar et al. 2003). Conclusion: There is evidence from one large randomized trial to suggest that injectable bulking agents are effective up to 12 months. There is evidence to suggest that injectable bulking agents are reasonably safe in the short term. There is no evidence to permit conclusions about long term safety or efficacy of injectable bulking agents for fecal incontinence.

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Articles: A literature search was conducted revealing a variety of publications including multiple case-series reports as well as case-control and cohort studies. One recent Cochrane review was also revealed which included five randomized trials measuring the effects of bulking agents versus placebo, bulking agents versus other types of bulking agents and bulking agents versus other minimally invasive interventions. No studies that compared the injection of bulking agent versus conservative treatment were revealed. Four of the studies included reporting of adverse events up to 12 months post treatment. The Cochrane review did not pool the results of the trials due to their heterogeneity. Four of the five trials included in the Cochrane Review were selected for appraisal:
Graf W, Mellgren A, Matzel KE, Hull T et al. Efficacy of dextranomer in stabilized hyaluronic acid for treatment of faecal incontinence: a randomized, sham-controlled trial. *Lancet* 2011; **377**(9770):997-1003.
See Evidence Table 1. Siproudhis, L., J. Morcet, et al. Elastomer implants in faecal incontinence: a blind, randomized placebo-controlled study. *Alimentary Pharmacology & Therapeutics* 2007;**25**(9):1125-1132.
See Evidence Table 2. Tjandra, J., W. Han, et al. (2004). "Injectable silicone biomaterial for faecal incontinence due to internal sphincter dysfunction is effective." *Diseases of the Colon & Rectum* **47**(12): 2138-2146. See Evidence Table 3. Tjandra, J, Chan M, et al. Injectable silicone biomaterial (PTQTM) is more effective than carbon-coated beads (Durasphere®) in treating passive faecal incontinence – a randomized trial." *Colorectal Disease* 2009;**11**(4):382-389. See Evidence Table 4.

The use of Injectable Bulking Agents for Fecal Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Dates	Date Last Revised
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[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/9/2015	Added LCA A52922

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Clinical Review Criteria
Inpatient Rehabilitation

- Admission guidelines

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	See the Medicare Benefit Policy Manual Chapter 1 - Inpatient Hospital Services Covered Under Part A 110 - Inpatient Rehabilitation Facility (IRF) Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Inpatient Rehabilitation Facility (IRF - acute rehabilitation) admission is indicated by **ALL of the following**:

1) No acute hospital care needs.
   The inpatient rehabilitation benefit is not to be used as an alternative to completion of the full course of treatment in the referring hospital. (e.g. for completion of antibiotics or to observe renal failure)
2) A preadmission screening assessment must be completed. A preadmission screening assessment is an evaluation of the patient's condition and need for rehabilitation therapy and medical treatment that must be conducted by licensed or certified clinician(s) (Registered Nurse, Physical or Occupational Therapist, Nurse Practitioner, or Medical Doctor) within the 48 hours immediately preceding the IRF admission. A preadmission screening that includes all of the required elements, but that is conducted more than 48 hours immediately preceding the IRF admission, will be accepted as long as an update is conducted in person or by telephone to document the patient's medical and functional status within the 48 hours immediately preceding the IRF admission in the patient's medical record at the IRF.
3) There must be documentation in the preadmission screening assessment (a copy of the assessment must available for review) that includes **ALL of the following**:
   a) Must indicate the patient's prior level of function (prior to the event or condition that led to the patient's need for intensive rehabilitation therapy),
   b) Expected level of improvement and
   c) Expected length of time necessary to achieve that level of improvement.
   d) Nature and degree of improvement identified with practical goals established for patient's condition
   e) Conditions that caused the need for rehabilitation,
   f) Treatments needed (i.e., physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics),
   g) Expected frequency and duration of treatment in the IRF,
   h) Discharge plan that includes **ALL of the following**:
      - Anticipated discharge destination including documentation that patient will be appropriate for discharge to home or to a community-based environment. (not to a SNF or LTC facility)
   i) Any anticipated post-discharge treatments and any other information relevant to the care needs of the patient.

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4) In order for IRF care to be considered reasonable and necessary, the documentation must demonstrate a reasonable expectation that **ALL of the following** criteria will be met at the time of admission to the IRF:
   a) The patient must require the active and ongoing therapeutic intervention of more than two therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy.
   b) Need for an intensive rehabilitation therapy program that includes **ONE or more** of the following:
      - Therapy at least 3 hours per day for 5 days per week OR
      - Therapy at least 15 hours per week consecutive days
   c) Therapy must not exceed the patient's need or tolerance or compromise the patient safety.
   d) The patient must reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program. Also, there should be a reasonable expectation that a measurable, practical improvement in the patient's functional condition can be accomplished within a predetermined and reasonable period of time.
   e) Close physician involvement with need for treating rehabilitation physician face-to-face assessment at least 3 days per week (e.g. monitoring of uncontrolled pain, bowel and bladder issues, and complex rehabilitation needs such as adapting mobility devices.)
   f) The patient must require an intensive and coordinated interdisciplinary approach to providing rehabilitation

5) Document must state why an equivalent outcome will not be achieved in a Skilled Nursing Facility.

The following indications are not covered:
- Coma stimulation
- Custodial care
- Routine services for maintenance of medication administration, routine enteral feedings, routine colostomy care, ongoing straight catheterization for chronic conditions.
- Single joint replacement unless the individual has significant comorbidity(ies) resulting in functional deficits which would necessitate an acute inpatient level of rehabilitation in order to achieve a satisfactory outcome within a reasonable time period.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Inpatient rehabilitation hospital admissions provide intensive rehabilitation to patients with various neurological, musculo-skeletal, orthopedic and other medical conditions following stabilization of their acute medical issues. The inpatient rehabilitation bed is specifically licensed for the rehabilitation services and is sometimes part of an acute hospital or a separate facility.

Rehabilitation hospitals were created to meet a perceived need for facilities which were less costly on a per diem basis than general hospitals, but which provided a higher level of professional therapies such as speech therapy, occupational therapy, and physical therapy than can be obtained in a "skilled nursing care" facility. Prior to admission to an inpatient rehabilitation facility an evaluation is conducted by a physiatrist to determine appropriateness for this level of admission.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
03/04/2014	02/02/2010 MDCRPC, 01/04/2011 MDCRPC, 01/03/2012 MDCRPC, 02/05/2013 MPC, 2/04/2014 MPC, 03/04/2014 MPC, 02/03/2015MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	06/21/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
06/21/2017	Added a clarifying sentence to 4 d

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Insulin Pump
- InPen System

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Criteria
For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Infusion Pumps (280.14)
Local Coverage Determinations (LCD)	External Infusion Pumps (L33794)
Local Coverage Article	External Infusion Pumps – Policy Article (A52507)
Kaiser Permanente Medical Policy	For **InPen System Requests** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"***InPen System***"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Initial Insulin Pump:

I. To qualify for an insulin pump the member must meet **ALL of the following:**
   A. Patient has Type 1 diabetes of at least six months' duration or Type 2 diabetes requiring a basal/bolus insulin regimen of multiple daily injections using long-acting basal insulin and a rapid-acting analogue
   B. Referral initiated by a Diabetes specialist* that will manage therapy with an insulin pump.
   C. Documentation from the Diabetes specialist* that includes **ALL of the following:**
      1. Assessment for clinical therapeutic value of an insulin pump.
      2. Assessment of patient pump education and skill training preparation prior to pump start (either one-on-one or within a group).
      3. Assessment of the patient's (or caregiver's) ability to safely and appropriately participate in an insulin-pump self-management plan.
   D. Has been on a treatment regimen of multiple daily injections (MDI) of insulin that includes a trial of both a long-acting insulin analog and a short-acting insulin analog with a plan for pre-meal short acting insulin dose adjustment for at least 3 – 6 months prior to initiation of the insulin pump.
   E. Require less than 200 units of total insulin per day prior to pump therapy.
   F. Has documented logs of glucose self-testing or CGM results - at least 4 times per day during the 1 month prior to consideration of an insulin pump.
   G. Meets **ONE or more of the following** while on an MDI regimen:
      1. Recent history (within last six months) of significant, recurring hypoglycemia (blood glucose < 70 mg/dl).
      2. Wide fluctuations (well below and above the set glycemic targets) in blood glucose before and after mealtimes, despite appropriate MDI using up to date insulins (analogs) and dose adjustments to affect control.
   H. Patient has advanced carbohydrate counting skills and actively uses this information for insulin dosing

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I. Patient demonstrates ability to recognize their glucose patterns and safely problem-solve these
J. Has no other illness that could impede use of the pump (i.e., alcohol/chemical abuse, psychological instability, difficulty with digital dexterity, visual impairment).
K. Pediatric Patients
   1. On a case-by-case basis, upon review by a clinical review medical director, pediatric patients under the age of 13 may waive the 6-month time period, if patient monitoring is occurring per the diabetes management plan outlined by an Endocrinologist.

*Note – Requests for an insulin infusion pump used with continuous glucose sensing (HCPCS code E0787 or E0784 + K0554 for Medicare) will only be authorized if the patient meets both criteria for initial or replacement insulin pump as outlined in this criteria and all criteria outlined in the Continuous Glucose Monitoring clinical review criteria including that current device is no longer under warranty.

Ongoing Coverage of Pump and Supplies:
To qualify for ongoing coverage of an insulin pump the member must meet **ALL of the following**:
A. There is documentation that patient monitors glucose at least four times daily, or appropriately uses a continuous glucose monitor.
B. Patient maintains advanced carbohydrate counting skills and actively uses this information for insulin dosing
C. Patient maintains ability to recognize their glucose patterns and safely and appropriately problem-solve these, including troubleshooting pump malfunction
D. Patient does not have other conditions or psychosocial stressors which might impede safe use of an insulin pump
E. Patient has at least one visit per year with diabetes specialist* (face-to-face, secure message, or telephone encounter)

InPen System
To qualify for an InPen System the member must meet **ALL of the following:**
A. Patient has Type 1 diabetes of at least six months' duration or Type 2 diabetes requiring a basal/bolus insulin regimen of multiple daily injections using long-acting basal insulin and a rapid-acting analogue
B. Referral initiated by a Diabetes specialist* that will manage therapy with an InPen System.
C. Documentation from the Diabetes specialist* that includes **ALL of the following:**
   1. Assessment for clinical therapeutic value of an InPen System.
   2. Assessment of patient InPen education and skill training preparation prior to InPen start (either one-on-one or within a group).
   3. Assessment of the patient's (or caregiver's) ability to safely and appropriately participate in an InPen System self-management plan.
D. Has been on a treatment regimen of multiple daily injections (MDI) of insulin that includes a trial of both a long-acting insulin analog and a short-acting insulin analog with a plan for pre-meal short acting insulin dose adjustment for at least 3 – 6 months prior to initiation of the InPen System.
E. Has documented logs of glucose self-testing or CGM results - at least 4 times per day during the 1 month prior to consideration of an InPen System.
F. Meets **ONE or more of the following** while on an MDI regimen:
   1. Recent history (within last six months) of significant, recurring hypoglycemia (blood glucose < 70 mg/dl).
   2. Wide fluctuations (well below and above the set glycemic targets) in blood glucose before and after mealtimes, despite appropriate MDI using up to date insulins (analogs) and dose adjustments to affect control.
G. Patient has advanced carbohydrate counting skills and actively uses this information for insulin dosing
H. Patient demonstrates ability to recognize their glucose patterns and safely problem-solve these
I. Prescriber has documented a need for detailed electronic monitoring the patient's blood glucose levels and insulin dose administered

Ongoing Coverage of InPen System:
To qualify for ongoing coverage of an InPen System the member must meet **ALL of the following**:
A. There is documentation that patient monitors glucose at least four times daily, or appropriately uses a continuous glucose monitor.
B. Patient maintains advanced carbohydrate counting skills and actively uses this information for insulin dosing
C. Patient maintains ability to recognize their glucose patterns and safely and appropriately problem-solve these, including troubleshooting InPen malfunction
D. Patient has at least one visit per year with diabetes specialist* (face-to-face, secure message, or telephone encounter)

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Replacement When Insulin Pump is No Longer under Warranty
The following considerations apply for replacement of an insulin pump that is no longer under warranty:

A. The warranty for the current device has expired (requests for replacement are not covered when the device is still under warranty). Currently, Medtronic and Tandem have 4-year warranty periods, OmniPod Dash does not have a warranty period. It is recommended to check the manufacturer's website for current information.
   A prior-authorization request from the treating diabetes specialist* managing the insulin pump to the Kaiser Permanente Pre-Service department is always required when an insulin pump is being replaced.
B. A face-to-face visit with the treating diabetes specialist* managing the insulin pump is documented within the past year.
C. The reason for the replacement request is fully documented in the member's medical treatment plan.
D. The current pump was previously approved by Kaiser Permanente or the current pump was approved by another non-Medicare plan, and the member meets the medical necessity and coverage criteria for Kaiser Permanente.
E. Suitability for continuance of pump therapy has been reviewed and confirmed by the Diabetes specialist*.
F. The item is not lost or damaged as a result of abuse.

A treating provider may order ongoing pump supplies in the interval between annual visits with the Diabetes specialist*

*Diabetes Specialist= Adult or Pediatric Endocrinologist or a provider under his or her direct supervision (eg. PA or ARNP with CDE or BC-ADM certification or Diabetes Team RN-CDE) or a Perinatologist managing a patient with diabetes during pregnancy.

Documentation requirements to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (endocrinology, primary care)
- Last 6 months of lab work
- Last 1-2 months of legible home monitoring logs or a printout of CGM results

Links to Request Forms:
Insulin Pump Request for New Pump Start Form
Insulin Pump Replacement Request Form

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 1998, the state of Washington passed the Diabetes Cost Reduction Act that requires that major health carriers provide coverage (all, or in part) for diabetes supplies (insulin, syringes, and delivery devices) and education. This new law includes insulin pumps.

Insulin pumps are high technology infusion devices, about the size of a small tape cassette. Flexible tubing connects to the pump that contains the insulin, and then to the patient via a needle that is put in place and changed every 2 to 3 days. The pump itself can then be programmed to deliver 'background' insulin on a continuous basis, and also allow pre-meal "boluses" to accommodate meals. The pump is NOT a system that a patient can just plug into and forget diabetes.

In fact, patients who use the pump have to learn how to program and trouble-shoot the technology, and also learn how to do complex decision-making. This intensive management approach requires multiple daily blood testing, learning how to recognize and use types of food in a very sophisticated way, keeping records, and learning to use the information for complex problem solving. This education is an absolute prerequisite to being on the insulin pump, so special education classes and supervised care are required.

Medical Technology Assessment Committee (MTAC)

Insulin Pump Type II Diabetes
04/20/2015: MTAC REVIEW

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Evidence Conclusion: *Effectiveness* At baseline, the mean HbA1c was 9.0% (75 mmol/mol) in both groups. At six months, both groups saw a decrease in HbA1c (7.9% in the pump group vs. 8.6% in the MDI group) with a -0.7% (95% CI -0.9 to -0.4; -8 mmol/mol, 95% CI -10 to -4 mmol/mol, adjusted p<0.0001) difference between groups favoring pump treatment. Reduction in HbA1c in the pump group was also associated with a 20% lower daily dose of insulin compared with the MDI group, and was not accompanied by an increase in hypoglycemia or weight gain. Ultimately, the investigators concluded that patients with poorly controlled T2DM who received CSII over six months achieved significantly greater reductions in HbA1c.In a separate analysis, the investigators retrospectively stratified the study population according to concentrations of two different biomarkers determined from plasma collected at baseline. The first biomarker, anti-glutamic acid decarboxylase (anti-GAD) antibody (Ab), was present in 18% of the population at baseline indicating that the study population may include patients with T1DM. The investigators attribute this high rate to false-positives, relatively low cutoff values or a combination of both. The second biomarker, C-peptide, a measure of insulin production, did not appear to be associated with A1C level. Ultimately, the analysis demonstrated that HbA1c values were independent of both biomarkers (Reznik and Huang 2014). *Safety* The investigators reported five episodes of hyperglycemia related to the device or study procedure in the pump group and two diabetes related serious adverse events (SAE) resulting in hospital admission. Comparison with the MDI group is not possible as the collection of safety data appears to be incomplete. The investigators noted that data on self-reported mild hypoglycemia and hyperglycemia were not collected, nor were data for hyperglycemia in the MDI group. The studies strengths include randomization, sufficient sample size and the utilization of an intent-to-treat (ITT) analysis. To add to this, the study was conducted across 36 hospitals in five different countries. Methodological limitations of the study can be attributed to the nature of the treatments preventing blinding of patients and assessors. In addition, the investigators acknowledge that the average number of daily glucose self-monitoring tests in both groups was below the generally recommended standard of care, however, this may be consistent with real-life experiences. Finally, the investigators note that due to the inclusion/exclusion criteria and run-in phase, the results of the study may not be generalizable. As a final note, the study was designed and sponsored by Medtronic, the manufacturer of the device. Although they had no role in data collection, the analysis was carried out by statisticians employed by Medtronic. Conclusions: There is evidence to support the efficacy of CSII in achieving glycated hemoglobin targets in highly motivated patients with T2DM with have poor glycemic control, who are taking a total daily dose of insulin less than 220 units. There is limited evidence to support the safety of CSII patients with T2DM.
Articles: The literature was searched for studies assessing the effectiveness of CSII for glycemic control in patients with T2DM. A variety of publications were revealed including several observational studies and four small randomized controlled trials (RCT) with conflicting results. The best available evidence was a recent RCT comparing CSII with multiple daily injections (MDI). The following articles were selected for critical appraisal:
Reznik Y, Cohen O, Aranson R, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (opT2mise): a randomized open-label controlled trial. The Lancet. 2014;384(9950):1265-1272.
See Evidence Table 1

The use of Insulin Pump for Type II diabetes does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Pancreas

BACKGROUND

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action or both. More specifically, in type 1 diabetes, the pancreas is unable to produce insulin which results in increased blood glucose levels, and ultimately, leads to complications which may affect the eyes, kidneys, nerves, heart and blood vessels. As a result, an essential part of diabetes management is to maintain blood glucose levels to as near normal as possible over all hours of the day. Implementation of this approach requires the individual to be capable of and committed to a day-to-day medical program. It requires ongoing compliance with multiple daily glucose measurements accompanied by appropriate adjustments in insulin dose and insulin injection. Additionally, successful intensive diabetic management requires response to a variety of external factors including changes in diet, exercise, and presence of infection.

Typically, patients self-monitor their blood glucose via fingerprick in an effort to optimize glycemic control, however, this technique is tedious and uncomfortable for the patient. In addition, this technique only provides information about a single point in time making it difficult to recognize trends. In any case, intensive glucose monitoring and insulin therapy can be challenging as they require obtaining, retaining, processing and applying vast amounts of information in the course of everyday life (Watkins, Connell et al. 2000; Boland, Monsod et al. 2001; Brauker 2009).

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Evolving technologies such as continuous subcutaneous insulin infusion (CSII), and continuous glucose monitoring (CGM) have allowed patients to safely maintain glycemic goals and prevent other related complications. While there is evidence to support the efficacy of CSII (Misso, Egberts et al. 2010), the reliability and robustness of CGMs leaves much to be desired. Even with the aid of these devices, maintaining blood glucose concentrations within a suggested optimal range is a constant struggle.

Most recent technologic advancements have integrated these components into an Artificial Pancreas Device System (APDS). In addition to CSII and CGM, the APDS incorporates a control algorithm designed to facilitate communication between the different components thus automating the process of maintaining blood glucose concentrations at or near a specified target or range and, ultimately, improving glucose control, preventing complications, and decreasing disease burden. With a wide range of current products available on the market, there is potential for a large variety of different types and designs of ADPSs.

In an effort to help advance the development of the diabetes technologies, the U.S. Food and Drug Administration (FDA), in 2011, established three new product classifications for APDSs including threshold suspend, single hormonal control, and bihormonal control, all of which are regulated as class III device systems (general controls and premarket approval). In September of 2013, Medtronic's MiniMed® 530G was the first system approved under this new product classification. ADPSs have not previously been reviewed by the Medical Technology Assessment Committee (MTAC) and are currently being reviewed due to provider request.

The development of an "artificial pancreas" has been the "holy grail" for management of Type 1 diabetes for several decades. To understand why this is such a difficult task it helps to understand what the normal non-diabetic person's body actually does in response to changes in blood glucose. Within the pancreas we all have 1-2 million groups of cells called the Islets of Langerhans which function together to help maintain the blood glucose levels within a quite narrow range (of around 70-160mg/dl). The islets make two main hormones (insulin from the beta-cells and glucagon from the alpha cells) which work together in concert. These islet cells monitor the blood glucose flowing through them constantly. Whenever the blood goes up (after a meal, for example) the islets increase the amount of insulin that they are secreting from the beta-cells and decrease the amount of glucagon that they are secreting from the alpha cells. Whenever the blood glucose drops below normal the beta-cells turn off completely (so that no insulin is secreted) and the alpha cells crank out lots of glucagon. Glucagon (as well as other hormones like epinephrine, growth hormone and cortisol) stimulate the liver to release glucose into the blood stream (the liver stores about 300 grams of glucose in the form of a kind of starch called glycogen). The insulin and glucagon are released directly into the portal circulation of blood flowing from the pancreas to the liver. In other words, a non-diabetic person is functioning with millions of blood glucose measurements being done every day with the results connected to a continuously variable secretion of both insulin and glucagon released directly into the blood flowing to the liver. Even though the commercially made components of an "artificial pancreas" may seem very sophisticated they are a very crude and imprecise way of trying to do what the real non-diabetic person's pancreas can do.

First consider the delivery of insulin. Rather than having both insulin and glucagon being released directly into the blood flowing to the liver we have a continuous subcutaneous infusion of insulin alone. The insulin is absorbed out of the subcutaneous fat into the peripheral systemic circulation and only then gets to the liver. This can give a fairly accurate and stable basal delivery of insulin but when larger amounts of insulin are delivered immediately before meals (bolus insulin delivery) the rate of rise and fall of insulin in the bloodstream is a lot slower than in a healthy non-diabetic person's body.

Second, consider the measurement of blood glucose. Typically, diabetic patients test the capillary glucose level in their fingertips 2-8 times per day. This can give useful information but does not show the constant rising and falling of blood glucose excursions throughout the day. If needle sensors are placed in the subcutaneous tissue this can give a reading of interstitial fluid glucose (similar to plasma glucose) every 10-20 minutes throughout the day and so can show the trends as the blood glucose rises and falls. Several companies now make these continuous glucose monitoring systems (CGMS). There are two practical issues with CGMS, however: a) the interstitial fluid glucose lags behind the actual plasma glucose by 15-20 minutes and so can give a falsely low or high value if it is measured at times when the blood glucose is rising rapidly (after a meal) or is falling rapidly (after exercise or after injecting a bolus of insulin), and b) the glucose oxidase enzyme system for measuring blood glucose can drift over time and so the readings from a CGMS will be inaccurate unless they are calibrated several times a day by doing a capillary blood glucose test at a time when the blood glucose is expected to be stable (not rising or falling rapidly).

The concept of an "artificial pancreas" is that a person could wear both and insulin pump and a CGMS device and that the insulin pump uses the information from the CGMS to automatically make adjustments to the rate of insulin

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infusion. The person would not need to worry about testing their blood glucose or of thinking about what they eat and when they exercise but could go about their day-to-day life safe in the knowledge that their blood glucose would stay within normal limits. It is because of the practical limitations of the technology (outlined above) that we are still a long way away from that idealized situation.

02/14/2014: MTAC REVIEW
Artificial Pancreas
Evidence Conclusion: In this review, the results of four RCTs were included. One of these studies compared sensor-augmented insulin pumps to multiple daily insulin injections while two of them compared threshold suspense systems with standard insulin pumps. The last study compared two closed-loop algorithms to patient self-control with CSII. *Effectiveness*: Comparison of the effectiveness of sensor augmented pump therapy versus multiple daily injections (MDI) was examined in a one year multicenter, randomized and controlled phase of the sensor-augmented pump therapy for hemoglobin A_{1C} reduction (STAR-3) study. Compared with 241 subjects on MDI, those on pump therapy (n=244) experienced greater reductions in A_{1C} levels by three months, with the trend continuing throughout the remainder of the study. By the end of the study, the baseline A_{1C} level (8.3% in the two study groups) had decreased to 8.1% in the MDI group compared with 7.5% in the pump therapy group ($P<0.001$). Participants were offered an optional six-month continuation phase which allowed subjects in the pump therapy group to continue therapy and allowed subjects in the MDI group to cross over to pump therapy. The continuation phase resulted in a sustained lower mean A_{1C} value for patients in the pump therapy group and decreased the mean A_{1C} values to 7.6% ($P<0.001$) among MDI subjects who crossed over to pump therapy for the continuation phase. (Bergenstal, Tamborlane et al. 2010; Bergenstal, Tamborlane et al. 2011).See Evidence Table. In the three-month automation to simulate pancreatic insulin response trial (ASPIRE), 247 patients with type 1 diabetes and nocturnal hypoglycemia were randomized to sensor augmented insulin pump therapy with the threshold suspend feature (Paradigm group) or to the standard sensor-augmented insulin pump therapy (control group). The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemic events. At the end of three months, the mean AUC for nocturnal hypoglycemic events was found to be significant through supportive analysis at 37.5% lower in the Paradigm group than in the control group ($P<0.001$) (Bergenstal, Klonoff et al. 2013). See Evidence Table. In another trial, 95 adults and children with type 1 diabetes were randomized to use of a sensor-augmented insulin pump with threshold suspension or a standard insulin pump. After six months, the combined incidence of moderate and severe hypoglycemic events was significantly lower in patients using the pump with the threshold suspension compared with the standard insulin pump (9.5 vs. 34.2 per 100 patient-months) (Ly, Nicholas et al. 2013). See Evidence Table. Most recently, Luijf and colleagues compared two validated closed-loop algorithms versus patient self-control with CSII in terms of glycemic control. The investigators concluded that both the algorithm developed by the University of Cambridge (CAM) and the algorithm developed by the University of Pavia, Padova, University of Virginia and University of California Santa Barbara (international artificial pancreas [iAP]) provide safe glycemic control. This study, however, occurred in a highly controlled environment for short periods of time. While the algorithms may have the benefit of less time in hypoglycemia, this came at the expense of higher mean glucose values when compared to self-management (open loop) and thus, more time spent in hyperglycemia (Luijf, DeVries et al. 2013). See Evidence Table.

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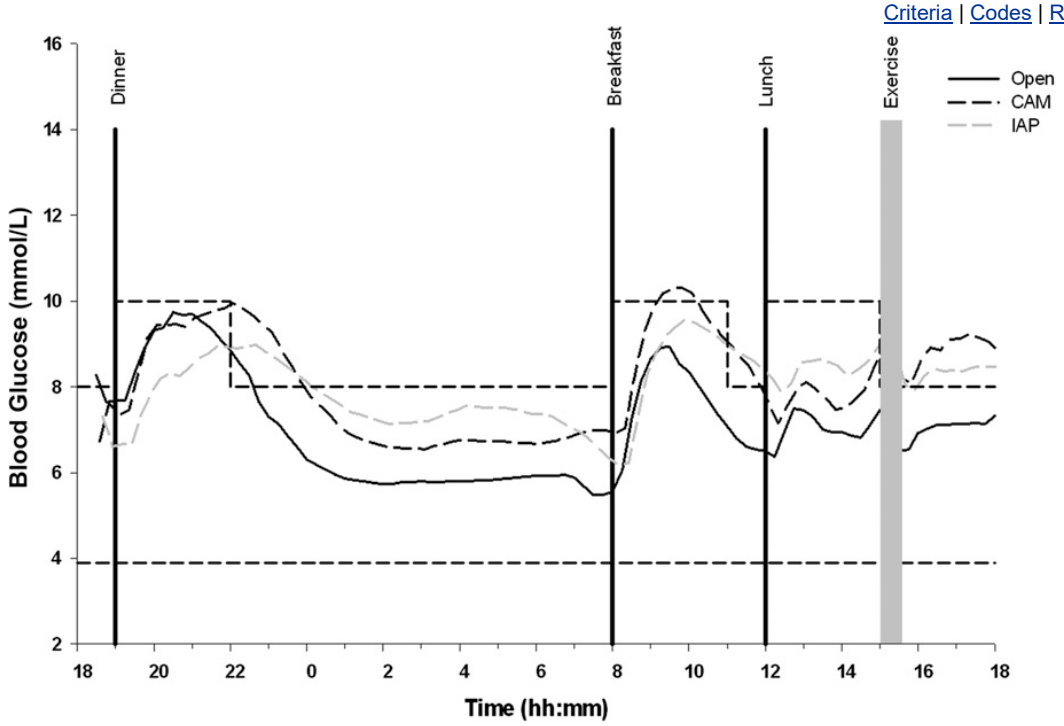

Safety and Adverse Events: Safety and adverse events were included as endpoints in two of the four selected studies. In the STAR 3 study, data on adverse events were collected at each follow up clinic visit. Severe hypoglycemia was defined as an episode requiring assistance and was confirmed by documentation of a blood glucose value of less than 50 mg per deciliter (Bergenstal, Tamborlane et al. 2010). In the ASPIRE study, the primary safety endpoint was the change in glycated hemoglobin level. The change in the glycated hemoglobin level from randomization to study end was not significant in both groups, and the difference in hemoglobin level between groups was only 0.05 percentage points. Beyond that, no episodes of diabetic ketoacidosis occurred in either group or no severe hypoglycemic events occurred in the Paradigm group. During the study phase there were seven adverse events thought to be related to the study device which included skin irritation and device malfunction resulting in severe hyperglycemia (Bergenstal, Klonoff et al. 2013). Generally speaking, the studies had the advantage of randomization and control, however, the lack of blinding makes the evidence vulnerable to bias. In addition, the Ly et al. study relied on patient recall for their results and some of the experimental subjects may have had more contact with physicians opening up the results to recall and observation bias. Sample size ranged anywhere from 48 to 495 participants and most of the studies, with the exception of the STAR 3 Trail, did not report on the racial and ethnic composition of the study samples, and for those that did, participants were predominantly white. Furthermore, inclusion criteria were extremely selective with few studies including children younger than 12 years. In the same way, the data lack generalizability because management was limited to expert settings and among highly motivated patients. Further limitations include heterogeneity in definitions of hypoglycemia and short duration of follow-up ranging anywhere from 24 hours to 18 months. With many complications of diabetes developing over many years it would be ideal to see results allowing for multiple periods of sensor wear and to evaluate changes in subject needs over time. With that said, at the current point in time, APDSs are a rapidly evolving technology that should only be considered in select patients.

Conclusion:

- The results of the published studies suggest that APDS may be effective in reducing hypoglycemia in highly selected, motivated and compliant groups of individuals.
- There is some evidence to support the safety of APDS in highly compliant adult patients.

Articles: The search revealed over 500 articles many of which were commentary, discussion, or systematic review articles. Articles were screened for randomized, comparison studies of outcomes between patients using APDS and a control group of patients using currently available technology. The following articles were selected for critical appraisal: Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy for type 1 diabetes. *New England Journal of Medicine*. 2010;**363**(4):311-320. See Evidence Table. Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *New England Journal of Medicine*. 2013;**369**(3):224-232. See Evidence Table. Ly TT, Nicholas JA, Retterath A, et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspensions vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes a randomized clinical trial. *JAMA*. 2013; 310:1240-1247. See Evidence Table**.** Luijf YM, DeVries JH, Zwinderman K, et al. Day and night closed-loop control in adults with type 1 diabetes. *Diabetes Care.* 2013;**36**: 3882-3887. See Evidence Table.

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The use of Artificial Pancreas does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Insulin Pump and supplies – Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0784	External ambulatory infusion pump, insulin
A4230	Infusion set for external insulin pump, nonneedle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
K0552	Supplies for external noninsulin drug infusion pump, syringe type cartridge, sterile, each

Insulin Pump *used with continuous glucose monitor*
Medicare - Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week

Artificial Pancreas -
Medicare - Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

InPen Smart Insulin Pen –
Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes – often submitted as *E1399 Durable medical equipment, miscellaneous* or *A4211 Supplies for self-administered injections*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised

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09/1988	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012 [MDCRPC], 06/04/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPCC], 07/07/2015[MPC], 08/04/2015[MPC], 09/01/2015[MPC], 06/07/2016[MPC], 01/03/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	12/02/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of Change
04/07/2015	Revised C-peptide testing requirement.
04/27/2015	Added MTAC review on Insulin Pump for Type II Diabetes
07/07/2015	Revised criteria to include indications for Type II Diabetes
09/03/2015	Added criteria for Pediatrics – 18 years and under
11/09/2015	Merged Artificial Pancreas criteria with Insulin Pump
02/17/2016	Added HCPCS codes
01/03/2017	Revisions made to insulin pump criteria; combined adult and pediatric into one policy
02/07/2017	MPC approved criteria to manage insulin pumps for pregnant patients
10/08/2018	Updated request form links
11/03/2020	Added note about combined insulin pump/CGM device and documentation requirements to support medical necessity; removed insulin brand names
07/20/2021	Added note about InPen Smart Insulin Pen not currently considered medically necessary pending MTAC review.
11/02/2021	MPC approved to waive the 6-month period typically used to learn how to monitor diet and other factors that impact blood sugar results prior to being eligible for an insulin pump for patients under the age of 13. This will be on a case-by-case basis as approved by a medical director. Requires 60-day notice, effective 04/01/2022.
01/04/2022	Updated required length of time to provide self-testing/CGM logs from 2 months to 1 month for initial insulin pump. MPC approved clinical criteria for the InPen System. 60-day notice is required; effective June 1, 2022.
02/24/2022	Updated applicable codes
07/05/2022	MPC approved to cover the Omnipod 5 system and will apply to the Insulin Pump criteria.
12/02/2022	Updated Medicare Policy to defer to KP Non-Medicare criteria for InPen system requests. Updated Medicare LCD L33794 and LCA A52507 links.

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Clinical Review Criteria
Intrastromal Corneal Ring Segments (INTACS Inserts)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Intrastromal Corneal Ring Segments (INTACS Inserts)," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

1) Implantation of intrastromal corneal ring segments may be considered medically necessary for the treatment of keratoconus when **ALL of the following** criteria are met:
   - Functional vision cannot be achieved with contact lenses or spectacles
   - Age 21 years or older
   - Clear central cornea
   - Corneal transplantation is the only other remaining option to improve functional vision
2) Implantation of intrastromal corneal ring segments is considered not medically necessary for the treatment of myopia.
3) Implantation of intrastromal corneal ring segments is considered investigational for all other conditions including, but not limited to, pellucid marginal degeneration.

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Background

Keratoconus is a progressive noninflammatory corneal disorder characterized by corneal thinning and protrusion of the central cornea. Signs and symptoms of keratoconus vary and depend on disease severity. In the early stages of keratoconus, individuals may be asymptomatic; however, as the disease progresses, there is considerable distortion of vision in the form of myopia and irregular astigmatism. For patients with mild to moderate keratoconus, vision may be corrected with spectacles or contact lenses. However, as the disorder progresses, or when the patients can no longer tolerate contact lenses, they are referred for corneal transplant (penetrating keratoplasty). The outcomes of this surgery are generally favorable; however, the surgery is not

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without complications. Complications of penetrating keratoplasty include graft rejection, intraocular damage, postoperative astigmatism, recurrence of keratoconus, and side effects from the long-term use of topical corticosteroids (Ambekar 2011, Ertan 2007, Romero-Jimémez 2010).

Intrastromal corneal ring segments (Intacs®) inserts are an alternative treatment strategy for patients with mild to moderate keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option. Intacs® inserts are small rings of synthetic material that are implanted in the deep corneal stroma with the aim of generating modifications of corneal curvature in an attempt to improve visual acuity, contact lens tolerance, and prevent or delay corneal transplant. The procedure is performed outside the corneal visual axis and the inserts may be removed or replaced if the desired outcome is not achieved. Intacs® inserts should not be used in patients who can achieve functional vision on a daily basis using contact lenses, are younger than 21 years of age, do not have clear corneas, or have corneal thickness less than 450 microns at the proposed incision site. Complications associated with Intacs® inserts include patient dissatisfaction with visual quality, discomfort, and ring segment extrusion or migration (Ambekar 2011, Bromley 2010, Ertan 2007, Romero-Jimémez 2010).

Intacs® inserts received FDA approval in 2004.

Medical Technology Assessment Committee (MTAC)

INTACS Inserts in the Treatment of Keratoconus

10/03/2005: MTAC REVIEW

Evidence Conclusion: The studies reviewed, as well as others revealed by the literature search, were all case series comparing the postoperative results to the preoperative values among the same groups of patients. Case series have potential selection and observation biases as well as other threats to internal validity. The results of these series may indicate some improvement in visual acuity after the implantation of Intacs in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to penetrating keratoplasty or other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (PK). In conclusion, larger studies with longer follow up and that compare the outcomes of the technology with those achieved with PK are needed to determine the efficacy and long-term stability, benefits, and harms of the technology.

Articles: The search revealed 18 articles. There were no meta-analyses or randomized controlled trials. All published studies identified were prospective or retrospective case series and had no control groups. Two prospective series on the use of Intacs for the management of keratoconus were selected for critical appraisal. Selection was based on the sample size, duration of follow-up, and quality of study. *Evidence tables were created for the following studies:* Hellstedt T, Makela J, Uusitalo R, et al. Treating keratoconus with Intacs corneal ring segments. *J Refract Surg.* 2005; 21:236-246. See Evidence Table. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. *AM J Opthalmol* 2003; 135:64-70. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/19/2011: MTAC REVIEW

INTACS Inserts in the Treatment of Keratoconus

Evidence Conclusion: The study reviewed for the 2011 update, as well as those reviewed in the original 2005 MTAC review, were all case series comparing postoperative results to the preoperative values among the same groups of patients. Results from case series should be interpreted with caution as this type of study design is prone to bias. The results of these studies may indicate some improvement in visual acuity after the implantation of Intacs® inserts in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (Colin 2007, Hellstedt 2005, Siganos 2003). Conclusion: There is insufficient evidence to determine the safety and efficacy of Intacs® inserts for the treatment of keratoconus.

Articles: The literature search did not reveal any meta-analyses or randomized controlled trials. The published studies identified were prospective or retrospective case series. The largest prospective case series with the longest duration of follow-up was selected for review.

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The following study was critically appraised: Colin J and Malet F. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg. 2007;* 33:69-74. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
65785	Implantation of intrastromal corneal ring segments

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To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Dates Reviewed	Date Last Revised
10/03/2005	Reinstated criteria on 01/03/2012 MDCRPC, 12/04/2012 MDCRPC ,10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015 MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC , 10/04/2022MPC	12/05/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/18/2015	Revised LCD L35008
12/05/2017	Adopted Kaiser Permanente Policy for Medicare

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Clinical Review Criteria

Intermittent Pneumatic Compression for the Treatment of Peripheral Arterial Occlusive Disease

- ArtAssist Device
- ArterialFlowTM System
- Flow MedicTM System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pneumatic Compression Devices (280.6)
Local Coverage Determinations (LCD)	Pneumatic Compression Devices (L33829)
Local Coverage Article	Pneumatic Compression Devices (A52488)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Peripheral arterial disease (PAD) is a common condition that affects approximately 8-12 million people in the US. The prevalence of the disease increases rapidly with age and is associated with significant morbidity and mortality. PAD commonly affects the arteries supplying the leg and is mostly caused by atherosclerosis. Restriction of blood flow due to arterial stenosis or occlusion is commonly clinically presented as intermittent claudication which is pain in the calf muscles that occurs on walking or exercising and is rapidly relieved by resting.

The clinical course of patients with intermittent claudication is variable. Most patients either improve or have a stable condition, but over one fourth will experience deterioration in symptoms. These patients may eventually develop critical leg ischemia or gangrene which can lead to amputation. Fontaine classified chronic leg ischemia into four stages: Stage I: asymptomatic, stage II: intermittent claudication, stage III: ischemic rest pain, and stage IV: ulceration, gangrene, or both (Hirsch 2001, Leng 1993, Delis 2000, 2005, Beard 2000).

The treatment of PAD aims at increasing blood flow to alleviate symptoms and prevent arterial leg ulcers, critical leg ischemia, and major complications. Management options for claudication include a structured program of regular exercise, smoking cessation, control of risk factors or associated medical diseases, percutaneous

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transluminal angioplasty, and surgical revascularization. Drug therapy, even with the most effective agents, was found to result in only a modest improvement. Surgical bypass reconstruction is indicated for severe cases and after failure of other forms of conservative therapy. Patients with non-healing ulcers may not be suitable for revascularization for technical reasons, frail condition, or rejection of surgical intervention. Due to the limited non-operative treatment options, long-term graft failure, perioperative deaths, and imitations or contraindications to intervention, researchers have focused their attention on mechanical methods as potential means for augmenting arterial volume flow in lower limbs (Delis 2000, Montori 2002, 2005).

The concept of using mechanical means to increase blood flow to an ischemic limb dates back to 1930s when a group of investigators applied alternating external pressure to ischemic legs with advanced atherosclerotic peripheral vascular disease. They were however unable to measure blood flow or optimize pneumatic compression. The interest in using intermittent pneumatic compression was renewed in the late 1970s when researchers observed that intermittent pneumatic compression can temporarily increase the arterial blood flow to the limbs. The devices developed apply high pressures by compression cuffs placed on the thigh, calf, and/or foot, intermittently inflate and deflate with cycle times and pressures that vary between devices.

The ArtAssist© Device (ACI Medical Inc., San Marcos, California), is a mechanical pneumatic pump consisting of an impulse generator and two plastic inflatable cuffs. It applies high pressure in a synchronized manner to the foot and calf. This outpatient treatment usually performed for three 1-hour sessions per day while the patient is sitting upright. According to the manufacturer, when the device compresses tissue below the knee, venous blood is emptied, and the venous pressure drops to near zero. The resultant increase in the arteriovenous pressure gradient increases arterial blood inflow. Another potential mechanism also described by the manufacturer involves the release of vasodilating substances as endothelial nitric oxide due to the decreased local vascular resistance. Stimulation of collateral blood vessel formation may also occur (ACI medical Inc. web site).

The ArtAssist device as well as the Flow MedicTM system, and ArterialFlowTM system are all FDA approved for use to improve blood circulation in the lower extremities to help prevent and reduce complications of poor circulation.

Medical Technology Assessment Committee (MTAC)

Intermittent Pneumatic Compression

02/04/2008: MTAC Review

Evidence Conclusion: The trials on intermittent pneumatic compression (IPC) studied the efficacy of the therapy, mainly using the ArtAssist device, for patients with stable intermittent claudication. There were no RCTs with clinical outcomes that evaluated the IPC for use among patients with more severe condition or those who failed revascularization. All published trials were small, single centered, conducted among highly selected groups of patients, were not blinded, short-term, and none compared IPC to a sham therapy. Kakkos and colleagues (2005), randomized 34 highly selected patients with stable intermittent claudication to receive IPC (n=13), supervised exercise (n=12), or unsupervised exercise (n=9). The study was too small, was unblinded, and had a high dropout rate. Its results show that compared to the unsupervised exercise, both IPC and supervised exercise increased the initial claudication distance (ICD) and the absolute claudication distance (ACD). The difference in improvement observed was statistically significant at the end of the six-month treatment and after six additional months of follow-up. There was no significant difference however between the IPC and supervised exercise groups.

In their pilot study, Ramaswami and colleagues (2005) evaluated the efficacy of IPC among 34 patients with stable intermittent claudication who were randomized to receive IPC with daily unsupervised exercise or to just perform daily unsupervised exercise. IPC was not compared to sham treatment or to a supervised exercise program. The results showed an increase in the initial and absolute claudication distances with IPC at 4 and 6 months of treatment and the improvement was sustained at 1 year. Delis and Nicolaides (2005) also evaluated the effectiveness of IPC in 41 highly selected patients with stable intermittent claudications. These were randomly assigned to receive IPC and salicylic acid (75 mg/dL), or salicylic acid (75 mg/dL) alone. All participants in the two groups were encouraged to exercise daily and were followed up for 12 months after the treatment period. The results of the trial show that the ICD, ACD, increased significantly in the IPC group starting at the first month of treatment and was sustained for one year after completing the therapy. Only a small insignificant change was observed in the control group, and the difference between the two study groups was significant. The quality of life also improved significantly in the IPC group, but not in the control group. *Conclusion*: The available evidence from these trials as well as other earlier studies and case series suggest that intermittent pneumatic compression therapy of the foot and calf with ArtAssist device might be associated with improvement in the arterial blood flow and in the walking distance over a short term among patients with stable intermittent claudication. However, the studies included highly selected groups patients with stable claudications who had superficial femoral artery

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occlusion, and patent iliac arteries (also patent popliteal artery as indicated by some studies). Those with a history of a lower extremity revascularization history were excluded, as well as those with several other comorbidities. Moreover, the studies had control groups not placebo groups undergoing a sham IPC treatment. There were no long-term outcomes beyond one year of follow-up, and the studies did not determine the effectiveness of treatment in improving rest pain, ulcer healing, or reducing amputation rate, all of which may limit generalization of the results. In conclusion there is insufficient evidence to determine the efficacy of pneumatic compression devices for the treatment intermittent claudication, or more severe symptoms among patients with peripheral artery occlusive disease.

Articles: There were five small RCTs, one nonrandomized controlled study, and several prospective and retrospective small case series with no control or comparison groups. The majority of trials were conducted among patients with stable claudication. There was a small trial, with intermediate outcomes that compared three modes of IPC in healthy limbs as well as those with successful grafts. The literature search did not reveal RCT that evaluated the IPC use for patients with more severe condition or those who failed revascularization. *Studies with an appropriate comparison group and/or longer follow-up duration were selected for critical appraisal:* Kakkos SK, Geroulakos G, Nicolaides AN. Improvement of the walking ability in intermittent claudication due to superficial femoral artery occlusion with supervised exercise and pneumatic foot and calf compression: A randomized controlled trial. Eur J Vasc Endovasc Surg. 2005; 30:164-175. See Evidence Table
Ramaswami G, D'ayala M, Hollier LH, et al., rapid foot and calf compression increases walking distance in patients with intermittent claudication: Results of a randomized study. J Vasc Surg. 2005; 41:794-801. See Evidence Table Delis KT, Nicolaides AN. Effect of intermittent pneumatic compression on foot and calf on walking distance, hemodynamics, and quality of life in patients with arterial claudication. A prospective randomized controlled study with 1-year follow-up. Ann Surg 2005;241:431-441 See Evidence Table

The use of Intermittent pneumatic compression in the treatment of peripheral arterial occlusive disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

HCPC Codes	Description
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)

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Creation Date	Review Date	Date Last Revised
02/26/2008	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC] ·08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/04/2020	Added Medicare LCD L33829 and LCA A52488

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Patient Referral Guidelines
Intestinal and Multi-Visceral Transplantation

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Intestinal and Multi-Visceral Transplantation (260.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral.

Intestinal Transplantation alone may be considered for selected pediatric and adult patients with Short Bowel Syndrome and/or intestinal failure who require chronic Total Parenteral Nutrition (TPN) and have severe complications that lead to serious morbidity and could lead to mortality.

Combined Intestinal/Liver Transplantation may be considered in selected pediatric and adult patients with Short Bowel syndrome and irreversible progressive chronic liver disease when there is no prospect for prolonged survival with conventional therapy.

The following are current, generally accepted, guidelines for Intestinal Transplantation.

1. GENERAL PRINCIPLES

1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.

1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

1.3. Uncontrollable active infection is a contraindication to transplant.

1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low[1,2,3] Exceptions may be made on a case-by-case basis.

1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.

1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

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1.7. Patients must be willing and able to travel within short notice to a KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

1.8. Patient must have a caregiver or caregivers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

1.9. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.10. Evidence of such nonadherence may be: failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required.

1.11. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR INTESTINAL TRANSPLANT

2.1. Intestinal Transplant

2.1.1. Pediatric or adult patients with irreversible Short Bowel Syndrome or intestinal failure[4], who have severe complications of TPN, including, but not limited to the following:

2.1.1.1. Lack of vascular access

2.1.1.2. Recurrent central venous catheter-related infections

2.1.1.3. Metallic bone disease

2.1.1.4. Evidence of severe or progressive hepatic dysfunction

2.2. Combined intestinal-liver transplant.

2.2.1. Adult and pediatric patients with Short Bowel Syndrome and/or intestinal failure and irreversible progressive chronic liver disease.

3. CONTRAINDICATIONS FOR INTESTINAL TRANSPLANT

3.1. Advanced cardiopulmonary disease or any other life limiting disorders, excluding hepatopulmonary syndrome.

3.2. Inability to accept the procedure, understand its nature, or cooperate with the treatment protocol.

3.3. Patients with HCC, who exceed Region 5[5]/UCSF[4] criteria, should not be sent for intestinal transplant evaluation at this time because they are not medically appropriate. Exceptions may be made on a case by case basis for hepatoblastoma.[5]

3.4. Irreversible brain damage or significant neurologic dysfunction.

4. RELATIVE CONTRAINDICATIONS FOR INTESTINAL TRANSPLANT

4.1. Relative contraindications include, but not necessarily limited to:

4.1.1. Renal Failure (excluding hepatorenal syndrome)

4.1.2. Portal Vein thrombosis

4.1.3. Active infection outside the hepatobiliary system

4.1.4. Advanced malnutrition

4.1.5. Severe diabetic complications

4.1.6. Multiple abdominal surgeries

Footnotes:

1. Liver Transplantation 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.

2. Liver Transplant Surg, 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.

3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), TPMG New Medical Technology

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4. May be due, but not necessarily limited, to the following examples:
   a. Volvulus
   b. Atresia
   c. Necrotizing Enterocolitis
   d. Crohn's Disease
   e. Gastroschisis
   f. Superior Mesenteric Artery Thrombosis
   g. Trauma

5. The Region 5 criteria for intestinal patients with HCC is 1 tumor: S5 cm or 2 – 3 lesions, none >3 cm and no vascular invasion. NEJM 1996, 334: 633-699. Pediatr Surg Int. 2016 Oct 11., J Pediatr Surg. 2007 Jan;42(1):184-7., Pediatr Transplant. 2016 Jun;20(4):515-22. doi: 10.1111/petr.12699. Epub 2016 Mar 27.

REVISED BY CLINICAL MANAGEMENT SUBCOMMITTEE: SEPTEMBER 23, 2020
ADVISORY COUNCIL APPROVED AND EFFECTIVE DATE: OCTOBER 22, 2020

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Intestinal transplantation is an evolving procedure that was experimentally developed more than 30 years ago. It involves transplantation of a cadaveric intestinal allograft for the purpose of restoring bowel function for patients with irreversible failure. The intestine's massive lymphocyte content and heavy bacterial load provided barriers for nearly three decades. Intestines are more susceptible to rejection and carry higher risk of graft versus host disease (GVHD). The procedure proved to be clinically feasible for humans in the late 1980s but had considerable morbidity and mortality. The initial recipients of the intestinal grafts did poorly because of technical complications, graft rejection and sepsis. Recently better results were reported due to improved surgical techniques, more potent immunosuppressive drugs, and standard prophylaxis for infections and lymphoproliferative disease. Although the purpose of intestinal transplantation is to restore bowel function, patient survival should be considered the primary outcome of interest.

The first long-term success was reported in 1988 when cyclosporin-based immunosuppression was used, yet there were many failures due to rejection. The introduction of FK 506 or Tacrolimus have led to an explosion of the intestinal transplantation activity in the 1990s. It is 100 times more potent than cyclosporin and is somewhat less toxic. Steroids are administered during the early postoperative period and discontinued completely within a month. Since 1990 surgeons at the University of Pittsburgh Medical Center (UPMC) and Children's Hospital of Pittsburgh have performed more than 115 transplants involving the small intestine. This is close to half the total number performed worldwide.

There are three types for intestinal transplantation: small bowel transplantation (SBT), Small bowel/liver transplantation (SB/LT), and multivisceral transplantation (MVT) which is defined as en-bloc transplantation of 3 or more abdominal organs that include liver, stomach, pancreatic-duodenal complexes as well as the intestine with or without the right hemi-colon. Intestinal transplantation is not an alternative to total parenteral nutrition (TPN) but is only intended for selected patients who are predicted to have poor survival on TPN. It should be considered as a life-saving procedure. Patients who can be maintained on long term TPN are not considered for transplantation at the present time.

An isolated intestinal graft is recommended for patients who have fluid and electrolyte loss that cannot be managed by TPN, those with severely limited venous access and/or moderate liver dysfunction secondary to TPN. Combined SB/LT is offered to patients with irreversible liver failure due to TPN, or intestinal/liver failure associated with a hyper-coagulable state that is corrected by a simultaneous liver graft. Multivisceral

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transplantation is offered to patients with locally aggressive tumors that can only be removed by a massive evisceration of the abdominal organs. Intestinal transplantation is contraindicated in old age, cardiopulmonary deficiency, AIDS, systemic malignancy and life-threatening infections.

The FDA does not regulate surgical procedures such as intestinal and multivisceral transplantation. However, immunosuppressive drugs are FDA regulated. Tacrolimus, the primary immuno-suppressant used with these transplants was approved by the FDA in April 1994 for rejection prophylaxis in allogenic liver transplantation.

Medical Technology Assessment Committee (MTAC)

Intestinal Transplantation

04/10/2002: MTAC REVIEW

Evidence Conclusion: The literature reviewed did not reveal any study that compared intestinal transplantation to the long term TPN therapy, and the evidence available does not allow for definitive conclusions. The studies reviewed show that the one- year survival rate of intestinal transplantation varied among studies from 54% to 75%. This dropped to around 42-50% at 5 years. Infection was responsible for more than 40% of the deaths. All studies were case series with limitations including potential selection bias, and lack of control or comparison group. However, it is unlikely that controlled trials, in which outcomes from intestinal/multivisceral transplantation are compared to TPN and medical management, would be conducted. The current use of intestinal transplantation as a rescue therapy for TPN-dependent patients invalidates any comparison with TPN.
Articles: Articles were selected based on study type. The search yielded 175 articles most of which were reviews, opinion pieces, editorials, and letters. The literature did not reveal any randomized controlled trials, or meta-analyses, only clinical reports and case series. The articles with the largest size, longest follow-up duration, and with patient survival as the primary outcome of interest were selected for critical appraisal. *Evidence tables were created for the following case series:* Abu-Elmagd K, et al. Clinical intestinal transplantation. Annals of Surgery 2001;234(3):404-17. See Evidence Table Jamieson NV. Adult small intestine transplantation in Europe. Acta Gastro- Enterologica Belgian 1999;62(2):239-43. See Evidence Table Madariaga JR, et al. The long-term efficacy of multivisceral transplantation. Transplantation proceedings 2000; 32:1219-20. See Evidence Table.

The use of Intestinal Transplantation in the treatment of irreversible intestinal failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/30/2001	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	06/12/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision	Description

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History	
04/07/2020	MPC approved to adopt Kaiser Permanente National coverage policy
06/12/2020	Added “Patient Referral Guidelines” to title

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Clinical Review Criteria
Intraocular Lens Following Cataract Extraction

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Intraocular Lens (80.12)
Local Coverage Determinations (LCD)	Refractive Lenses (L33793)
Local Coverage Determinations (LCA)	Refractive Lenses (A52499)

For Non-Medicare Members

Accommodative Intraocular Lens

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Multifocal Intraocular Lens

Multifocal intraocular lenses will not be covered. Standard monofocal intraocular lenses are covered following cataract surgery. The patient may elect to pay for the multifocal lens.

Toric Intraocular Lens

Toric intraocular lenses to correct astigmatism are not covered. The purposes of these lenses are to reduce dependence on glasses. Improved vision with glasses is the purpose of standard cataract surgery, the additional benefit of improved vision without glasses is not a covered service.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

It is estimated that over 20 million Americans older than 40 years have cataract in at least one eye. It is predicted that this number will increase to 30 million by 2020. The current approach of treating cataracts is to replace the natural crystalline lens of the eye with an artificial intraocular lens (IOL). Traditionally intraocular lenses are monofocal lenses, which can provide excellent distance vision and optical quality, but they do not deliver functional vision at other ranges of distance. After their implantation most patients need spectacles at least for near vision. Bifocal and multifocal IOLs were developed to overcome the lack of accommodation in these pseudophakic patients (i.e. patients with an artificial IOL). They provide good functional distance, near, and intermediate vision without the use of corrective lenses. However, multifocal and bifocal IOLs may have optical side effects such as decreased contrast sensitivity, glare disability, and halos, which can reduce the retinal image quality and affect the patient's visual performance (Harman 2008, Alio 2010, Alio 2011, Cochener 2011).

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Accommodative Intraocular Lens

Positional accommodating IOLs were developed to avoid the optical side effects of the multifocal IOLs and provide some accommodative capability and functional near vision. The basic mechanism of these lenses is the transmission, by haptics (plastic plates or struts), of the contracting forces of the ciliary body to the flexible lens. The design of these IOLs is based on the optic-shift concept i.e. on the axial (backward and forward) movement of the optic resulting from the contraction and relaxation of the ciliary muscle. A hinge between the optic and haptics allows the lens to move forward as the eye focuses on near objects and backward as the eye focuses on distant objects, thereby increasing the dioptric power of the pseudophakic eye. The first developed accommodative IOLs were positional single optic lenses used for both cataract and surgical correction of presbyopia. Among these are the Crystalens™ (Eyeonis, Inc., 1CU [Human Optics Erlangen, Germany], and Tetraflex [KH3500, Lenstec, St Petersburg Florida]) (Marchini 2007).

The Crystalens™ AT-45 IOL is the seventh design of the Crystalens™. It consists of a single biconvex lens with a 4.5 mm optic with two plate haptics each terminating in two polyamide loops that anchor it to the capsular bag. Adjacent to the optic are grooved flexible hinges in the plates that allow forward movement of the optic during accommodative effort to provide near and intermediate vision in pseudophakic patients. The optic is square-edged and is made of silicone to maximize biocompatibility and flexibility and allow easy insertion of the lens through a 3 mm corneal incision. A newer Crystalens™ model (Crystalens HD) has a mechanism of action based on the transitional movement of the lens in anterior and posterior direction due to ciliary muscle contraction and vitreous mass displacement (Macsai 2006, Cumming 2006).

The Tetraflex (Lenstec) lens is an anteriorly vaulted, single-piece, foldable, accommodating IOL that is implanted using a custom-designed injector system through an incision as small as 3 mm. The lens' optic is 5.75 mm and is made of a highly biocompatible and extremely flexible hydrophilic acrylic material (HEMA). The IOL's two haptics, each with two footplates, sit posteriorly in the peripheral capsular bag (Sheppard 2010).

The 1CU is a foldable single-piece lens with an optic diameter of 5.5 mm and an overall length of 9.8 mm. It is made of a hydrophilic acrylic material and has a biconvex square-edged optic and 4 modified flexible haptics that are designed to bend when constricted by the capsular bag after ciliary muscle contraction. This allows anterior displacement of the optic resulting in an increase in the refractory power (Pallikaris 2011).

The single-optic passive shift IOLs are considered pseudoaccommodative and have limited accommodative ability as their anterior movement is insufficient to provide functionally significant amplitudes of accommodation. The limited optic power of the single optic lenses led to the development of dual-optic devices as the Synchrony (Visiogen, Irvine, California, USA), and the Sarfarazi IOL (developed by FM Sarfarazi of Shenasa Medical LLC, Carlsbad, CA, USA). The configuration of these devices with a high positively-powered mobile anterior optic, connected to a stationary negatively-powered posterior optic, is designed to increase the potential accommodative amplitude (Alio 2009, Sheppard 2010).

Investigators indicate that the way of measuring the range of accommodation in pseudophakic eyes is still unclear. In a recent review article, Pallikaris and colleagues state “Objective measurement of the accommodative capability offered by the accommodative IOLs is extremely difficult to obtain, and different methods such as autorefractometers, retinoscopy, and ultrasound imaging during accommodative effort, ray tracing, or pharmacological stimulation have been developed but the results are sometimes inconsistent… Pseudophakic accommodation, that is, the dynamic component of ocular refractive variation during near vision, and pseudophakic pseudoaccommodation, that is, the depth of focus and the subjective adaption to defocus during near vision, are the two core parts of pseudoaccommodation. Currently there is no consensus in the literature on the percentage of the participation of each part in the phenomenon of pseudoaccommodation. Several different methods are utilized by investigators for the study of the phenomenon thus resulting in different results.” (Pallikaris 2011).

Multifocal Intraocular Lens

Bifocal and multifocal intraocular lenses have optical side effects such as glare, halos, and decreased contrast sensitivity, which can reduce the retinal image quality and affect the patient’s visual performance. The Array IOL (Advanced Medical Optics [AMO], Santa Ana, CA), one of the first IOLs approved by the FDA (1997) is a typical refractive multifocal IOL. Earlier trials demonstrated that Array IOL improved distance and near visual acuity and reduced spectacle dependency after cataract extraction, but it was also associated with problems as decreased contrast sensitivity, glare, and halos. Newer generations of multifocal IOLs have been developed with the aim of providing better visual acuities at various distances with less glare and halos and without need for any spectacles. Currently in the United States, multifocal lens options include the ReZoomTM lens (Abbott Medical Optics [AMO]

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Inc, Santa Ana, CA), ReSTOR® lens (Alcon Laboratories Inc, Fort Worth, TX), and the Tecnis® lens (Abbott Medical Optics Inc, Santa Ana, CA) (Kawamorita 2009).

The ReZoom™ (AMO) is a second-generation multifocal refractive lens that improved on the design of the Array with the aim of decreasing the symptoms of glare and halos. It is a three-piece multifocal lens made of hydrophobic acrylic material and has five refractive optical zones; each zone designed for different light and focal distances: zones 1, 3, and 5 are adjusted for far vision, while zones 2 and 4 are adjusted for near vision. The design of ReZoom is different from the Array in that the second and third zones have been enlarged, and the fourth and fifth zones have been reduced in size. An aspheric transition between zones provides balanced intermediate vision. These changes potentially reduce in night-time glare and improves uncorrected near visual acuity (Forte 2009, Kawamorita 2009, Alio 2011, Kubal 2011, Lichtinger 2012).

The ReSTOR® (Alcon Laboratories Inc) is a diffractive one-piece posterior chamber IOL. It is the first diffractive IOL to be approved by the FDA. ReSTOR® is a biconvex lens made of a soft plastic that can be folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore vision. The supporting arms (haptics) provide for proper positioning of the IOL within the eye. ReSTOR® lens has 12 concentric diffractive rings that cover the central 3.6 mm of the lens. The diffractive portion of the lens is apodized i.e. the height of each diffractive step decreases with increasing distance from the lens center in order to create a smoother transition between focal points. The ReSTOR® is considered a hybrid of diffractive and refractive IOLs with the lens periphery functioning as a refractive zone focusing for distance vision. In 2007, the FDA approved the aspheric version of the ReSTOR® (AcrySof IO, ReSTOR), which has a 10 µm of negative asphericity, while maintaining its apodization and diffractive and refractive components. Recently, a new +3.0 diopter (D) was introduced to improve intermediate vision, which was suboptimal with the +4 D models (Alio 2011, Sood 2011, Zhang 2011, Kubal 2011, Lichtinger 2012).

The Tecnis® Multifocal Intraocular Lens (AMO) is an ultraviolet light-absorbing posterior chamber lens. It was first available as a 3-piece silicone lens (ZM900), then later it became available as a 3-piece acrylic (ZMA00), or a single piece acrylic (ZMB00) lens. The lens is foldable so that it can be inserted into the eye through a very small incision that is actually smaller than the diameter of the lens itself. It has an optical design based on a principle of diffraction similar to the AcrySof ReSTOR® IOL, but with the diffractive rings covering the entire posterior surface of the lens. The rings start very close to the center of the lens and then continue out toward the periphery, usually with an increasing distance between the rings. As a result, the lens achieves its multifocal effects with minimal dependence on the size of the pupil (Sood 2011, Lichtinger 2012).

The ReZoom™, AcrySof ReSTOR 3.0 and 4.0 D, and Tecnis® multifocal intraocular lenses have all received FDA clearance for the visual correction after cataract extraction in adult patients with and without presbyopia.

Medical Technology Assessment Committee (MTAC)

Multifocal Intraocular Lens

04/11/2001: MTAC REVIEW

Evidence Conclusion: A single well-done RCT provides evidence that multifocal IOL are as effective as monofocal IOL for distance acuity. Patients with multifocal IOL had better uncorrected near VA and distance-corrected near VA than monofocal IOL patients, but similar best-corrected near VA add power. A case series with long-term follow-up showed a high rate of efficacy on visual acuity with multifocal IOL. All studies reviewed indicated that a limitation of multifocal IOL is decreased contrast sensitivity. The cohort study, which had compromised validity, found less contract sensitivity with multifocal compared to monofocal IOL in daylight and twilight with no glare and twilight with central glare. The benefits of multifocal IOL should be weighed against possible decreases in contrast sensitivity and the efficacy of monofocal IOLs with glasses for near focus.
Articles: The search yielded 30 articles. There were 2 RCT articles; these were based on data from the same study. The majority of the articles were case series with small numbers of patients. Evidence tables were created for three studies: The most recent report of RCT data: Javitt JC, Steinert RF. Cataract extraction with multifocal intraocular lens implantation: A multinational clinical trial evaluating clinical, functional and quality-of-life outcomes. Am Acad Ophthalmol 2000; 107: 2040-2048. See Evidence Table. A cohort study examining possible adverse effects of multifocal IOL: Winther-Nielsen A, Corydon L, Olsen T. Contrast sensitivity and glare in patients with a diffractive multifocal intraocular lens. J Cataract Refract Surg 1993; 19: 254-257. See Evidence Table**.** A case series with long-term follow-up data: Slagsvold JE. 3M diffractive multifocal intraocular lens: Eight year follow-up. J Cataract Refract Surg 2000; 26: 402-407. See Evidence Table.

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The use of multifocal Intraocular Lens in the treatment of visual correction following cataract surgery does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/2005: MTAC REVIEW
Intraocular Lens
Evidence Conclusion*: Accommodative Intraocular Lens* The evidence on Crystalens™ is insufficient to draw conclusions about its efficacy and safety compared to standard intraocular lenses. The single published comparative study (Alio et al., 2004) had threats to validity. It was a non-randomized comparison of three case series, one on Crystalens, one on the Array multifocal lens and one on the Twinset bifocal IOL. The study is subject to selection bias because patients were not randomized, and the authors did not control statistically for confounding factors. The study was also non-blinded and thus subject to observation bias. The study had four primary outcomes. Between-group differences were statistically significant for one out of the four outcomes, mean best corrected near acuity, but not for mean uncorrected distance acuity, mean best corrected distance acuity or mean uncorrected near acuity. There were two studies on the 1CU IOL by HumanOptics, a non-FDA approved accommodative IOL. This evidence is also weak. One of the studies (Kuchle et al., 2004) was non-randomized and did not control for confounding factors and is therefore subject to selection bias. The other study (Dogru et al., 2005) was randomized, but the study methodology was not well described, making it impossible to assess validity. There were also validity issues with the statistical analysis in the Dogru study.
Articles: *Accommodative Intraocular Lens* There was one study comparing the FDA approved accommodative IOL, Crystalens, to other types of IOLs. There were two studies comparing the non-FDA approved 1CU accommodative IOL (HumanOptics: Erlangen, Germany) to other IOLs. Like Crystalens, the 1CU IOL has a hinge-like design which allows for forward and backward movement. These three empirical studies were critically appraised. In addition, there was a small case series (n=14) reporting on the initial phase of the Crystalens FDA clinical trial. This study was excluded from further review. Evidence tables were created for the following studies: Crystalens™ Alio JL, Tavalato M, De la Hoz F et al. Near vision restoration with refractive lens exchange and pseudoaccommodating and multifocal refractive and diffractive intraocular lens. J cataract Refract Surg 2004; 30: 2494-2503. See Evidence Table. Human Optics 1CU. Dogru M, Honda R, Omoto M. Early visual results with the 1CU accommodating intraocular lens. J Cataract Refract Surg 2005; 31: 895-902. See Evidence Table. Kuchle M, Seitz B, Langenbucher A et al. Comparison of 6-month results of implantation of the 1CU accommodative intraocular lens with conventional intraocular lens. Ophthalmology 2004; 111: 318-324. See Evidence Table.

The use of Accommodative Intraocular Lens in the treatment of visual correction following cataract surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/16/2012: MTAC REVIEW
Intraocular Lens
Evidence Conclusion: *Accommodative Intraocular Lens* Crystalens™: AT-45 The literature search did not reveal any published large good quality RCTs that compared the implantation of the accommodative Crystalens™ with multifocal or monofocal intraocular lenses after cataract extraction. The best published evidence on Crystalens™ comes from the FDA multicenter clinical trial with 12 months follow-up (Evidence table 1). The initial study was a phase II trial that evaluated the efficacy and safety of the CrystalensTM AT-45. It was a prospective cohort study with no control or comparison group. The results of 12 months follow-up of 263 patients receiving the implant in the primary eye showed that the accommodating CrystalensTM AT-45 provided good uncorrected near and distance visual acuity with minimal adverse effects. In a substudy the authors compared contrast sensitivity under mesopic conditions with and without glare in a subgroup of patients who received the Crystalens versus a matched population of 64 patients who received standard IOL. The results of this substudy showed that the difference in contrast sensitivity between the two groups of patients was clinically irrelevant.
ICU (Human Optics) Several randomized and nonrandomized trials compared the performance of 1CU with monofocal and multifocal intraocular lenses (IOLs) (Evidence tables 2-4). The results of the studies showed that distance corrected near vision was significantly better in the 1CU group versus other groups receiving non-accommodating IOLs. Two small studies showed that the accommodative ability of the lens may decrease by time (8 months in Sauder and colleagues' trial and 12 months in Dogru and colleagues' study) leading to a reduction in the near vision acuity. The studies had some limitations and long-term follow-up is needed to determine the long-term safety and efficacy of the lens. In a large prospective, controlled, but non-randomized trial with potential biases (Evidence table 3), Uthoff and colleagues found that 1CU had a minor statistical advantage of half a reading step towards monofocal IOLs measured with subjective methods in near point, defocusing curve, and near visual acuity with BSCVA. They explained that this could be due to the pseudophakic accommodation by the optic shift or as a result of the additional pseudophakic pseudoaccommodation. The accommodative effect differed between patients and was unpredictable. *Tetraflex*: The prospective nonrandomized US Food and Drug Administration trial (Sanders 2010) on Tetraflex accommodative IOL is ongoing. In this study 255 patients

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received Tetraflex IOLs and 101 received monofocal IOLs. Interim results of 12 months follow-up of 239 patients in the Tetraflex arm and 96 controls show that the Tetraflex patients read better than the controls at print sizes of 20/80 (P=.04), 20/63 (P=.01), 20/50 (P<.001), 20/40 (P=.001), 20/32 (P<.001), and 20/25 (P=.001). The proportion of patients reading at a speed of ≥80 words per minute was significantly higher with the Tetraflex IOL (P=.003). Ninety-six percent of Tetraflex patients reported never wearing glasses for distance compared with 80% of control patients (P<.001). Seventy-five percent of the Tetraflex patients reported that they did not or occasionally needed to wear glasses for near reading small print and/or dim light compared with 46% of control patients (P<.001). The trial had its limitations and the study groups were not randomly assigned to type the IOL implanted which is a source of selection bias. They were also not blinded to the IOL received, which is another source of bias especially with subjective outcomes as self-reporting of use of spectacles. Moreover, the reading ability and speed is dependent on many factors in addition to visual acuity. In conclusion, large randomized, controlled, and blinded trials with long-term follow-up are needed to determine the long-term efficacy, durability of benefit, and safety of the accommodative intraocular lenses.
Multifocal Intraocular Lens: A Cochrane meta-analysis with valid methodology (Leyland et al, 2008, evidence table 1) pooled the results of ten randomized controlled trials that compared visual outcomes of multifocal IOLs versus monofocal IOL implantation after cataract surgery. There were variations between the studies in population sizes, measures and outcomes reported, as well as follow-up durations. The main pooled results of the analysis showed no significant differences between multifocal and monofocal IOLs in uncorrected distance visual acuity or the proportion of patients achieving distance 6/6 best-corrected distance visual acuity. The uncorrected near vision was improved with the multifocal IOLs, and the rate of freedom from use of glasses was also higher with the multifocal IOLs. Contrast sensitivity was lower among participants receiving multifocal IOL implants who also experienced significantly higher rates of glare and halos. The results of another meta-analysis (Cochener et al 2011, Evidence table 2) that had the limitation of pooling results of observational studies together with randomized controlled trials, also showed that multifocal IOLs provided better uncorrected near visual acuity and less need for spectacles compared to monofocal IOLs. The results of the analysis also showed that diffractive multifocal lenses led to better results than the refractive IOLs, and that ReSTOR® had better uncorrected near visual acuity, uncorrected distance visual acuity, and higher spectacle independence rates compared with other multifocal IOLs. The incidence of halos was higher with multifocal lenses versus monofocal IOLs, but there was no significant difference between the different multifocal IOLs. No sensitivity analysis including only RCTs was made, and the results of the meta-analysis should be interpreted with caution. A more recent randomized controlled trial by Alió and colleagues (2011, Evidence table 3) compared the visual performance of 4 different IOLs: monofocal Acri. Smart, multifocal AcrySof ReSTOR® SN6AD3, multifocal Acri.Lisa 366D, and multifocal ReZoom refractive IOL. The same type of lens was implanted bilaterally in each of the 152 participants (304 eyes). After six months of follow up, the results showed that all patients had postoperative significant improvement in uncorrected and corrected visual acuities. Patients with the ReSTOR® and Acri.Lisa multifocal lens implants had significantly better uncorrected reading acuity than those in the monofocal or the refractive ReZoomTM groups. The monofocal group had the greatest uncorrected reading distance at 1 and 6 months postoperatively. The authors did not evaluate patient satisfaction with the different types of IOLs, nor did they assess the contrast sensitivity, or presence of glare and halos. Studies comparing ReSTOR® +3.0 D versus ReSTOR® +4.0 D were not critically appraised in this report, but their overall results showed better intermediate visual acuity, but more glares with the +3.0 D vs.+4.0 D IOLs. Conclusion: There is good evidence from the published literature that multifocal intraocular lenses improve near visual acuity when compared to monofocal lenses, without compromising distance visual acuity.
There is good evidence that patients undergoing multifocal IOLs implantation have higher rates of spectacle independence compared to those with monofocal lens implants. There is evidence that patients with multifocal IOL implants experience more halos and glare and have lower contrast sensitivity than those with monofocal implants. There is fair evidence that optical outcomes are better with diffractive versus refractive multifocal IOLs, and that improvement in near vision without use of glasses and patient satisfaction are more evident with ReSTOR® compared to other multifocal IOLs. There is insufficient evidence to determine any significant difference in contrast sensitivity, glare, or halos between multifocal IOLs.
Articles: *Accommodative Intraocular Lens* Single optic IOLs - The majority of studies published on the accommodative intraocular lenses evaluated single optic accommodative IOL, mainly the ICU (Humans Optics), and to a lesser extent the CrystalensTM AT-45. The search identified one meta-analysis of RCTs, a small number of controlled randomized and nonrandomized trials, and case series. The larger trials with more valid methodology and longer-term follow-up were selected for critical appraisal. The meta-analysis was not critically appraised as it had a low methodological quality and only included only 5 RCTs with very small sample sizes, along with other nonrandomized, and non-controlled studies published from 1996-2006. Dual optic IOLs - The literature search revealed a small pilot prospective case series with a retrospective control on the Synchrony dual-optic IOL. Phase III FDA clinical trials are still ongoing. The following studies were critically appraised: Harman FE, Maling S, Kampougeris G, et al. Comparing the 1CU accommodative, multifocal, and monofocal intraocular lenses: a randomized trial. Ophthalmology. 2008; 115:993-1001. See Evidence Table. Cumming JS, Colvard DM,
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Dell SJ, et al. Clinical evaluation of the Crystalens AT-45 accommodating intraocular lens: results of the U.S. Food and Drug Administration clinical trial. J Cataract Refract Surg. 2006;32:812-825 See Evidence Table. Mesci C, Erbil HH, Olgun A, et al. Visual performances with monofocal, accommodating, and multifocal intraocular lenses in patients with unilateral cataract. Am J Ophthalmol. 2010; 150:609-618. See Evidence Table. Uthoff D, Gulati A, Hepper D, Potentially accommodating 1CU intraocular lens: 1-year results in 553 eyes and literature review. J Refract Surg. 2007; 23:159-171. See Evidence Table.

Multifocal Intraocular Lens The literature search revealed a large number of studies on multifocal intraocular lenses. The majority were prospective or retrospective observational studies and case series with different population sizes and follow-up durations and no comparison or control groups. There were also a number of published randomized or nonrandomized controlled trials that evaluated the visual function, and /or quality of life after the implantation of monofocal versus multifocal lenses. The search also identified three meta-analyses that pooled the results of trials comparing multifocal versus monofocal intraocular lenses, one meta-analysis of studies compared different IOLs, as well as a pooled analysis of two non-randomized trials that compared outcomes of ReSTOR vs. monofocal IOLs lenses. The most recent meta-analysis comparing outcomes of monofocal versus multifocal lenses, and the meta-analysis that compared different multifocal lenses were selected for critical appraisal. A recent RCT that compared outcomes of one monofocal and three different multifocal IOLs was also critically appraised. Alió JL, Grabner G, Plaza-Puche AB., et al. Postoperative bilateral reading performance with 4 intraocular lens models: six-month results. Cataract Refract Surg. 2011; 37:842-852. See Evidence Table**.** Cochener B, Lafuma A, Khoshnood B, et al. Comparison of outcomes with multifocal intraocular lenses: a meta-analysis. Clin Ophthalmol. 2011; 7:45-56. See Evidence Table. Leyland M, Pringle E. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database of Systematic Reviews 2008, issue 4. See Evidence Table.

The use of Accommodative Intraocular Lens in the treatment of visual correction following cataract surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered not medically necessary:

HCPC Codes	Description
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
8/1/2005	5/3/2011[MDCRPC], 10/4/2011[MDCRPC], 6/5/2012[MDCRPC], 4/02/2013[MDCRPC], 02/04/2014 [MPC],12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	08/02/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/02/2016	Added criteria for Toric Intraocular Lens

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intraoperative Neurophysiological Monitoring (IONM)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Noridian retired LCD Sensory Evoked Potentials & Intraoperative Neurophysiology Monitoring (L34072). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

GENERAL CRITERIA

- Intraoperative neurophysiologic monitoring must be performed by either a licensed physician trained in clinical neurophysiology or a trained technologist who is practicing within the scope of his/her license/certification as defined by state law or appropriate authorities and is working under direct supervision of a physician trained in neurophysiology; AND

- Intraoperative neurophysiologic monitoring must be interpreted by a licensed physician trained in clinical neurophysiology, other than the operating surgeon, who is either in attendance in the operating suite or present by means of a real-time remote mechanism for neurophysiologic monitoring situations and is immediately available; AND

- Monitoring is conducted and interpreted real-time (either on-site or at a remote location) and continuously communicated to the surgical team; AND

- The physician performing, or supervising monitoring must be monitoring no more than three cases simultaneously; AND

- Charges related to intraoperative monitoring will only be reimbursed when billed on a HCFA 1500 claim form for professional charges; AND

- Any charges related to intraoperative monitoring billed on a UB form are not reimbursable.

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INDICATIONS

Intraoperative neuromonitoring may be indicated for a variety of spinal, intracranial, and vascular procedures. The specific type of monitoring indicated for each procedure varies, as outlined in the below criteria and summarized in the following tables. Pre-procedural baseline testing may be separately reported, but only once per operative session.

Somatosensory-evoked potentials with or without motor-evoked potentials

Intraoperative neuromonitoring using somatosensory-evoked potentials (SSEP), with or without motor-evoked potentials (using electrical stimulation), may be medically necessary during the following procedures:

- Spinal procedures
    - Dorsal rhizotomy
    - Correction of scoliosis
    - Correction of deformity involving traction on the spinal cord
    - Spinal cord tumor removal
    - Surgery due to traumatic injury to spinal cord
    - Surgery for arteriovenous (AV) malformation of spinal cord
- Intracranial procedures
    - Microvascular decompression of cranial nerves
    - Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
    - Cholesteatoma, including mastoidotomy or mastoidectomy
    - Vestibular neurectomy for Meniere's
    - Removal of cranial nerve neuromas affecting any of the following nerves:
        - Abducens
        - Facial
        - Glossopharyngeal
        - Hypoglossal
        - Oculomotor
        - Recurrent laryngeal
        - Spinal accessory
        - Superior laryngeal
        - Trochlear
    - Deep brain stimulation
    - Endolymphatic shunting for Meniere's disease
    - Oval or round window graft
    - Removal of cavernous sinus tumors
    - Resection of brain tissue near primary motor cortex and requiring brain mapping
    - Resection of epileptogenic brain tissue or tumor
    - Other intracranial procedures (e.g., aneurysm repair, intracranial AVM)
- Non-cranial vascular procedures
    - Carotid artery surgery
    - Arteriography with test occlusion of carotid artery
    - Deep hypothermic circulatory arrest
    - Distal aortic procedures
    - Surgery of the aortic arch, its branch vessels, or thoracic aorta

Electroencephalographic monitoring

Intraoperative electroencephalographic (EEG) monitoring may be considered medically necessary for any of the following procedures

- Intracranial procedures
    - Microvascular decompression of cranial nerves
    - Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions

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  - Cholesteatoma, including mastoidotomy or mastoidectomy
  - Vestibular neurectomy for Meniere's
  - Removal of cranial nerve neuromas affecting any of the following nerves:
    - Abducens
    - Facial
    - Glossopharyngeal
    - Hypoglossal
    - Oculomotor
    - Recurrent laryngeal
    - Spinal accessory
    - Superior laryngeal
    - Trochlear
  - Deep brain stimulation
  - Endolymphatic shunting for Meniere's disease
  - Oval or round window graft
  - Removal of cavernous sinus tumors
  - Resection of brain tissue near primary motor cortex and requiring brain mapping
  - Resection of epileptogenic brain tissue or tumor
  - Other intracranial procedures (e.g., aneurysm repair, intracranial AVM)
- Non-cranial vascular procedures
  - Carotid artery surgery
  - Arteriography with test occlusion of carotid artery

Electromyographic monitoring

Intraoperative electromyographic (EMG) monitoring may be considered medically necessary when monitoring is during any of the following procedures:

- Dorsal rhizotomy
- Microvascular decompression of cranial nerves
- Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
- Cholesteatoma, including mastoidotomy or mastoidectomy
- Vestibular neurectomy for Meniere's
- Removal of cranial nerve neuromas affecting any of the following nerves:
  - Abducens
  - Facial
  - Glossopharyngeal
  - Hypoglossal
  - Oculomotor
  - Recurrent laryngeal
  - Spinal accessory
  - Superior laryngeal
  - Trochlear

SPINAL PROCEDURES	SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939	EEG 95822 95955	EMG 95860 95861 95867 95868 95870
Dorsal rhizotomy	☑		☑
Correction of scoliosis	☑		

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Correction of deformity involving traction on the spinal cord	☑		
Spinal cord tumor removal	☑		
Surgery due to traumatic injury to spinal cord	☑		
Surgery for AV malformation of spinal cord	☑		

NON-CRANIAL VASCULAR PROCEDURES	SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939	EEG 95822 95955	EMG 95860 95861 95867 95868 95870
Carotid artery surgery	☑	☑	
Arteriography w/ test occlusion of carotid artery	☑	☑	
Deep hypothermic circulatory arrest	☑		
Distal aortic procedures (due to risk of ischemia to spinal cord)	☑		
Surgery of aortic arch, its branch vessels, or thoracic aorta	☑		

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INTRACRANIAL PROCEDURES*	SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939	EEG 95822 95955	EMG 95860 95861 95867 95868 95870
Microvascular decompression of cranial nerves	☑	☑	☑
Removal of acoustic neuroma, congenital auricular lesions, cranial base lesions	☑	☑	☑
Cholesteatoma, including mastoidotomy or mastoidectomy	☑	☑	☑
Vestibular neurectomy for Meniere's	☑	☑	☑
Removal of cranial nerve neuromas affecting any of following nerves: *Abducens* *Facial* *Glossopharyngeal* *Hypoglossal* *Oculomotor* *Recurrent laryngeal* *Spinal accessory* *Superior laryngeal* *Trochlear*	☑	☑	☑
Deep brain stimulation	☑	☑	
Endolymphatic shunt for Meniere's disease	☑	☑	
Oval or round window graft	☑	☑	
Removal of cavernous sinus tumors	☑	☑	
Resection of brain tissue near primary motor cortex and requiring brain mapping	☑	☑	
Resection of epileptogenic brain tissue or tumor	☑	☑	
Other intracranial vascular procedures (e.g. aneurysm repair, intracranial AV malformation)	☑	☑	

*Intraoperative brainstem auditory evoked response monitoring may also be appropriate for intracranial procedures in which auditory function is at risk, such as acoustic neuroma resection or brainstem tumor resection.

EXPERIMENTAL AND INVESTIGATIONAL

IONM is considered experimental/investigational for all indications not meeting the above criteria. Examples of procedures for which there is insufficient evidence to establish net benefit of IONM include, but are not limited to, the following:

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- Routine lumbar or cervical laminectomies and fusions
- Spinal cord stimulator implantation
- Thyroid or parathyroid surgery
- Cochlear implantation
- Vagal nerve stimulator implantation
- Spinal injections
- Hip replacement
- Parotid gland surgery

Intraoperative monitoring of visual evoked potentials is experimental and investigational for all indications.

Intraoperative monitoring of motor evoked potentials using transcranial magnetic stimulation is experimental and investigational for all indications.

Nerve conduction studies for intraoperative monitoring purposes are considered experimental and investigational for all indications.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

EVIDENCE BASIS

There is moderate strength of evidence that IONM may identify patients at greater risk of adverse outcomes due to neurological injury among individuals undergoing certain spinal procedures. For surgeries that risk damaging the spinal cord (e.g., scoliosis correction, spinal cord tumor removal), the effectiveness of IONM has been assumed. As such, the evidence base for comparative studies is minimal. However, multiple retrospective and prospective cohort studies indicate that IONM may accurately identify those with postoperative neurological deficits. Less clear is whether knowledge of injury, intraoperatively, can lead to intervention which prevents or reverses said neurological deficits.

A systematic review (Fehlings 2010) concluded that IONM is sensitive and specific for detecting neurological complications during spinal surgery. That review included 14 prospective cohort studies addressing a variety of spinal indications. Across all included studies, IONM was not associated with any serious harms. Authors concluded that IONM can be a valuable tool during spinal surgery when the spinal cord or nerve roots are at risk.

IONM has also been proposed as potentially valuable during thyroid surgery as a means to prevent injury to the recurrent laryngeal nerve. A systematic review (Malik 2016) evaluated 17 studies comparing thyroid surgery with and without IONM. Using pooled data from those studies, authors found no statistically significant difference in recurrent laryngeal nerve palsy (RLNP) between those who had undergone thyroid surgery with or without IONM. Another systematic review (Yang 2017) reported a slightly lower incidence of RLNP among those who had thyroid surgery with IONM, but this difference was not statistically significant.

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) released a position statement on IONM in April 2014. The AANS/CNS concluded that there is insufficient evidence to show that the use of IONM mitigates the severity of neurological injury or reduces its incidence. However, the position statement did note that use of IONM may help to diagnose neurological injury during surgery. Later that year, an analysis of all spine surgeries performed from 2007-2011 that were included in the Nationwide Inpatient Sample database was published by James WS, et all. This study included 443,194 spine procedures in which 31,680 cases utilized IONM. Iatrogenic neurological injury was rare, occurring in less than 1% with no difference in cases where IONM was used. In 2015, Hawksworth et al, from the University of Texas Health Sciences Center, published an analysis of their department's spine surgeries completed from 2011-2013, before and after adopting a departmental policy limiting IONM use to intradural procedures and those for spinal deformity correction. While utilization of IONM dropped from 38% of spinal cases to 7%, there was no change in

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incidence of neurological injury. In fact, the only observed cases of injury occurred in cases utilizing IONM where the monitoring did not alert the surgeon to the injury.

In 2017, Hadley, et al published, "Guidelines for the Use of Electrophysiological Monitoring for Surgery of the Human Spinal Column and Spinal Cord" which was approved by both the American Association for Neurological Surgeons and he Congress f Neurological Surgeons. This Guideline was based on review of relevant published literature from 1966-2017. Similar to the aforementioned 2014 position statement, this new Guideline found that IONM "has not been shown to be successful in reducing the rate or perioperative neurological deterioration or to improve neurological outcome during spinal surgery procedures." The authors later conclude that because use of IONM during spina surgery has not been correlated with improvements in neurological outcome that its expense does not appear justified.

In a systematic review on IONM for cervical degenerative myelopathy and radiculopathy, authors concluded that altering of the surgical plan or intraoperative steroid administration based upon IONM monitoring was not shown to decrease the incidence of neurological injury. However, the review concluded that IONM may be sensitive for assessing neurological injury for diagnostic information.

The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) released a position statement in 2014 supporting the use of intraoperative SSEP for certain spinal surgeries, particularly those with increased risk for nerve root or spinal cord injury (including complex, extensive, or lengthy procedures). Authors also stated that intraoperative SSEP was not indicated for routine lumbar or cervical root decompression.

In 2012, the American Academy of Neurology (AAN) and the American Clinical Neurophysiology Society (ACNS) identified 11 studies as part of their evidence-based guidelines process, from which they concluded the IONM is safe and effective for identifying increased risk of adverse outcomes, including paraparesis, paraplegia, and quadriplegia during spinal surgery (Nuwer 2012).

Medical Technology Assessment Committee (MTAC)

Intraoperative Neurophysiologic Monitoring (IONM)

08/17/2015: MTAC REVIEW

Evidence Conclusion: The selected studies offer a small sample of the extensive literature currently available relating to IONM. For the most part, the available evidence is descriptive and details the experience of IONM in various surgical settings. In the selected studies, IONM is using to support surgeries in various specialties including neurosurgery (brain and spine), cardiac, and vascular. Population sizes range from 62 to 119 and assessed pre- and post- surgical outcomes such as neurophysiologic alerts during surgery and post-operative neurological deficits. Conclusions from the selected studies conflict with some asserting the utility of IONM technology and others finding minimal utility due to the inability to predict post-operative complications (Schramm, Koht et al. 1990; Linstedt, Maier et al. 1998; Ghariani, Liard et al. 1999; Bose, Sestokas et al. 2004). Surgical procedures and interventions are not always based on scientific evidence and instead, tend to evolve over time. Today, IONM is considered to be a standard of care limiting the ability to carry out methodologically sound comparative studies due to equipoise. Beyond that, the existing literature base is extremely heterogeneous addressing various surgical procedures in different populations with varying and conflicting conclusions. As a result, the evidence is insufficient to be able to determine if IONM is truly effective at detecting and preventing neurologic complications.

Conclusions: There is insufficient evidence to establish that IONM, either on-site or remote, reduces the risk of neurologic injuries during surgical procedures. There is insufficient evidence to support the safety of IONM.

Articles: The literature search revealed a large number of publications relating to IONM. There were no randomized controlled trials (RCTs) comparing the outcomes of surgeries that employed the use of IONM (either remote or on-site) with those not utilizing the monitoring technique nor where there any studies making a comparison between remote and onsite monitoring. The search yielded a wide variety of observational studies the majority of which had no comparison group. Due to the extensive amount of literature identified, the following studies are a small sample of the available evidence: Bose B, Sestokas AK, Schwartz DM. Neurophysiological monitoring of spinal cord function during instrumented anterior cervical fusion. *The Spine Journal*. 2004;4(2):202-207. See Evidence Table 1. Schramm J, Koht A, Schmidt G, et al. Surgical and electrophysiological observations during clipping of 134 aneurysms with evoked potential monitoring. *Neurosurgery*. 1990;26(1):61-70. See Evidence Table 1. Ghariani S, Liard L, Spaey J, et al. Retrospective study of somatosensory evoked potential monitoring in deep hypothermic circulatory arrest. *The Society of Thoracic Surgeons*. 1999; 67:1915-1918. See Evidence Table 1. Linstedt

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U, Maier C, Petry A. Intraoperative monitoring with somatosensory evoked potentials in carotid artery surgery – less reliable in patients with preoperative neurologic deficiency? *Acta Anaesthesiol Scand*. 1998;42(1):13-16. See Evidence Table 1.

The use of Intraoperative Neurophysiologic Monitoring (IONM) does not meet *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

General Neuromonitoring:

CPT® or HCPC Codes	Description
95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)
95941	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure)
G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)

Somatosensory-evoked potentials (SSEP):

NOTE: CPTs 95925 and 95926 should not be billed during the same procedure if both upper and lower limbs are monitored; instead, CPT 95938 should be used. CPT 95938 should not be coded in conjunction with either 95925 or 95926. Similarly, 95928 and 95929 should not be billed together; instead 95939 should be used if both upper and lower limbs are monitored.

CPT® or HCPC Codes	Description
95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs

Motor evoked potentials (MEP):

CPT® or HCPC Codes	Description
95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs
95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs
95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs

Electroencephalography:

CPT® or HCPC Codes	Description
95822	Electroencephalogram (EEG); recording in coma or sleep only
95955	Electroencephalogram (EEG) during nonintracranial surgery (eg, carotid surgery)

Electromyography:

CPT® or HCPC	Description

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Codes	
95860	Needle electromyography; 1 extremity with or without related paraspinal areas
95861	Needle electromyography; 2 extremities with or without related paraspinal areas
95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95868	Needle electromyography; cranial nerve supplied muscles, bilateral
95870	Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters

Considered not medically necessary:

CPT® or HCPC Codes	Description
95907	Nerve conduction studies; 1-2 studies
95908	Nerve conduction studies; 3-4 studies
95909	Nerve conduction studies; 5-6 studies
95910	Nerve conduction studies; 7-8 studies
95911	Nerve conduction studies; 9-10 studies
95912	Nerve conduction studies; 11-12 studies
95913	Nerve conduction studies; 13 or more studies
95930	Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method

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[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt KP National criteria for IONM.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Iontophoresis
Phonophoresis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Iontophoresis"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Treatment	Criteria Used
Iontophoresis	Kaiser Permanente has elected to use the Iontophoresis (KP-0617) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Phonophoresis	Kaiser Permanente has elected to use the MCG Phonophoresis guideline (A-0616): this is not covered per MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
For Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction and Joint Pain or Devices for use in the member's home	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Evidence and Source Documents

Iontophoresis for Hyperhidrosis using Drionic or Idrostar Devices
Iontophoresis for Joint Pain
Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction

Background

Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients' have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Drugs used for iontophoresis may include lidocaine hydrochloride (a positive ion forming drug) and dexamethasone sodium phosphate (a negative ion forming drug). Possible advantages include greater convenience and less discomfort compared to injection, less variation in absorption, and fewer side effects compared to oral administration of medication.

Medical Technology Assessment Committee (MTAC)

Iontophoresis for Hyperhidrosis using Drionic or Idrostar Devices

BACKGROUND

Hyperhidrosis or excessive sweating may be classified into primary or essential hyperhidrosis with an unknown cause, and secondary hyperhidrosis which is due to an underlying condition as hyperthyroidism, menopause, obesity, psychiatric disorder, and others. It may be localized in one or several locations of the body, most often in the hands (palmer hyperhidrosis) but may also be planter, axillary, facial, or general. Several methods are used to treat patients with primary hyperhidrosis, or secondary cases with heavy sweating or untreatable conditions. These include the use of antiperspirants, drugs, psychotherapy, surgery, iontophoresis, use of botulinum toxin, alternative medicine, and others. Iontophoresis can be defined as a means of delivering medication to a localized tissue area by applying electrical current to a solution of the medication. It consists of applying low intensity current (15-18 mA) supplied by a D/C generator to the palms and/or soles immersed in an electrolyte solution. The procedure has to be repeated regularly, and the results may vary among patients. The Drionic and Idrostar devices are battery- operated methods of inducing tap water iontophoresis.

06/12/2002: MTAC REVIEW
Iontophoresis for Hyperhidrosis using Drionic or Idrostar Devices
Evidence Conclusion: There is not enough evidence to permit conclusions on the use of either the Drionic or Idrostar device for treating hyperhidrosis.
Articles: The search yielded three articles, two of which were reviews, and the third was a small case series with 22 patients with hyperhidrosis treated with the Drionic unit.

The use of Idrostar in the treatment of hyperhidrosis via iontophoresis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/03/2009: MTAC REVIEW
Iontophoresis in the Treatment of Hyperhidrosis
Evidence Conclusion: There is insufficient evidence to draw conclusions on the safety and efficacy of iontophoresis for treating hyperhidrosis. No published comparative studies were identified. The literature base consists of case series, mostly with fewer than 25 patients and one case series with 112 patients. The larger series reported that about 81% of participants responded to treatment. The criteria provided for response was not clearly defined and there was no long-term follow-up.
Articles: Four empirical studies specifically evaluating iontophoresis for hyperhidrosis were identified. There were no randomized or non-randomized controlled studies. All of the empirical studies were case series. Three had

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fewer than 25 patients and were excluded from further review. The fourth (Karakoc et al., 2002) included 112 patients and was critically appraised. See Evidence Table.

The use of iontophoresis in the treatment of hyperhidrosis does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Iontophoresis for Joint Pain

BACKGROUND

Iontophoresis is proposed as a treatment for joint pain. It has been used for various types of tendonitis including epicondylitis, patellar tendonitis, biceps tendonitis, rotator cuff tendonitis and Achilles tendonitis (Winn, unpublished manuscript). Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Dexamethasone sodium phosphate, a negative ion, is a commonly used drug used for iontophoresis treatment of joint pain. Possible advantages include greater convenience and less discomfort compared to injection, less variation in absorption, and fewer side effects compared to oral administration of medication. Common treatments for joint pain include rest, ice after exercise, stretching, bracing and immobilization; medications such as analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) and injection of corticosteroids. A well-done randomized controlled trial (Hay et al., 1999) found that local injection of corticosteroid was more effective for treating lateral epicondylitis than NSAID treatment, but that more than 80% of patients were improved at 12 months regardless of treatment.

10/08/2003: MTAC REVIEW

Iontophoresis for Joint Pain

Evidence Conclusion: There is insufficient evidence to conclude that iontophoresis for joint pain is effective compared to the accepted alternatives, corticosteroid injection and NSAID treatment. No studies compared iontophoresis with one of these established treatments. There is some evidence that iontophoresis is not more effective than placebo treatment, although the data are limited. The highest quality study identified was an RCT comparing active iontophoresis with placebo iontophoresis in patients with epicondylitis (Nirschl). This study found a greater effect with active iontophoresis two-days after treatment, but no difference in efficacy after one-month. The study was powered to detect a 20% difference between groups. Another RCT conducted with patients with epicondylitis (Runeson) found no difference in the efficacy of active or placebo iontophoresis 3- and 6-months after treatment. Neither RCT had an intention to treat analysis, but follow-up was much higher in the Nirschl study (90% compared to 64% in the Runeson study). Statistical power was not discussed in the Runeson study. The quality of evidence for conditions other than epicondylitis was low.

Articles: The search yielded 12 articles. None of the studies compared iontophoresis to corticosteroid injection or oral medication treatment. There were four RCTs conducted with patients who had epicondylitis. Two studies compared active iontophoresis treatment to placebo treatment and were critically appraised. The two other studies had irrelevant comparison groups and were not reviewed: one compared iontophoresis with two types of active substances and one compared iontophoresis to an experimental treatment, phonophoresis. In addition, there were three controlled studies conducted among patients with other types of tendonitis. All three had weaker methodology than the placebo-controlled epicondylitis studies and were not reviewed. Two did not compare the different treatment groups in analysis and one had a sample size of only 22 patients. *The following studies were critically appraised:*

Nirschl RP, Rodin DM, Ochiai et al. Iontophoretic administration of dexamethasone sodium phosphate for acute epicondylitis. *Am J Sports Med* 2003; 31: 189-195. See Evidence Table. Runeson L, Haker E. Iontophoresis with cortisone in the treatment of lateral epicondylalgia (tennis elbow)- a double blind study. *Scand J Med Sci Sports* 2002; 12: 136-142. See Evidence Table.

The use of iontophoresis in the treatment of joint pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction

BACKGROUND

Temporomandibular joint (TMJ) dysfunction is a common condition and involves pain, particularly in the chewing muscles and jaw joint, radiating pain in the face, neck or shoulders, painful clicking sounds in the jaw joint, and restricted jaw movement. Drug therapies for TMJ dysfunction include analgesics, minor tranquilizers or muscle relaxants at bedtime, antidepressants, injections of a local anesthetic and cortisone injections.

Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis

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uses a low current and patients' have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Drugs used for iontophoresis to treat TMJ include lidocaine hydrochloride (a positive ion forming drug) and dexamethasone sodium phosphate (a negative ion forming drug) (Lark & Gangarosa). Iontophoresis is proposed as an alternative to local anesthetic injections for the treatment of TMJ dysfunction. Possible advantages are less discomfort than interarterial injection and fewer side effects than systemic medications.

02/13/2002: MTAC REVIEW
Iontophoresis in the Treatment of Temporomandibular Joint Syndrome
Evidence Conclusion: There is insufficient published scientific evidence on which to base conclusions about the effect of medication delivery with iontophoresis on health outcomes in patients with temporomandibular joint syndrome. Two small RCTs were reviewed, both of which may have had insufficient statistical power to detect clinically important differences between groups; neither of the study discussed statistical power calculations. Shiffman did not compare the randomized groups in analysis. Reid did not find that iontophoresis was more effective than placebo.
Articles: The search yielded eight articles. The majority were review articles/opinion pieces. There were two small randomized controlled trials (RCTs) with clinical outcomes. These two articles were critically appraised: Shiffman EL, Braun BL, Lindgren BR. Temporomandibular joint iontophoresis: A double-blind randomized clinical trial. J Orofacial Pain 1996; 10: 157-65. See Evidence Table. Reid KJ, Dionne RA, Sicard-Rosenbaum L, Lord D, Dubner RA. Evaluation of iontophoretically applied dexamethasone for painful pathologic temporomandibular joints. Oral Surg Oral Med Oral Pathol 1994; 77: 605-9. See Evidence Table.

The use of Iontophoresis in the treatment of temporomandibular joint syndrome does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Iontophoresis -

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes

Phonophoresis - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Review Date	Date Revised
02/13/2002	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/03/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

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MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/13/2017	Added home unit language
09/03/2019	MPC approved to add clinical indication for Palmar/Plantar Hyperhidrosis
11/05/2019	MPC approved to adopt non coverage criteria for Phonophoresis; adopting MCG A-0616
06/15/2020	60-day notice required for non-coverage of phonophoresis, updated effective date to 10/1/2020
08/04/2020	Added Medicare LCA A57642
08/03/2021	Removed LCD L35008 and LCA A57642; added KPWA medical policy statement under Medicare section.

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Clinical Review Criteria
Intraoperative Radiation Therapy (IORT)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	4/01/2016 Noridian retired LCD Brachytherapy: Non-Intracoronary (L34065). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

Intraoperative radiation therapy (IORT) may be considered medically necessary in the following situation:

- Rectal cancer with positive or close margins with T4 lesions or recurrent disease.

IORT is considered investigational when used for all other oncologic applications, including but not limited to:

- Breast cancer
- Fibromatosis
- Gastric cancer
- Glioma
- Gynecologic cancers
- Head and neck cancers
- Neuroblastoma
- Pancreatic cancer
- Renal cell cancer
- Soft tissue sarcoma

Some requests may be approved on a case-by-case basis by the Medical Director.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

The usual method for delivering radiation is external beam with high-energy photons. However, the external beam doses required to achieve local tumor control can exceed the radiation tolerance of some normal organs and other structures of the body.

Intra-operative radiation therapy (IORT) is being investigated as a technique to deliver a high dose of radiation to a locally advanced tumor while attempting to protect adjacent normal tissues at the time of surgery. It is delivered with applicators and cones attached to the treatment head of high-energy medical linear accelerators. After all or most of the cancer is surgically removed, a large, single-dose of high-energy radiation is aimed directly at the tumor site. Nearby healthy tissue is protected with special shields.

The goal of IORT is to enhance local tumor control. Most patients receiving IORT are concurrently treated with high-dose external beam photon irradiation. The term “intraoperative radiation therapy” may also refer to intra-operative brachytherapy, the temporary or permanent implantation of radioactive seeds. Intra-operative radiation therapy is usually a component of a multi-disciplinary treatment approach for localized cancers that cannot be completely removed or that have a high risk of recurring in nearby tissues.

Medical Technology Assessment Committee (MTAC)

Intraoperative Radiation Therapy (IORT) for Breast Cancer

BACKGROUND

Breast cancer is the most common cancer in women of all races and ethnicities (not counting skin cancer), and the second most common cause of death from cancer among white, black, Asian/Pacific Islander, and American Indian/Alaska Native women. The American Cancer Society (ACS) estimated that in 2015, 231,840 new cases of invasive breast cancer and 62,570 breast carcinoma in-situ, will be diagnosed among women in the U.S. and that 40,290 will die from breast cancer. The reported five-year relative survival rate is 98.5% for women diagnosed with localized breast cancer. This drops to 84% among women with cancer that has spread to nearby lymph nodes (regional stage) and to 24% in those with metastases in distant lymph nodes and/or other organs (CDC and ACS web pages accessed October 27, 2015). The widespread screening programs and new developments in early detection of cancer have led to an increase in the incidence of early stage breast cancer. Surgical treatment has thus shifted from radical mastectomy to personalized local treatment that preserves the breast and axillary lymph nodes, together with adjuvant therapy. Breast conserving surgery (BCS) followed by postoperative whole breast external beam radiotherapy (EBRT or WBRT) is currently considered the standard treatment for patients with early-stage breast cancer. This approach has been shown to reduce local recurrence (LR) and improve the overall survival. Traditional whole breast EBRT is administered in the postoperative setting as 45-50 Gy in daily fractions for 5 consecutive weeks. An additional external beam boost of 10-16 Gy is often delivered to the tumor bed to improve local control and reduce local recurrence. It is reported that almost one third of the patients undergoing BCS in North America do not receive post-BCS breast radiation therapy and many others choose mastectomy instead, for several reasons including the long course of treatment, comorbidities, advanced age, distance from the radiation therapy facility, inconvenience, and cost (Vaidya, 2010, Esposito 2014, Abbott 2015, Zhang 2015). Accelerated partial breast irradiation (APBI), is a radiation technique that targets partial breast tissue around the tumor cavity with fewer fractions. APBI has emerged in the last 2 decades and is increasingly being accepted as an alternative to whole breast EBRT. It is based on the observation that more than 90% of local recurrences occur at /or near the tumor bed after BCS. There are several techniques for delivering APBI, including multi-catheter interstitial brachytherapy, balloon catheter brachytherapy, 3D- conformal radiation therapy, and intraoperative radiation therapy (IORT). These techniques differ widely in regard to the degree of invasiveness, radiation delivery, operator proficiency, acceptance between radiation oncologists, and length of treatment (Njeh 2010, Vaidya 2010, Abbott 2015, Esposito 2015, Zhang 2015). IORT is an APBI approach that delivers a single dose of irradiation directly to the tumor bed at the time of surgery. Unlike other APBI techniques that target the index quadrant, IORT specifically targets the tumor cavity. The index quadrant is not demarcated anatomically, whereas the tumor cavity is easily located by the operating surgeon. IORT can be delivered by

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using low-energy X-rays, electron beam radiation therapy, brachytherapy, high-dose-rate (HDR) after loaders, and other hybrid devices (Esposito 2015). The intrabeam® device (Carl Zeiss, Oberkochen, Germany) is a device used to deliver IORT during surgery after removal of the tumor. It comprises a miniature low-energy X -ray source (50 kVp) that delivers a dose of 20 Gy at the surface of the applicator and 5-5 Gy at 1 cm deep, in 20-40 minutes treatment time. Tungsten-impregnated sheets are used to shield the wound before treatment. Access to the operating room should be controlled and the medical personnel shielded during treatment. The intraoperative electron radiation therapy (IOERT) is another method for delivering IORT that involves the application of electron radiation directly to the tumor bed at the time of surgery. Compared to the X-ray beams, the electron beams have limited penetration into the tissue and faster delivery of the required radiation dose. The IOERT systems are designed to deliver radiation in non-shielded operating theaters. Currently there are three mobile linear accelerators that can be moved easily into an operating room and deliver IOERT (Novac 7®, Liac®, and the Mobetron®). The radiation procedure is completed in 2 minutes delivering a dose of 21 Gy with the depth of 90% isodose ranging from 13-24 mm (Esposito 2015). The advantages of IORT include the reduced treatment visits by delivering a single radiotherapy fraction during surgery, immediate visualization of the operative bed before delivering the radiotherapy, minimizing the possibility of missing the target, shielding the surrounding organs, avoiding treatment delay for patients who may also need to undergo chemotherapy, and reducing healthcare costs. Disadvantages of IORT on the other hand, include longer operating time, reported increased local recurrence compared to EBRT, and lack of final pathological results before delivering the IORT. In patients with positive margins that require re-excision, an IORT boost may be ineffective and may cause complications in re-excision of the margins and difficulty in interpreting the pathology. In addition, IORT requires training of staff, operating room equipment efforts, and expensive devices (Hanna 2014, Esposito 2015).

12/21/2015: MTAC REVIEW
IROT for breast cancer
Evidence Conclusion: There are two large published intraoperative radiation therapy (IORT) trials that investigated whether IORT is equivalent (ELIOT) or noninferior (TARGIT-A) to standard EBRT for the treatment of women with early stage breast cancer undergoing breast conservative surgery, The ELIOT trial used electron IORT (using 2 linear accelerators; NOVAC 7 and Liac) and the TARGIT-A trial used a point source low- energy x-rays (50kV maximum) using the Intrabeam device. TARGIT-A trial (Vaidya et al, 2010, 2014), Evidence Table 1 This was a large multicenter trial that examined the noninferiority of IORT to EBRT (within a specified margin of 2.5%) after breast conserving surgery (BCS). 2,232 women 48-75 years of age, with invasive ductal breast cancer undergoing BCS were randomly assigned to receive either a standard regimen of 25-25 fractions (40-56 Gy) EBRT or a single fraction low energy IORT. Randomization was performed either before surgery (pre-pathology entry) or after surgery (post-pathology entry). In the latter group IORT was given after surgery by reopening the wound. 15% of the patients in the IORT group received additional EBRT (the trial protocol allowed recipients of IORT to receive additional EBRT based on unfavorable features found in the pathology [risk adapted policy]). The primary outcome of the trial was pathologically confirmed ipsilateral breast tumor recurrence (IBTR). The initial results of the trial were published in 2010 when only less than one fifth of the participants were followed-up for at least 4 years (median 25 months for all subjects). These results showed that the IBTR rate was 1.2% in the IORT arm and 0.95% the EBRT arm (p=0.41). More recent results were published in 2014 after the addition of 1,219 participants, and longer follow-up for the initial cohort. The estimated 5-year risk of local recurrence was 3.3% in the IORT group and 1.3% in the EBRT group (p=0.042) (median follow-up was 29 months due to the short follow-up of the additional patients; only 18% of the patients had 5 years of follow-up). The results published in the first report indicate that rate of ipsilateral local recurrence in the IORT group IORT met the noninferiority margin of 2.5% (prespecified by the investigators) for the overall patient population, and for the pre-pathology subgroup, but not for the post-pathology group. However, the incidence of the local recurrence was significantly higher with IORT vs. EBRT. This higher rate was observed at a median follow-up of 29 months which is below the median time when local recurrences are expected, especially when 90% of the women had estrogen receptor positive tumors that tend to recur later. In addition, almost two thirds of the women received adjuvant hormonal therapy which delays recurrence in estrogen receptor positive cases (Silverstein 2014). The results also show that the women who received IORT alone had 3 times the recurrence rate vs. those who received IORT+EBRT (2.7 vs. 0.9%). The authors indicated that the difference was not statistically significant, but no p value was provided. The trial was multicenter, randomized, and controlled. However, it had several methodological limitations, mainly the inadequacy of follow-up duration needed to provide conclusive evidence on the noninferiority of IORT to EBRT. The prespecified non-inferiority margin of 2.5% required a 5-year follow-up for all patients, which was only fulfilled by 20% of the study cohort. Other limitations of the trial include the open-label design (due to the nature of the intervention), and the multiple amendments made to the protocol along the course of the study such as the addition of more participating countries, increasing the population size, changing the start and ending date of the trial, and changing the funding source. In addition, each center participating in the trial managed the EBRT group according to its institutional guidelines and determined its own criteria for treating patients with IORT given alone or as a boost therapy. ELIOT trial (Veronesi, et al 2013), Evidence Table 2 This was a prospective single-center

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trial that randomized 1,305 women 48-75 year of age with clinically invasive T1-T2, ≤2.5 cm breast cancer suitable for breast conservative surgery (BCS), to undergo whole breast EBRT delivered over 6 weeks, or receive a single dose of electron beam IORT. The primary outcome of the trial was ipsilateral breast tumor recurrence (IBTR). The results of the analysis show that after a median follow-up of 5.8 years the IBTR fell within the pre-defined equivalence margin of 4.5%, but the rate was significantly higher in the IORT group (4.4% vs. 0.4% in the EBRT group, p<0.0001, NNH of 25). The significantly higher rates of IBTR in the IORT group were observed for both the true local recurrence in the index quadrant, and for new ipsilateral breast tumors in other quadrants. The author indicated that the difference may be attributable to the very low recurrence rates in the EBRT group because of the high experience and quality of management. Some investigators raised the question on whether the 4-cm applicator size used in the trial might have been too small to adequately treat microscopic disease that extended beyond the existed tumor. Axillary or other regional lymph node metastasis and locoregional tumor recurrence were also significantly higher in the IORT group (NNH=143 and 22 and respectively). There were no significant differences between the two study arms in the development of contralateral breast metastasis, distant metastasis, or in the 5-year overall survival rate. Subgroup analysis according to patients' risk based on tumor size, grade, receptor status, and nodal positivity, showed that low risk women (69.4% of the study participants) had a 5-year IBTR rate of only 1.5% compared to 11.3% of those with one or more high-risk factors. A multivariate analysis showed that tumors size >2 cm, ≥4 positive lymph nodes, poorly differentiated tumors, and tumors with triple negative subtypes doubled the risk of IBTR. The rate of adverse skin effects (erythema, dryness and hyperpigmentation) was significantly higher in the EBRT group, and the rate of fat necrosis was significantly higher in the IORT group. There were no significant differences between the groups in mammary retraction, pain, or burning. Conclusion: The results of the two large published RCTs show that the rate of local recurrence with IORT was non-inferior (TARGIT-A trial) or equivalent (ELIOT trial) to EBRT. However, these results were based on margins prespecified by the investigators of the trials. The results of both TARGIT-A and ELIOT trials show that the risk of ipsilateral tumor recurrence was significantly higher with the IORT compared to EBRT. The published trials had relatively short follow-up duration and do not provide sufficient evidence to determine the long-term risk of delayed cancer recurrence inside or outside the index quadrant, as well as the long-term efficacy and safety of the therapy. There was significant heterogeneity between the published studies as regards to the study design, patients' ages, tumor size, threshold values, radiation sources and techniques used for delivering the IORT, as well as the follow-up duration. Multivariate analysis of the ELIOT trial results showed that the risk of ipsilateral local recurrence in women receiving IORT was almost double in patients with tumors size >2 cm, ≥4 positive lymph nodes, poorly differentiated tumors, or with triple negative subtypes.
Articles: The literature search revealed two large RCTs on IORT (TARGIT-A trial and ELIOT trial) as well a systematic review and meta-analysis of published studies, and a large number of single institution cohort studies. The two large RCTs and the meta-analysis were selected for critical appraisal. Vaidya JS, Joseph DJ, Tobias JS, et al. Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): an international, prospective, randomised, non-inferiority phase 3 trial. *Lancet*. 2010 Jul 10; 376 (9735):91-102. See Evidence Table 1**.** Vaidya JS, Wenz F, Bulsara M, et al. Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial. *Lancet.* 2014 Feb 15; 383 (9917):603-613. See Evidence Table 1**.** Veronesi U, Orecchia R, Maisonneuve P, et al. Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): A randomized controlled equivalence trial. *Lancet Oncol*. 2013 Dec; 14 (13):1269-1277. See Evidence Table 2**.** Zhang L, Zhou Z, Mei X, et al. Intraoperative Radiotherapy versus Whole-Breast External Beam Radiotherapy in Early-Stage Breast Cancer: A Systematic Review and Meta-Analysis. *Medicine (Baltimore).* 2015 Jul; 94(27):e1143. See Evidence Table 3**.**

The use of IORT for breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19294	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (List separately in addition to code for primary procedure)
77424	Intraoperative radiation treatment delivery, x-ray, single treatment session
77425	Intraoperative radiation treatment delivery, electrons, single treatment session
77469	Intraoperative radiation treatment management

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HCPC Codes	Description
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure

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Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	04/20/2016

[MPC] Medical Policy Committee

Revision History	Description
01/06/2016	MPC approved the MTAC recommendation of insufficient evidence for IORT for breast cancer
04/20/2016	Changed Medicare language as LCD 34065 was retired.

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Clinical Review Criteria
Total Knee Arthroplasty

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Total Knee Arthroplasty (L36577) Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule
Local Coverage Article (LCA)	None
MLN Matters Article	Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule Jan 2020 MLN Article: Update of the Hospital Outpatient Prospective Payment System (OPPS) - Topic 5. Changes to the Inpatient-Only list (IPO) for CY 2020

For Non-Medicare Members

Effective October 1, 2022

ADD SOC for IP requests also

*This criteria does not apply to revision or replacement of a previous knee arthroplasty.

Total knee and unicompartmental arthroplasty may be considered medically necessary for degenerative joint disease when **ALL of** the following are met:

1. Treatment is needed because of functional disabling pain of at least 3 months duration which interferes with the ability to carry out activities of daily living

AND

2. Radiographic imaging or arthroscopic evidence of moderate or severe osteoarthritis as evidenced by **ONE of the following**:
   a. Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour (Kellgren-Lawrence Grade 3)
   b. Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (Kellgren-Lawrence Grade 4)
   c. Exposed subchondral bone (full thickness cartilage loss with underlying bone reactive changes) noted on arthroscopy or MRI (Outerbridge Grade IV)

AND

3. Patients must have three months of non-operative, conservative treatment as demonstrated by a trial of one or more of the following medications:
   A. Non-steroidal anti-inflammatory drugs (oral or topical)
   B. Acetaminophen

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C. Intra-articular injection of corticosteroids as appropriate

AND

4. A trial of **All** of the following physical measures:
   i. Supervised Physical therapy, attends >75% of sessions
      - At least half of PT must be in person (not virtual)
   ii. Flexibility and muscle strengthening exercises
   iii. Reasonable restriction of activities
   iv. If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.

AND

5. All patients who meet the above criteria to undergo standard elective surgery must also meet **ALL of the following**:
   A. BMI < 35: if BMI is > 35, optimization efforts must be documented, demonstrating active attempts towards weight loss as shown by sustained weight loss over 3-6 months OR stagnant weights despite documented active participation in a weight loss or exercise program. Formal nutritional counseling must be documented. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. However, BMI > 40 is a relative contraindication. Despite not achieving this BMI, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.
   B. No diabetes, or diabetes with HbA1c < 7.5 (with the presence of heart disease, no lower than 7.5). Members who have an A1C >7.5 must actively be involved with medical management and demonstrate a reduction in A1c over 3-6 months. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. A1c > 8.0 is a relative contraindication. Despite not achieving this A1c, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.
   C. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery or have a 90% reduction in nicotine/tobacco use. If nicotine/tobacco reduction attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. No changes in nicotine/tobacco use is a relative contraindication.

Knee arthroplasty may ALSO be considered medically necessary, after failure of nonoperative interventions, for the following diagnoses:

- Distal femur fracture repair in a patient with osteoporosis
- Failure of a previous proximal tibial or distal femoral osteotomy
- Hemophilic arthroplasty
- Limb salvage for malignancy
- Posttraumatic knee joint destruction
- Avascular necrosis (osteonecrosis) of tibial or femoral condyle
- Inflammatory Arthritis

***Kellgren-Lawrence Classification of Osteoarthritis**

Grade	Description
grade 0 (none)	definite absence of x-ray changes of osteoarthritis
grade 1 (doubtful)	doubtful joint space narrowing and possible osteophytic lipping
grade 2 (minimal)	definite osteophytes and possible joint space narrowing
grade 3 (moderate)	moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends
grade 4 (severe)	large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends

Osteoarthritis is deemed present at grade 2 although of minimal severity.

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Reference: Pai, V., Knipe, H. Kellgren and Lawrence system for classification of osteoarthritis. Reference article, Radiopaedia.org. (accessed on 29 Mar 2022) https://doi.org/10.53347/rID-27111

Outerbridge
Outerbridge 0: Cartilage is normal
Outerbridge 1: Cartilage shows chondromalacia,
Outerbridge 2: Cartilage shows partial thickness fibrillation
Outerbridge 3: Cartilage shows deep fibrillation
Outerbridge 4: Full thickness cartilage loss

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist, including a history & physical

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Joint replacement surgery has been performed on millions of people over the past several decades and has proved to be an important medical advancement in the field of orthopedic surgery. The hip and knee are the two most commonly replaced joints. The knee is the largest joint in the body and includes the lower end of the femur, the upper end of the tibia and the patella. The knee joint has three compartments, the medial, the lateral and the patellofemoral. The surfaces of these compartments are covered with articular cartilage and are bathed in synovial fluid. The bones of the knee joint work together, allowing the knee to function smoothly.

The most common reason for total knee replacement surgery is arthritis of the knee joint. Types of arthritis include:

• osteoarthritis,
• rheumatoid arthritis and
• traumatic arthritis (arthritis which occurs as a result of injury).

Arthritis causes a severe limitation in the activities of daily living (ADLs), including difficulty with walking, squatting, and climbing stairs. Pain is typically most severe with activity and patients often have difficulty getting mobilized when seated for a long time. Other findings include chronic knee inflammation or swelling not relieved by rest, knee stiffness, lack of pain relief after taking non-steroidal anti-inflammatory medications and failure to achieve symptom improvement with other conservative therapies such as steroid injections and physical therapy.

Osteonecrosis and malignancy are additional reasons to proceed with total knee replacement surgery. The use of TKR in patients with malignancy must be weighed against considerations of life expectancy and possible alternative procedures to relieve pain. The goal of total knee replacement surgery is to relieve pain and improve or increase patient function.

Occasionally, there may be a need to perform a reoperation on a previous total knee replacement. This is often referred to as a revision total knee.

Circumstances that lead to the need for a revision Total Knee Arthroplasty continued disabling pain, continued decline in function which can be attributed to failure of the primary joint replacement. Failure can be due to infection involving the joint, substantial bone loss in the structures supporting the prosthesis, fracture, aseptic loosening of the components and wear of the prosthetic components.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Total Knee:

CPT® or HCPC	Description

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Codes	
27438	Arthroplasty, patella; with prosthesis
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; 1 component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/03/2022	05/03/2022[MPC],	

[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Total Hip Arthroplasty

- Inpatient Hip Arthroplasty Indications (SOC)
- Hip Arthroplasty Medical Necessity Criteria

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Total Hip Arthroplasty (L36573)
Local Coverage Article (LCA)	Billing and Coding: Total Hip Arthroplasty (A57684)
MLN Matters Article	Jan 2020 MLN Article: Update of the Hospital Outpatient Prospective Payment System (OPPS) - Topic 5. Changes to the Inpatient-Only list (IPO) for CY 2020

****The following codes are listed in the Medicare inpatient list and should not be reviewed for ambulatory or outpatient status for Medicare members: 27132, 27134, 27137, and 27138. These codes are applicable for ambulatory or outpatient status for all other plans.**

Effective until June 1, 2023

For Non-Medicare Members

I. Site of Care (SOC) - Inpatient Total Hip Arthroplasty

For total hip replacement (27130) or revision of total hip arthroplasty (27132**, 27134**, 27137**, or 27138**) to be approved as *inpatient,* **ONE of the following** criteria must be met:

- Bilateral total hip
- Coexisting neurologic condition (such as multiple sclerosis, history of stroke, or other neurologic conditions) where the expected length of stay is planned to be longer than 2 midnights

Effective June 1, 2023

For Non-Medicare Members

I. Site of Care (SOC) - Inpatient Total Hip Arthroplasty (for ambulatory SOC, proceed to II.)

For total hip replacement (27130) or revision of total hip arthroplasty (27132**, 27134**, 27137**, or 27138**) to be approved as *inpatient,* **ONE of the following** criteria must be met:

- Bilateral total hip
- Coexisting neurologic condition (such as multiple sclerosis, history of stroke, or other neurologic conditions) where the expected length of stay is planned to be longer than 2 midnights

AND

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II. Request for ALL Total Hip Arthroplasty (includes ambulatory & inpatient) must meet the Medical Necessity Criteria:

**Preauthorization is not required for acute fractures admitted through the emergency department.*

1. Member has advanced joint disease demonstrated by:

- Pain and functional disability that interferes with activities of daily living (ADLs) from injury due to osteoarthritis, rheumatoid arthritis, avascular necrosis, or post -traumatic arthritis of the hip joint; *and*
- Limited range of motion (ROM), antalgic gait, and pain in hip joint with passive ROM on physical examination; ***AND* meet ONE of the following categories:**

2. Arthritis, Degenerative Hip Disease: Meets criteria above *AND*

A. Radiographic or imaging evidence (performed within the prior 12 months) of moderate/severe osteoarthritis; Xray findings should include **ONE of the following**:

- Subchondral cysts
- Subchondral sclerosis
- Periarticular osteophytes
- Joint subluxation
- Bone on bone articulation
- Moderate/Severe joint space narrowing
- Tönnis Grade 2 or 3 Osteoarthritis

Tonis Grading Scale of Hip Osteoarthritis	
Grade	**Radiographic Features**
0	-No signs of osteoarthritis
1	-Slight narrowing of joint space -Slight lipping at joint margin -Slight sclerosis of the femoral head or acetabulum
2	-Small cysts in the femoral head or acetabulum -Increasing narrowing of joint space -Moderate loss of sphericity of the femoral head
3	-Large cysts -Severe narrowing or obliteration of joint space -Severe deformity of the femoral head -Avascular necrosis

AND

B. Documentation of failure of non-surgical conservative management of **ALL of the following**:

i. Anti-inflammatory medication ≥ 3 weeks, one or more of the following:
- Non-steroidal anti-inflammatory drugs (oral or topical), unless contraindicated
- Acetaminophen
- Intra-articular injection of corticosteroids as appropriate

ii. A trial of Physical Therapy in the last 12 months, which should include some of the following features:
- Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits
- Flexibility and muscle strengthening exercises

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- Reasonable restriction of activities (activity or weightbearing modification or use of an assistive device)
  *If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable. Appropriate exemptions may include:
  - Rapid progression or advancement of radiographic arthritic severity
  - Rapid or progressive flexion contraction
  - Medical or social confounding factors precluding the safety or feasibility of conservative treatment

AND

3. All patients who meet the above criteria to undergo standard elective surgery must also meet **ALL of the following:**

i. BMI < 35: if BMI is > 35, optimization efforts must be documented, demonstrating active attempts towards weight loss as shown by sustained weight loss over 3-6 months OR stagnant weights despite documented active participation in a weight loss or exercise program. Formal nutritional counseling must be documented. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. However, BMI > 40 is a relative contraindication. Despite not achieving this BMI, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.

ii. No diabetes, or diabetes with HbA1c < 7.5 (with the presence of heart disease, no lower than 7.5). Members who have an A1C >7.5 must actively be involved with medical management and demonstrate a reduction in A1c over 3-6 months. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. A1c > 8.0 is a relative contraindication. Despite not achieving this A1c, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.

iii. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery or have a 90% reduction in nicotine/tobacco use. If nicotine/tobacco reduction attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. No changes in nicotine/tobacco use is a relative contraindication.

4. Avascular Necrosis
Radiographic or imaging evidence by plain film or MRI shows Avascular Vascular Necrosis/ bone infarct:
- Can proceed directly with surgery

5. Inflammatory Arthritis (may include but not limited to: Rheumatoid Arthritis, Psoriatic Arthritis, Spondyloarthropathy, pseudogout/Gout, Lupus, Non-DJD arthritis, Hemophilia related arthritis, among others) must meet **ALL of the following:**

A. Patient actively being followed by Rheumatology and has been judged to have exhausted all nonsurgical options including DMARDs

B. Radiographic or imaging evidence (performed within the prior 12 months) of moderate/severe osteoarthritis; Xray findings should include one of the following:
- Subchondral cysts
- Subchondral sclerosis
- Periarticular osteophytes
- Joint subluxation
- Bone on bone articulation
- Moderate/Severe joint space narrowing

C. Documentation of failure of non-surgical conservative management of **ALL of the following**:

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i. A trial of Physical Therapy in the last 12 months, which should include some of the following features:
   - Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits
   - Flexibility and muscle strengthening exercises
   - Reasonable restriction of activities (activity or weightbearing modification or use of an assistive device)

   **If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable. Appropriate exemptions may include:*
   - Rapid progression or advancement of radiographic arthritic severity
   - Rapid or progressive flexion contraction
   - Medical or social confounding factors precluding the safety or feasibility of conservative treatment

D. All patients who meet the above criteria to undergo standard elective surgery must also meet **ALL** of the following:
   i. BMI < 35: if BMI is > 35, optimization efforts must be documented, demonstrating active attempts towards weight loss as shown by sustained weight loss over 3-6 months OR stagnant weights despite documented active participation in a weight loss or exercise program. Formal nutritional counseling must be documented. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. However, BMI > 40 is a relative contraindication. Despite not achieving this BMI, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.
   ii. No diabetes, or diabetes with HbA1c < 7.5 (with the presence of heart disease, no lower than 7.5). Members who have an A1C >7.5 must actively be involved with medical management and demonstrate a reduction in A1c over 3-6 months. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. A1c > 8.0 is a relative contraindication. Despite not achieving this A1c, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.
   iii. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery or have a 90% reduction in nicotine/tobacco use. If nicotine/tobacco reduction attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. No changes in nicotine/tobacco use is a relative contraindication.

6. **Replacement/Revision of previous Arthroplasty** must meet **ALL of the following:**

A. Hip arthroplasty may be considered medically necessary for a replacement/revision of a previous arthroplasty as indicated by **ANY of the following**:
   - Aseptic loosening of one or more prosthetic components confirmed by imaging
   - Bearing surface wear leading to symptomatic synovitis or local bone or soft tissue reaction
   - Component instability
   - Periprosthetic fracture
   - Fracture, mechanical failure, or recall of a prosthetic component
   - Periprosthetic infection
   - Progressive or substantial periprosthetic bone loss
   - Recurrent or irreducible dislocation
   - Recurrent, disabling pain associated with clinically significant leg length inequality or audible noise

B. Conservative therapy not indicated

C. All patients who meet the above criteria to undergo standard elective surgery must also meet **ALL of the following** (**if the replacement is deemed urgent or time sensitive i-iii can be waived*):
   i. BMI < 35: if BMI is > 35, optimization efforts must be documented, demonstrating active attempts towards weight loss as shown by sustained weight loss over 3-6 months OR stagnant weights despite documented active participation in a weight loss or exercise program. Formal nutritional counseling must be documented. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared

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decision making. However, BMI > 40 is a relative contraindication. Despite not achieving this BMI, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.

ii. No diabetes, or diabetes with HbA1c < 7.5 (with the presence of heart disease, no lower than 7.5). Members who have an A1C >7.5 must actively be involved with medical management and demonstrate a reduction in A1c over 3-6 months. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. A1c > 8.0 is a relative contraindication. Despite not achieving this A1c, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.

iii. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery or have a 90% reduction in nicotine/tobacco use. If nicotine/tobacco reduction attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. No changes in nicotine/tobacco use is a relative contraindication.

7. **Other Conditions**
   A. Hip arthroplasty may be considered medically necessary for **ANY of the following** clinical situations:
      - Acute hip fracture by imaging
      - Conversion of previous surgeries of the hip due to progression of disease or failure. Scenarios include:
        - previous closed- or open-reduction and internal fixation of the femur or acetabulum (includes hip pinning)
        - intramedullary nail
        - hemiarthroplasty
        - hip resurfacing
        - hip fusion and resection arthroplasty (“Girdlestone”)

   AND

   B. Conservative therapy not indicated

8. **Situations where hip replacement is contraindicated:**
   A. Total hip arthroplasty is considered not appropriate when **ANY of the following** are present:
      - Active infection of the hip joint or active systemic bacteremia
      - Active skin infection (except for recurrent cutaneous staph infections) or open within the planned surgical site of the hip
      - Underlying medical/social issues such as:
        - Unstable angina
        - Dementia that interferes with successful rehabilitation
        - Lack of caregiver/unstable home situation for rehabilitation
      - Non-ambulatory patients

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- If the orthopedist has a patient who does not meet one of the criteria above but has determined that the procedure should be performed in an inpatient setting, the orthopedist can submit a separate explanation with the request that will be reviewed by clinical staff on a case-by-case basis.
- If a patient is approved for ambulatory status under the prior authorization request but ends up staying longer than expected, the inpatient claim could be adjusted to inpatient if deemed appropriate.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

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A total hip arthroplasty (aka total hip replacement, THA, THR) is one of the most common orthopedic surgeries currently performed. The surgical procedure involves removing damaged bone and cartilage of the hip joint and replacing it with a prosthetic implant. The hip joint consists of two main components: a ball (femoral head) which is the upper end of the femur (thighbone) and socket (acetabulum) which is part of the large pelvis bone. Total hip replacement surgery is most often performed due to severe pain caused by osteoarthritis (degenerative arthritis) of the hip joint that persists despite conservative treatment with non-steroidal anti-inflammatory medications, activity modification, or physical therapy. Pain from a damaged joint also limits a person's ability to carry out their everyday activities of living such as walking, bending, climbing stairs, bathing, and cooking. Other conditions that cause hip pain and loss of function that may result in the need of a total hip arthroplasty include rheumatoid arthritis, posttraumatic arthritis, avascular necrosis, and malignant tumors of the affected bones. The goal of a total hip arthroplasty is to provide pain relief and restore functional mobility and range of motion.
KPWA will use commercial criteria and Medicare criteria to assure that this invasive procedure is being done appropriately to help assure both safety and efficacy.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Total Hip:

CPT® or HCPC Codes	Description
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/19/2023	01/10/2023[MPC],	01/19/2023

[MPC] Medical Policy Committee

Revision History	Description
1/19/2023	MPC approved to adopt criteria for Total Hip Arthroplasty. Requires 60-day notice, effective date 06/01/2023.

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Clinical Review Criteria
Inpatient - Total Joint Arthroplasty

- Total Shoulder Arthroplasty
- Total Hip Arthroplasty
- Total Knee Arthroplasty

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Total Knee Arthroplasty (L36577) Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule Total Hip Arthroplasty (L36573)
Local Coverage Article (LCA)	Billing and Coding: Total Hip Arthroplasty (A57684)
MLN Matters Article	Jan 2020 MLN Article: Update of the Hospital Outpatient Prospective Payment System (OPPS) - Topic 5. Changes to the Inpatient-Only list (IPO) for CY 2020
Hospital Outpatient Prospective Payment System Final Rule, Calendar Year 2021	CMS-1736-FC
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Shoulder Arthroplasty - Inpatient"*** for medical necessity determinations. Use the Non-Medicare criteria below.

****The following codes are listed in the Medicare inpatient list and should not be reviewed for ambulatory or outpatient status for Medicare members: 23335, 23474, 27132, 27134, 27137, 27138, 27486, 27487, or 27488. These codes are applicable for ambulatory or outpatient status for all other plans.**

For Non-Medicare Members
Total hip or shoulder replacement/revision requested for ambulatory or outpatient status do not require review.

Service	Criteria

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Total Hip Arthroplasty	**Effective until June 1, 2023** For total hip replacement (27130) or revision of total hip arthroplasty (27132**, 27134**, 27137**, or 27138**) to be approved as *inpatient,* **ONE** of the following criteria must be met: • Bilateral total hip • Coexisting neurologic condition (such as multiple sclerosis, history of stroke, or other neurologic conditions) where the expected length of stay is planned to be longer than 2 midnights **Effective June 1, 2023** **Please see link to *Inpatient and Clinical Review Criteria for Total Hip Arthroplasty* here**
Total Shoulder Arthroplasty	For elective shoulder arthroplasty/hemi-arthroplasty (23470, 23472) or revision/replacement (23335**, 23473, 23474**) of a shoulder arthroplasty to be approved as *inpatient*, **ONE** of the following criteria must be met: • Bilateral shoulder arthroplasty or hemi-arthroplasty procedures • Coexisting neurological condition (such as multiple sclerosis, history of stroke, or other neurologic conditions)
Total Knee Arthroplasty	**Please see link to *Inpatient and Clinical Review Criteria for Total Knee Arthroplasty* here**

If the orthopedist has a patient who does not meet one of the criteria above but has determined that the procedure should be performed in an inpatient setting, the orthopedist can submit a separate explanation with the request that will be reviewed by clinical staff on a case-by-case basis.

If a patient is approved for ambulatory status under the prior authorization request but ends up staying longer than expected, the inpatient claim could be adjusted to inpatient if deemed appropriate.

The above policy is pertinent only to elective shoulder arthroplasty/revision and does not apply to unplanned or urgent/emergent procedures.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist, including a history & physical

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Background

The Centers for Medicare & Medicaid Services (CMS) removed the Current Procedural Terminology (CPT) codes describing shoulder arthroplasty and hemi-arthroplasty procedures from Medicare's Inpatient-Only List (IPO) effective January 1, 2021. This allows shoulder arthroplasty and hemi-arthroplasty procedures to be performed on an inpatient or outpatient basis. In other words, it allows Medicare payment to be made to the hospital for shoulder arthroplasty and hemi-arthroplasty procedures regardless of whether a beneficiary is admitted to the hospital as an inpatient or as an outpatient, assuming all other criteria are met. This does not have any impact on CMS' 2-midnight policy.

CMS policy does not dictate a patient's hospital admission status and has no default determination on whether a shoulder arthroplasty or hemi-arthroplasty procedure should be done on an inpatient or outpatient basis. Rather, CMS continues its long-standing recognition that the decision to admit a patient as an inpatient is a complex

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medical decision, based on the physician's clinical expectation of how long hospital care is anticipated to be necessary, and should consider the individual beneficiary's unique clinical circumstances.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Total Hip Arthroplasty:

CPT® or HCPC Codes	Description
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft

Total Shoulder:

CPT® or HCPC Codes	Description
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/03/2019	12/05/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	01/10/2023

[MPC] Medical Policy Committee

Revision History	Description
03/02/2021	MPC approved the additional codes for revision/replacement of a knee arthroplasty; Codes include 27486, 27487, or 27488. MPC approved the additional codes for revision/replacement of a hip arthroplasty; Codes include 27132, 27134, 27137, and 27138. Archived- Merged Total Knee, Total Hip and Total Shoulder criteria. Requires 60-day notice, effective date 08/01/2021.
07/27/2021	Updated policy effective date to September 1, 2021
05/03/2022	Removed Total Knee Arthroplasty from criteria page to its own separate criteria
06/21/2022	Added clarification around Medicare inpatient only list
10/13/2022	Revised effective date for updated Total Knee Arthroplasty criteria to 10/25/2022
10/18/2022	Moved Medicare IPO applicable codes up under Medicare Criteria for more clarity

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12/19/2022	Removed Total Knee Codes from this criteria page as they are listed on its own separate criteria page.
01/10/2023	MPC approved to adopt coverage for Total Hip Arthroplasty. 60-day notice required; effective June 1, 2023.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intraperitoneal Hyperthermic Chemotherapy (IPHC)

- Hyperthermic Intraperitoneal Chemotherapy (HIPEC)
- Intraoperative Chemo Hyperthermic Peritoneal Perfusion (CHPP)
- Intraperitoneal Hyperthermic Chemoperfusion (IHCP)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Hyperthermia for Treatment of Cancer (110.1) **Per NCD: Covered in connection with radiation therapy for certain types of malignancies, not covered in connection with chemotherapy*
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Service	Criteria Used
Cytoreductive Surgery Perioperative Hyperthermic Intraperitoneal Chemotherapy	Cytoreductive surgery and perioperative hyperthermic intraperitoneal chemotherapy may be considered **medically necessary** for the treatment of: • pseudomyxoma peritonei • diffuse malignant peritoneal mesothelioma • ovarian cancer Cytoreductive surgery and perioperative hyperthermic intraperitoneal chemotherapy is considered **investigational** for: • peritoneal carcinomatosis from colorectal cancer, gastric cancer, or endometrial cancer; • all other indications, including goblet cell tumors of the appendix.
Intraperitoneal chemotherapy without hyperthermic methodology	Intraperitoneal chemotherapy without hyperthermic methodology is considered standard therapy and is not subject for review and is covered.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Colon Cancer

In the United States, approximately 108,070 patients are diagnosed with colon cancer (CRC) per year, and between 10-30% of these patients will develop peritoneal carcinomatosis (PC) at some point after their initial diagnosis. PC is characterized by intraperitoneal spread of tumor nodules in the peritoneum which may occur as a result of growth of the tumor and its invasion through the serosal lining of the bowel lumen, or as result of iatrogenic manipulation during surgical procedures. PC of colorectal origin has poor survival and is the second most frequent cause of death in patients with colorectal cancer (CRC), after metastatic liver disease. It has always been regarded as a terminal condition and was commonly treated only with palliative therapies (Franko 2012, Macri 2010, Ripley 2010, Chua 2012).

Over the last two decades, significant advances made in the field of cytotoxic chemotherapy and biological agents have changed the treatment of PC from a palliative to a potentially curative approach. Modern chemotherapeutic regimens have increased the response rate and median survival of patients with PC. However, few patients experience long-term survival with chemotherapy alone. In the 1980s a multimodal technique was developed to manage PC based on cytoreduction of the primary tumor, peritonectomy, and hyperthermic antiblastic peritoneal perfusion (HIPEC). Theoretically cytoreductive surgery (CRS) treats the macroscopic residual disease and intraperitoneal (IP) chemotherapy treats the microscopic residual disease. IP chemotherapy is based on the principle that a high concentration of chemotherapy within the abdominal cavity will kill the tumor cells on the surface with less diffusion into the tissues and thus are less toxicity. Hyperthermia with IP chemotherapy optimizes the process as heat has direct cytotoxic effects on cancer cells and increases the cytoactivity and penetration of certain cytotoxic drugs (Verwaal 2008, Macri 2010, Ripley 2010, Vaira 2010, Glehen 2010, Mizumato 2012, Chua 2012, Miceli 2012).

HIPEC is achieved by the intraperitoneal administration of a large volume of chemotherapeutic agents in a carrier solution through an open or closed technique. It involves the placement of one inflow and three outflow catheters in the abdominal cavity after the cytoreduction surgery. The cytotoxic agent is applied through the inflow drainage using a roller pump and heat exchanger in a closed system that allows perfusion circulation. The intraperitoneal temperature should reach 41-42oC and is monitored by two sensors placed in the inflow catheter and in the Douglas pouch. At the end of the procedure the solution is drained, and the abdominal wall is closed. There is no standardized procedure for HIPEC and there are variations between the centers in the combinations and/ or concentrations for the cytotoxic agents used, as well as the intraabdominal temperature and duration of the treatment which ranges from 30 minutes to 2 hours depending on the protocol of the drug used. The combination therapy of cytoreductive surgery and HIPEC is complex, has a steep learning curve, and is associated with significant morbidity and mortality. Preoperative selection of patients to achieve complete cytoreduction plays a crucial role for the success of therapy regarding the clinical and ontological outcomes as well as the patient quality of life (Glockzin 2009, Mizumato 2012).

There is controversy around the use of cytoreduction therapy and HIPEC for peritoneal surface disease from CRC, and the procedure is not widely accepted despite the Consensus Statement (issued by representatives from the major Peritoneal Surface Malignancy Centers from around the world) on the role of cytoreductive surgery and HIPEC in the management of peritoneal surface malignancies of colonic origin (Esquivel 2007).

Ovarian Cancer

Ovarian cancer is the fifth leading cause of death in women in the US and the most common cause of death from gynecological cancer in the Western World. It was estimated that around 22,280 women will be diagnosed with ovarian cancer and that 15,500 women will die of the disease in the US in 2012. Approximately two thirds of the women are diagnosed at an advanced stage due to the nonspecific nature of the presenting symptoms of ovarian cancer and its high tendency for early peritoneal spread. Peritoneal carcinomatosis occurs through exfoliation of malignant cells into the peritoneal fluid and their dissemination along the abdominal and pelvic peritoneum. Traditionally these patients with extensive peritoneal carcinomatosis were often labeled as having terminal disease and were only given palliative therapy with no curative intent (Chua 2009, Spiliotis 2011, Chan 2012, de Bree E 2012, Mulier 2012, Siegal 2012, Tentes 2012).

The standard therapy for patients with ovarian cancer is maximal cytoreductive surgery (CRS) followed by systemic chemotherapy with a platinum-based agent and a taxane combination. Ovarian cancer is one of the most chemosensitive tumors, and its response to this initial therapy is high, but the disease often recurs, mostly locoregionally, involving the peritoneum and adjacent intra-abdominal organs. The sensitivity of epithelial ovarian

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cancer to chemotherapy and its tendency to remain confined to the peritoneal cavity through much of its natural history, have led the researchers to investigate regional treatment such as intraperitoneal (IP) administration of chemotherapy (IPC). The theoretical benefits include the achievement of a high drug concentration in the peritoneal cavity without the toxic effects of the systemic chemotherapy. IP chemotherapy has been investigated in clinical trials including the Gynecologic Oncology Group (GOG-172) phase III trial that showed approximately 16 months improvement in the median survival of women treated with a combination intravenous (IV) and IP chemotherapy compared to those treated with IV chemotherapy alone, but on the expense of the increased risk of toxicity and catheter-related complications. Based on the results of this as well as other trials, the National Cancer Institute (NCI) issued a clinical announcement in 2006 recommending that women with optimally debulked stage III ovarian cancer and their physicians consider a combination of intravenous (IV) and intraperitoneal chemotherapy (IPC). IPC has limited tissue penetration and may be indicated only following optimal resection of peritoneal disease when there is either no or very small macroscopic disease remaining (<1.0 cm). The use of IPC however, is controversial and is not widely accepted by the medical community as a standard treatment in the management of advanced epithelial ovarian cancer, due to its high toxicity, catheter-related complications, and negative impact on the patients' quality of life (Almadrones 2007, Trimble 2008, Runowicz 2008, Lim 2009, Spiliotis 2011, Tentes 2012, Chan 2012, de Bree 2012).

In the last two decades researchers investigated the synergistic effect of combining regional hyperthermia and intraperitoneal chemotherapy (hyperthermic IPC, or HIPEC) together with the CRS. Theoretically, in addition its tumoricidal effect, hyperthermia increases the permeability of the drug to the tumor cells (up to 5-6 mm compared to 2-3 mm of the conventional IPC). Hyperthermia may also alter the cellular metabolism, and cellular drug pharmacogenetics. A potential advantage of administrating HIPEC intraoperatively is providing superior and homogenous exposure of the seroperitoneal surface to the drug and heat before the development of adhesions. The disadvantage of HIPEC compared to IPC is the shorter tumor exposure time and its administration only once during the surgery or at the most twice when a secondary surgery is performed (de Bree 2012).

Other primary peritoneal malignancies or secondary dissemination from gastrointestinal tract or other pelvic organs.
Primary peritoneal malignancies such as peritoneal mesothelioma or papillary serous carcinoma are rare, but peritoneal dissemination form gastrointestinal tract and ovarian carcinomas are common. In the past these carcinomatosis were regarded as terminal and the patients were only treated with palliative measures. Over the last 30 years however, novel more aggressive treatment strategies that combine cytoreductive surgery with intraperitoneal (IP) chemotherapy were explored. Hyperthermic intraperitoneal chemotherapy (HIPEC) and early postoperative IP chemotherapy emerged as the most commonly used IP adjuvant therapies. Theoretically cytoreductive therapy treats the macroscopic disease, and intraperitoneal chemotherapy (IP) treats the microscopic disease and the residual or free tumor cells left in the peritoneal cavity after surgery, in order to prevent and control peritoneal dissemination. IP chemotherapy is based on the principle that a high concentration of chemotherapy within the abdominal cavity will kill the tumor cells on the surface with less diffusion into the tissues and less toxicity. Hyperthermia with IP chemotherapy optimizes the process as heat has direct cytotoxic effects on cancer cells and increases the cytotoxicity and penetration of certain cytotoxic drugs. Hyperthermia is also believed to modulate the cells of the innate and adaptive immune system, thereby improving effectiveness (Shen 2009, Glehen 2010, Mizumoto 2012, Sun 2012, MI 2013).

Medical Technology Assessment Committee (MTAC)

Intraperitoneal Hyperthermic Chemotherapy (IPHC)

04/02/2007: MTAC REVIEW

Evidence Conclusion: *Prevention of peritoneal carcinomatosis* Two randomized controlled trials from Japan, conducted among patients who underwent surgery for T2-T4 gastric carcinoma with serosal involvement, found a significant benefit from including HIPEC treatment. The study with the stronger methodology (Yonemura et al., 2001) found a higher estimated 5-year survival in the group receiving cytoreduction and HIPEC (61%), compared to two other groups (cytoreduction and normothermic intraperitoneal chemotherapy, 44%; and surgery alone 42%). The other RCT (Fujimoto et al., 1999) had poorly described methodology, and also found a significantly higher estimated survival rate in a group receiving cytoreduction plus HIPEC compared to surgery alone. The first study had a minimum of 2.4 years of follow-up; length of follow-up was not reported in the Fujimoto study. Findings from studies on Japanese gastric cancer may not be generalizable to the United States. *Treatment of peritoneal carcinomatosis* There is evidence from one reasonably valid randomized controlled trial that HIPEC is beneficial as a treatment for peritoneal carcinomatosis (Verwaal et al., 2003). The study, which included 105 patients with histologically proven peritoneal metastases of colorectal adenocarcinoma, compared an experimental treatment (cytoreduction and HIPEC, plus adjuvant chemotherapy) to standard treatment (outpatient chemotherapy, surgery only if necessary). After a median follow-up of 22 months, the survival rate was

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significantly higher in the experimental treatment group (56% vs. 39%). Sub-group analyses suggest that survival was lower in patients with extensive residual disease or involvement of more than 5 regions of the abdominal cavity. A case series by the same research group found an estimated one-year survival of 75% and three-year survival of 28% with the experimental treatment. There were no long-term survival data for the standard treatment group. The evidence base would be strengthened with additional comparative studies.
Articles: *Prevention of peritoneal carcinomatosis* Three RCTs were identified: all were conducted by Japanese investigators. The two trials with the larger sample sizes (n=139 and n=141) were critically appraised. The third study was smaller (n=82) and had limitations including a non-significant finding with no discussion of statistical power. *Citations for the reviewed studies are as follows:* Yonemura Y, deAretxabala X, Fukimura T et al. Intraoperative chemohyperthermic peritoneal perfusion as a adjuvant to gastric cancer: Final results of a randomized controlled study. Hepato-Gastroenterology 2001; 48: 1776-1782. See Evidence Table. Fujimoto S, Takahashi M, Mutou T et al. Successful intraperitoneal hyperthermic chemoperfusion for the prevention of postoperative peritoneal recurrence in patients with advanced gastric carcinoma. Cancer 1999; 85: 529-534. See Evidence Table. *Treatment of peritoneal carcinomatosis:*
One RCT from the Netherlands was identified and critically appraised (Verwaal et al., 2003). There have also been a number of case series, most had sample sizes under 100. The largest case series was a multicenter study by Glehen et al., 2004 and included 506 patients. This study was limited in that it combined data from different centers that had different protocols and patient populations. All of the centers used perioperative intraperitoneal chemotherapy, but it appears that not all used hyperthermic treatment. As a result, the Glehen article was excluded from further review. The next largest case series available in English was by Verwaal et al., 2005. This article reported long-term follow-up on 117 patients, 48 of whom were included in the 2003 RCT, and was critically appraised. *The two studies reviewed were as follows:* Verwaal VJ, van Ruth S, de Bree E et al. Randomized trial of cytoreduction and hyperthermic intraperitoneal chemotherapy versus systemic chemotherapy and palliative surgery in patients with peritoneal carcinomatosis of colorectal cancer. J Clin Oncol 2003; 21: 3737-3743. See Evidence Table. Verwaal VJ, van Ruth S, Witkamp A et al. Long-term survival of peritoneal carcinomatosis of colorectal origin. Ann Surg Oncol 2005; 12: 65-71. See Evidence Table

The use of intraperitoneal hyperthermic chemotherapy (IPHC) in the treatment of peritoneal carcinomatosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Intraperitoneal Hyperthermic Chemotherapy (IPHC)
10/16/2012: MTAC REVIEW
Evidence Conclusion: Verwaal and colleagues (2003, 2008) conducted a randomized controlled trial in one center in the Netherlands to compare the efficacy of cytoreductive surgery (CRS) and HIPEC versus systemic chemotherapy and surgery in the management of peritoneal carcinomatosis of colorectal origin. The study randomized 105 patients younger than 71 years of age, with peritoneal metastases of CRC to undergo CRS in combination with hyperthermic intraperitoneal therapy (HIPEC) or systemic chemotherapy and surgery. The authors published the results after a median of 21.6 months, and later after an extended follow-up of 91 month. The initial results of the trial showed a significantly higher median survival of the patients treated with CRS and HIPEC vs. standard therapy (22.3 months and 12.6 months respectively). After 8-years of follow-up, 9 patients were still alive. This long-term follow-up showed a median progression-free survival of 12.6 months in the CRS and HIPEC group and 7.7 months in the standard therapy group. Subgroup analyses of the results showed that patients with 6-7 regions had a very poor survival (median 5.4 months) compared to those with 0-5 regions (median >29 months), and that survival was significantly higher with success of surgical procedure i.e. complete cytoreduction. The trial had generally valid methodology; it was randomized and controlled. However, it was conducted over a decade ago and significant progress in chemotherapy has been accomplished since then. The systemic therapy with 5-FU and leucovorin used in the control group is outdated, and mitomycin-C, the HIPEC drug used in the experimental group is not the most effective drug for used for CRC. In addition, the experimental group underwent both cytoreduction and HIPEC and it is difficult to determine whether the survival benefit was due to one of the two treatment modalities or their combination, and whether heating of the chemotherapy had an additive effect to the IP therapy.
Articles: The search revealed one meta-analysis, one randomized controlled trial with long-term follow-up, and a number of observational studies with or without comparison groups. The randomized trial was selected for critical appraisal. The meta-analysis pooled the results of that RCT together with a retrospective study and was not critically reviewed. Verwaal VJ, van Ruth S, de Bree E, et al Randomized trial of cytoreduction and hyperthermic intraperitoneal chemotherapy versus systemic chemotherapy and palliative surgery in patients with peritoneal carcinomatosis of colorectal cancer. J Clin Oncol 2003;21:3737-3743 See Evidence Table. Verwaal VJ, Bruin S, Boot H, et al 8-year follow-up of randomized trial: cytoreduction and hyperthermic intraperitoneal chemotherapy versus systemic chemotherapy in patients with peritoneal carcinomatosis of colorectal cancer. Ann Surg Oncol.2008; 15:2426-2432 See Evidence Table.

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The use of intraperitoneal hyperthermic chemotherapy (IPHC) in the treatment of peritoneal carcinomatosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Intraperitoneal Hyperthermic Chemotherapy (IPHC)

02/11/2013: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of hyperthermic intraperitoneal chemotherapy for the treatment of patients with ovarian cancer whether as an initial therapy, consolidation therapy, or for the treatment of a persistent or recurrent disease. The published studies on HIPEC for ovarian cancer are all prospective or retrospective case series. The studies included heterogeneous groups of women of different ages, different disease characteristics, stages, and tumor load, previous use of systemic chemotherapy regimens, chemo resistance, and with different indications for HIPEC therapy (primary, consolidation, persistent, or recurrent disease after initial therapy). In addition, the published studies recruited patients over long periods of time and used different HIPEC protocols and chemotherapeutic regimens some of which were outdated by the time the studies were completed and their results published. In a small observational study, Spiliotis and colleagues (2011, evidence table 1) compared survival benefit of HIPEC for ovarian cancer among two case series: one with 24 patients treated with CRS followed by HIPEC and systemic chemotherapy, and the other with 24 were treated with CRS and systemic chemotherapy alone without HIPEC for various reasons not explained by the authors. The results of the study show that the median survival was significantly higher for those who received HIPEC vs. those who did not (19.4 months vs. 11.2 months). The 1-year and 3-year survival rates were also significantly higher among patients treated with HIPEC. Within each of the two groups survival outcomes were better among patients with less extensive peritoneal disease and more complete cytoreduction. Due to the study design, the potential selection bias and confounding, it is difficult to determine whether improved survival was due to HIPEC, successful cytoreduction, or other confounding factors. An earlier observational study (Gori et al, 2005) compared the outcomes of a second look surgery and HIPEC (4-8 weeks after standard CRS and systemic chemotherapy) in 29 patients, to the outcomes for 19 patients who refused the second look and HIPEC. All patients had stage III ovarian cancer and had undergone a primary complete or optimal cytoreductive surgery (residual lesion <2cm) and 6 cycles of systemic chemotherapy. After a median follow-up of 73 months (range 24-134 months) the results showed a higher but statistically insignificant median survival patients treated with HIPEC vs. those who refused to undergo the treatment. The results of a larger retrospective case series with a historical comparison group (Ryu et al 2004, evidence table 2) show that HIPEC may be associated with better disease response and survival in patients with ovarian cancer. However, these results must be interpreted cautiously due to the limitations of the study including but not limited to potential selection bias, confounding, and other inherent limitations of case series and the use of retrospective data.
Conclusion: Overall the results of the published observational studies suggest, but do not provide sufficient evidence to conclude, that HIPEC is feasible and may improve survival in women with advanced ovarian cancer. Due to the inherent limitations of the observational studies, it is hard to ascertain the extent at which the reported survival benefit resulted from selection bias, and whether it was due to the intraoperative intraperitoneal therapy, the hyperthermia, the aggressive cytoreduction therapy, the systemic chemotherapy regimens used, or other confounding factors. It is also difficult to determine whether complications occurring after major cytoreduction surgery and HIPEC were due to the surgery itself or the HIPEC. Only well conducted, adequately powered, randomized controlled trials with long-term follow-up may determine the net clinical benefit of incorporating HIPEC in the management of patients with ovarian cancer. Currently, at least three randomized controlled trials are ongoing to investigate the efficacy and safety of adding HIPEC to primary or secondary cytoreductive surgery in women with stage III or relapsing ovarian cancer. Among these trials are the OVIHIPEC trial in the Netherlands, the CHIPOR trial in France, and the HORSE trial in Italy. Their results may answer many questions about the role of HIPEC in treating ovarian cancers, its indications, efficacy, morbidity, and net clinical benefits.
Articles: The literature search did not reveal any randomized controlled trial that compared the efficacy of HIPEC to standard therapy for treatment of women with ovarian cancer. The published studies were mainly prospective or retrospective observational studies. The search identified one retrospective review and three case series that compared the outcomes of patients undergoing HIPEC to those who refused to undergo the procedure or did not receive the HIPEC therapy for various other reasons.
Two case series that compared the outcomes of patients who received HIPEC to those of patients who did not were selected for critical appraisal. Spiliotis J, Vaxevanidou A, Sergouniotis F et al. The role of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy in the management of recurrent advanced ovarian cancer: a prospective study. J Buon 2011; 16:74-75. See Evidence Table. Ryu KS, Kim JH, et al. Effects of intraperitoneal hyperthermic chemotherapy in ovarian cancer. Gynecol Oncol. 2004; 94:325–332. See Evidence Table.

The use of intraperitoneal hyperthermic chemotherapy (IPHC) in the treatment of ovarian cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Intraperitoneal Hyperthermic Chemotherapy (IPHC)

08/19/2013: MTAC REVIEW

Evidence Conclusion: The current review focuses on the safety and efficacy of HIPEC therapy for non-ovarian, non-colorectal cancers with serosal invasion or peritoneal carcinomatosis. Perioperative HIPEC in combination with cytoreductive surgery was evaluated in small, randomized controlled trials and a number of meta-analyses for patients with gastric cancer. The search did not identify any RCTs or large prospective studies that evaluated HIPEC for the treatment of peritoneal mesothelioma, pseudomyxoma peritonei, or for peritoneal carcinomatosis secondary to urinary bladder cancer, or uterine leiomyosarcoma. *HIPEC for Gastric cancer:* Mi DH and colleagues' meta-analysis (2013) pooled the results of 16 trials that examined the effectiveness and safety of radical surgery (RS) combined with HIPEC vs.RS without HIPEC in 1,906 patients with histologically diagnosed, primary, locally advanced gastric cancer with macroscopic serosal invasion, but with no peritoneal or distant metastases. The primary outcome of the analysis was overall survival. The pooled results indicate that compared with surgery alone, the combination of surgery with HIPEC was associated with a significant improvement in survival rate at 1,2,3,5 and 9 years. It was also associated with a significant reduction in recurrence rates at 2, 3, and 5 years. There was however, a significantly higher incidence of abdominal pain with HIPEC. The rates of other adverse events were too small to show a significant difference. Sun and colleagues' meta-analysis (2012) also examined the effectiveness and safety of gastrectomy combined with HIPEC versus gastrectomy alone in patients with advanced gastric cancer with serosal invasion but without distant metastases or peritoneal carcinomatosis. The analysis included 10 trials with a total of 1,062 patients. The primary outcome was overall survival defined as the time from treatment to the last follow-up or death. Similar to MI et al's analysis, the pooled results indicate that surgery combined with HIPEC may improve the overall survival for patients and prevent peritoneal local recurrence. There pooled results do not show a significantly higher risk of complications associated with HIPEC, but again the numbers were too small to provide sufficient statistical power. The two meta-analyses had had generally valid methodology and analysis. However, they had only 5 trials in common despite almost similar literature search dates. The trials included were small, all were conducted in Asia, and many were performed in the late 1980s and early 1990s and the procedures used may be currently outdated. In addition, there was no standardized agent or dose used for HIPEC; different chemotherapeutic agents were used among the trials and at different doses. The most commonly used agents in the trials were mitomycin C and cisplatin given alone, in combination together, or in combination with other agents. A small phase III RCT (Yang et al, 2011) conducted in Japan, evaluated the efficacy and safety of cytoreductive surgery (CRS) in combination with hyperthermic intraperitoneal therapy (HIPEC using mitomycin C and cisplatin) for the treatment peritoneal carcinomatosis (PC) from gastric cancer. The study randomized 68 participants to receive CRS combined with open HIPEC or CRS alone. The primary outcome was overall survival. After a median follow-up of 32 months (range 7.5-83.5 months), the results showed that patients in the CRS and HIPEC had significantly better overall survival compared to those who underwent CRS with no HIPEC. The numbers of serious adverse events were higher in the HIPEC group but were too small to allow any conclusion. *HIPEC for diffuse malignant peritoneal mesothelioma (DMPM)*: Baratti and colleagues (2009) analyzed data from a prospective database for 70 patients with DMPM who were treated with cytoreduction surgery and HIPEC by the same surgical team from 1996 to 2008 at a cancer institute in Italy. Disease progression was the primary outcome of the study. This occurred among 38 (54.28%) of the participants after a median follow-up of 43 months. The median time to disease progression (TTP) among these patients was 9 months and the median survival from progression was 8 months. Failure pattern was categorized as peritoneal progression, which occurred among 31(81.58%) patients, liver metastasis in one patient, abdominal lymph node involvement in 2, and pleural seeding in 4 patients. Residual tumor $\leq$2.2 mm was the only independent risk factor for disease progression. Progressive disease was treated with second HIPEC in 3 patients, debulking in 4, systemic chemotherapy in 16, and supportive care in 15. A multivariate analysis showed that time to progression <9 months, poor performance status, and supportive care correlated to reduced survival from progression. These results should be interpreted with caution as the study was small, observational, conducted in a single center, and had no comparison or control group. *HIPEC for Pseudomyxoma peritonei (PMP)* In a retrospective study, Chua and colleagues (2012) reported on the outcome of nearly 2,300 patients from 16 institutions worldwide that were treated with cytoreductive surgery (CRS) and HIPEC over an 18-years period for pseudomyxoma peritonei (PMP) that arose from the appendix. The study was based on data from the Peritoneal Surface Oncology Group International registry. The median survival was 16.3 years, and the median progression-free survival was 8.2 years, with 10-year survival rate of 63% and a 15-year survival rate of 59%. The postoperative mortality rate after cytoreductive surgery and HIPEC was low (2%), but 24% of patients experienced major complications and 10% of patients required surgery for their complications. Data on quality of life were not provided. A multivariate analysis indicated that prior chemotherapy treatment, peritoneal mucinous carcinomatosis (PMCA) histopathological subtype, major postoperative complications, high peritoneal cancer index, and debulking surgery were independent predictors for a poorer progression-free survival. Use of HIPEC was associated with a favorable progression- free survival. Older age, major postoperative complications, debulking surgery, prior chemotherapy treatment, and PMCA histopathological subtype were independent predictors of a poorer overall survival. Elias and colleagues (2010) also conducted a retrospective

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analysis of data from a registry with 301 patients with PMP treated with CRS and HIPEC between 1993 and 2007 in 18 French speaking centers in Europe and Canada. The mean follow-up was 88 months, the 5-year and 10-year overall survival rates were 73% and 54.8% respectively. The 5-year disease-free survival was 56%. 4.4 % of the patients died postoperatively, 40% had a grade 3-4 complication. 17.5% of all patients required a re-operation due to complications. These results of these retrospective analyses should be interpreted with caution due to the methodological limitations of retrospective studies, and lack of control groups. Conclusion: There is some evidence from small RCTs conducted in Asia, and meta-analyses pooling their results that cytoreductive surgery combined with intraperitoneal hyperthermic chemotherapy may improve the overall survival in patients with advanced gastric cancer without macroscopic
peritoneal carcinomatosis or distant metastases. There is insufficient evidence to determine the subgroup of patients with gastric cancer who would benefit most from HIPEC as the effectiveness of HIPEC may depend on size and depth of micrometastases. There is insufficient evidence to determine the optimal regimen for HIPEC. There is insufficient evidence to determine the efficacy of HIPEC in patients with peritoneal carcinomatosis from gastric cancer. There is insufficient evidence to determine the safety of HIPEC or its effect on the quality of life in patients with gastric cancer with or without dissemination to the peritoneum. There is insufficient evidence to determine the safety and efficacy of HIPEC for the treatment of other peritoneal malignancies, whether of a primary origin or peritoneal carcinomatosis secondary to cancer in other organs within the peritoneal cavity.
Articles: The literature search for studies on the efficacy and safety of HIPEC in patients with pseudomyxoma peritonei, GI cancers (other than colorectal cancer) identified two recent meta-analyses of RCTs, two older ones, and a phase III RCT on HIPEC for patients with gastric cancer. The search did not reveal any RCTs that evaluated HIPEC for primary peritoneal malignancies, or other peritoneal disseminations from other cancers evaluated in this review. The published studies were mainly small prospective or retrospective case series with no comparison or control groups. The two more recent meta-analyses and the RCT that evaluated the efficacy and safety of HIPEC for gastric carcinoma were selected for critical appraisal.
Mi DH, Li Z, Yang KH, et al. Surgery combined with intraoperative hyperthermic intraperitoneal chemotherapy (IHIC) for gastric cancer: a systematic review and meta-analysis of randomized controlled trials. Int J Hyperthermia. 2013; 29:156-167. See Evidence Table. Sun J, Song Y, Wang Z, et al. Benefits of hyperthermic intraperitoneal chemotherapy for patients with serosal invasion in gastric cancer: a meta-analysis of the randomized controlled trials. BMC Cancer. 2012; 12:526. See Evidence Table. Yang XJ, Huang CQ, Suo T, et al. Cytoreductive surgery and hyperthermic intraperitoneal chemotherapy improves survival of patients with peritoneal carcinomatosis from gastric cancer: final results of a phase III randomized clinical trial. Ann Surg Oncol. 2011; 18:1575-1581. See Evidence Table.

The use of intraperitoneal hyperthermic chemotherapy (IPHC) in the treatment of Gastric, DMPM, and PMP cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare – Considered not medically necessary for use of hyperthermia with chemotherapy
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
77600	Hyperthermia, externally generated; superficial (ie, heating to a depth of 4 cm or less)
77605	Hyperthermia, externally generated; deep (ie, heating to depths greater than 4 cm)
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
77620	Hyperthermia generated by intracavitary probe(s)

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Date Created	Date Reviewed	Date Last Revised
04/19/2007	04/02/2007, 04/16/2007 MDCRPC, (reinitiated policy document) 11/06/2012 MDCRPC, 03/05/2013 MDCRPC,10/01/2013 MPC, 01/07/2014 MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC, 03/07/2023MPC	03/01/2022

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
08/02/2016	Removed the diagnosis, Pseudomyxoma Peritonei (PMP), from the non-covered list
05/22/2020	Added CPT codes 77600, 77610, 77615, 77620 and removed 96446.
03/01/2022	Added ovarian cancer to the list of medically necessary diagnoses.

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Clinical Review Criteria
Intense Pulsed Light (IPL) for Meibomian Gland Dysfunction

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **Intense Pulsed Light (IPL) for Meibomian Gland Dysfunction,** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Meibomian glands are located in the eyelids and secrete lipids into the surface of the eye. These lipids prevent the tears from evaporating rapidly. Meibomian gland dysfunction (MGD) is an abnormality or obstruction of meibomian glands leading to evaporation of the tears which in turn results in dry eye. Increased evaporative loss results in tear film instability, hyperosmolarity and lacrimal system inflammation (https://www.uptodate.com/contents/dry-eye-disease).

Meibomian gland dysfunction affects 70% of the population in some parts of the world (Craig, Chen, & Turnbull, 2015). Risk factors include age (the risk of MGD increases with age), ethnicity (Asians have high risk of MGD), eye makeup, contact lenses. The pathophysiology of MGD is multifactorial; it includes inflammation, bacterial overgrowth, abnormal blood vessel growth around the meibomian gland, and abnormal meibum production (Sabeti, Kheirkhah, Yin, & Dana, 2019).
Clinical symptoms include dryness, red eyes, general irritation, gritty sensation, burning, paradoxical excessive tearing, and decreased visual acuity (https://www.uptodate.com/contents/dry-eye-disease).

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Treatment of MGD includes artificial tears, heat application, manual gland expression, warm compresses, lubricants with fatty acids, omega-3 supplementation, topical antibiotics, oral antibiotics, corticosteroids, or topical cyclosporine (Craig et al., 2015; Dell, Gaster, Barbarino, & Cunningham, 2017). However, these therapies come with adverse events, are temporarily effective and both physicians and patients are unsatisfied (Craig et al., 2015). IPL has garnered interest due to its concomitant effectiveness on ocular and dermatological manifestations in patients with rosacea. However, the mechanism by which this occurs is not well understood (Rennick & Adcock, 2018).

The most common indication for IPL has been skin disorders such as rosacea and acne. Regarding this treatment, the skin is exposed to the light with wavelengths from 500 to 1200 nm. The targeted tissue absorbed the light. This generates heat which destroys the lesions (Craig et al., 2015). In addition, the wavelengths stimulate melanin and hemoglobin in the skin causing coagulation and ablation of blood vessels ((Gao et al., 2019); Rennick & Adcock, 2018) and suppressing inflammation. IPL can also eliminate bacteria on treated zones of the skin. The theory is that IPL should improve MGD. There are several mechanisms by which IPL enhances MGD: heating, occlusion of abnormal blood vessels, liquefaction of meibum improving secretion and excretion, reduction in epithelial turnover, local photomodulation, activation of fibroblasts, enhancement of collagen synthesis, and destruction of Demodex mites (Sabeti et al., 2019).

The procedure starts with placement of shields over the eyes. This serves as protection from the light. A cooling gel is then applied to the area followed by administration of pulsed light around the eyelids. Manual gland expression is then performed, and normal oil flow is restored in the tear film. The procedure lasts approximately 20 minutes and is performed once a month for four months (https://www.theeyeinstitute.com/dry-eye/intense-pulsed-light-ipl-treatment/). Gao et al., 2019 (Gao et al., 2019) applied lidocaine cream for anesthesia for 30 minutes before placing the protective shield and administering IPL. Indications include rosacea, acne, MGD. Other indications include hypertrichosis, benign cavernous hemangiomas, benign venous malformations, telangiectasia, and pigmented lesions. It is also used in the cosmetic industry (Craig et al., 2015). IPL can only be used for patients whose skin is Fitzgerald type four or below (https://www.reviewofophthalmology.com/article/intense-pulsed-light-for-treating-dry-eye).

Medical Technology Assessment Committee (MTAC)

Intense Pulsed Light (IPL) for the treatment of meibomian gland dysfunction (MGD)

01/13/2020: MTAC REVIEW

Evidence Conclusion:

The evidence consists of six small randomized controlled trials. One RCT compared intense pulsed light (IPL) to tobramycin/dexamethasone, three RCTs compared IPL plus meibomian gland expression to meibomian gland expression alone, and two other RCTs compared IPL vs sham. Statistically significant reduction of symptoms was found in each study. In addition, IPL appears to be safe as no serious adverse events were reported. However, the studies have small sample size, short follow-up, the risk of bias is not low, power calculations were not consistently provided. High-quality studies with large sample size and long-term follow-up are warranted. The findings are promising.

Overall, the evidence is not sufficient to draw overarching conclusions on the effectiveness and safety of intense pulsed light for the treatment of meibomian gland dysfunction.

Articles: PubMed search was conducted up to December 2, 2019 with the search terms (intense pulsed light OR intense-pulsed-light OR intense pulse light OR intense-pulse-light OR IPL) AND (dry eye OR DED OR meibomian OR MGD OR meibomian gland dysfunction). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Non-randomized controlled trials were excluded. Only randomized controlled trials were included in the review.
The search yielded several articles. However, seven RCTs were retained and reviewed. See Evidence Table**.**

The use of Intense Pulsed Light (IPL) for the treatment of meibomian gland dysfunction (MGD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral

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0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report
0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral
May be submitted with unlisted code 17999 and ICD-10 codes H02.88-H02.88B	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
	Meibomian gland dysfunction of eyelid

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Date Created	Date Reviewed	Date Last Revised
03/03/2020	03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	09/11/2020

[MPC] Medical Policy Committee

Revision History	Description
03/03/2020	MPC approved to endorse a non-coverage policy for IPL.
09/11/2020	Added CPT codes 0207T, 0507T, 0563T and 17999 w dx codes H02.88-H02.88B

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Clinical Review Criteria
Islet Cell Transplantation for Type I Diabetes

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Some patients with Type I diabetes fail to obtain adequate glucose control despite insulin treatment. Pancreas allo-transplantation can restore metabolic control, but this procedure is limited by a shortage of donor organs and a complex surgical procedure with associated morbidity and mortality. Transplantation of pancreatic islet cells is a possible alternative treatment. The islet of Langerhans cells contains insulin-secreting *b* cells and make up only about 1% of the whole pancreas.

In the early 1970s, researchers found that islet cell transplantation could be used to treat diabetes in rats. Since that time, there have been attempts to apply this treatment to humans. Most of the applications of this procedure were unsuccessful; the Islet Transplant Registry estimated in 1996 that only 6 percent of islet transplantations done between 1990-1996 were successful (success defined as not needing insulin treatment for a year after transplantation).

Medical Technology Assessment Committee (MTAC)

Islet Cell Transplantation

10/11/2001: MTAC REVIEW

Evidence Conclusion: To date, there has been one report of some success with islet cell transplantation in 7 patients; only 3 of these were followed-up for at least a year. The effectiveness of islet cell transplantation for type 1 diabetes cannot be determined based on the current published scientific evidence. A randomized controlled trial, which will provide higher-quality data, was recently initiated by the Juvenile Diabetes Foundation and the National Institutes of Health to study the effectiveness of islet cell transplantation.

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Articles: The searches yielded 60 articles. These were predominantly review articles and articles on technical aspects of the procedure. There were no randomized controlled trials or meta-analyses. There were 3 empirical articles with clinical outcomes; all were case series studies with sample sizes less than n=10. An evidence table was done for the case series that used the most up-to-date techniques: Shapiro AMJ, Lakey JRT, Ryan EA, Korbutt GS, Toth E, Warnock GL, Kneteman NM, Rajotte RV. Islet cell transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. NEJM 2000; 343: 230-8. See Evidence Table.

The use of Islet Cell Transplantation in the treatment of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary

CPT® Codes	Description
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open
HCPC Codes	**Description**
S2102	Islet cell tissue transplant from pancreas; allogeneic ***S codes not covered by Medicare***

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered not medically necessary

HCPC Codes	Description
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

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Creation Date	Review Date	Date Last Revised
11/17/2000	05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC,12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	06/23/2020

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
06/23/2020	Added CPT codes 0584T, 0585T and 0586T

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Jaw Motion Rehabilitation Device (Jaw Stretch Device)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Jaw Motion Rehabilitation Device***," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Jaw motion rehabilitation system is medically necessary to treat mandibular hypomobility when caused by radiation therapy in persons with head and neck cancer.

It is **not medically necessary** for any other indication, as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

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Background

Trismus, defined as a tonic spasm of the muscles of mastication from diseases of the trigeminal nerve, is often used to describe mandibular hypomotility of any cause. Mandibular hypomotility is a common symptom in patients suffering from temporomandibular disorders as well as variety pathologies of the masticatory system. It may be related to intra- or extra-articular conditions such as synovitis, osteoarthritis, fibrosis, facial space infections, coronoid hyperplasia, fibrosis following radiation therapy, and tumors involving the head and neck regions. Patients with mandibular hypomotility experience limitations during eating, speaking, and with oral hygiene (Israel 1997, Cohen 2005, Melchers 2009).

The temporomandibular joint (TMJ) is a synovial joint that functions according to the same biological rules as other synovial joints and follows the same principles of joint motion and rehabilitation. Several manual, mechanical, and electromechanical approaches have been used for TMJ mobilization and increasing mouth

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opening. The most common methods used are isometric and range of motion exercises, tongue depressor therapy, and mechanical stretching devices (Israel 1997).

The Therabite System (Therabite Corporation, Bryn Mawr, PA) is a handheld patient controlled, mechanical device with two mouthpieces that are inserted between the teeth of the upper and lower jaw. By squeezing the handles, the mouthpieces open and assist the opening of the mouth. The horseshoe-shaped surfaces on the arms come in contact with the teeth and spread the load across 10 anterior teeth in each jaw. This generates less force on the incisors than spatulas or screws and makes the Therabite appliance more comfortable to use. The force applied by squeezing and releasing the handle stretches the fibrosis intermittently. Maximum device opening can be adjusted between 25 and 45 mm using a single screw and can be sequentially increased by the patient or clinician. Similar to other exercise regimens and physiotherapy, the patient must be motivated and must use the device correctly and regularly. Adherence to exercise regimens has a positive effect on outcome, and poor adherence may be a barrier to treatment success (Buchbinder 1993, Gibbons 2007, Melchers 2009).

Medical Technology Assessment Committee (MTAC)

Jaw Motion Rehabilitation Device

04/16/2012: MTAC REVIEW

Evidence Conclusion: In a relatively small unblinded, randomized, controlled trial, Maloney and colleagues (2002) compared the effectiveness of a passive jaw motion device (Therabite) and wooden tongue depressors (WTD) in patients with temporomandibular joint and muscle disorders that did not respond to manual manipulation and bite plane therapy. The authors did not discuss the cause of mouth opening restriction. After undergoing manual manipulation of the mandible combined with flat bite plane therapy for 4 weeks, eligible patients were randomly assigned to one of three treatment groups: Therabite group, wooden tongue depressor group, or control group. Patients in the first 2 intervention groups received treatment for 4 weeks, and the control group received a total of 8 weeks of flat bite plane therapy only. The authors did not discuss compliance with therapy or completeness of follow-up. The results of the trial show that passive jaw motion therapy using Therabite was more effective than using wooden tongue depressor in reducing pain and increasing the maximum interincisal opening.

In a smaller RCT, Buchbinder and colleagues (1993) compared the use of Therabite system plus unassisted exercise vs. tongue blade therapy plus unassisted exercise, or unassisted exercise only for 10 weeks in 21 patients with decreased interincisal opening secondary to radiation therapy after head and neck cancer resection. The initial average maximum interincisal opening (MO) was 21.6 mm. All three groups showed an initial increase in the MO in the first 4 weeks, after which there was only minimal further gain in the unassisted exercise group with or without tongue blade therapy. After 6 weeks of treatment, the net increase in MO in the Therabite group was significantly greater than either of the other 2 groups. In conclusion, evidence from two small RCTs suggest that passive jaw motion rehabilitation using Therabite device may be more effective than unassisted exercise, manual manipulation, and bite plane therapy with or without tongue blade therapy in reducing pain and improving maximum interincisal opening in patients with mandibular hypomobility.

Articles: The literature on the use jaw motion rehabilitation devices for patients with mandibular hypomotility is limited. Only two small RCTs comparing TheraBite to other treatment were identified and critically appraised, Maloney GE, Mehta N, Forgione AG, et al. Effect of a passive jaw motion device on pain and range of motion in TMD patients not responding to flat plane intraoral appliances. Cranio. 2002; 20:55-66. See Evidence Table**.** Buchbinder D, Currivan RB, Kaplan AJ, et al. Mobilization regimens for the prevention of jaw hypomobility in the radiated patient: a comparison of three techniques. J Oral Maxillofacial Surg. 1993; 51:863-867.

The use of jaw motion rehabilitation device for mandibular hypomobility does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E1700	Jaw motion rehabilitation system
E1701	Replacement cushions for jaw motion rehabilitation system, package of 6
E1702	Replacement measuring scales for jaw motion rehabilitation system, package of 200

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
05/01/2012	05/01/2012[MDCRPC], 06/05/2012[MDCRPC], 04/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	06/06/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/06/2017	Adopted Kaiser Permanente policy for Medicare members

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Clinical Review Criteria

Ketamine for the Treatment of Depression and Other Psychiatric Disorders

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Ketamine for the Treatment of Depression and Other Psychiatric Disorders"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Ketamine (intranasal, intravenous, or subcutaneous) is considered experimental and investigational as its clinical value has not been established. Non-covered diagnoses include but are not limited to:

- Chronic pain
- Depression
- Generalized anxiety and social anxiety disorders
- Substance use disorder
- Suicidal ideation

*Esketamine nasal spray (Spravato) has separate criteria for pharmacy review:
https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/list-officeinject.pdf

For non-covered criteria

If requesting review for this service please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Hayes Review

Ketamine Infusion for Treatment-Resistant Bipolar Depression

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Conclusion - D[2]
A small body of very low-quality evidence found that ketamine infusion rapidly reduces symptoms of severe bipolar depression. Although the antidepressant effects appear to last for only a few days, this can be clinically significant if it improves the mood of severely depressed, potentially suicidal patients. In all of the studies, only a single dose of ketamine was administered; the safety and effectiveness of repeated administration of ketamine for treatment of bipolar depression is unknown. The evidence suggests that ketamine is reasonably safe. Additional large, well-designed studies with adequate follow-up are needed to evaluate the long-term effects of prolonged ketamine treatment.
Insights
- Ketamine is administered by infusion because it does not have good bioavailability via alternative routes, such as oral or intramuscular injection.
- The low oral bioavailability and potential for abuse makes ketamine an unlikely first- or second-line therapy for bipolar depression.
- Persons with bipolar disorder are more apt to seek medical attention when they are depressed; therefore, a careful medical history must be obtained to avoid misdiagnosis of the patient's disorder as major depression.
- None of the reviewed payers had policies available for the use of ketamine to treat bipolar depression.

Ketamine as Primary Therapy for Treatment-Resistant Unipolar Depression Or Posttraumatic Stress Disorder
Conclusion- C (For ketamine as a treatment for treatment-resistant unipolar depression)
D2 (For ketamine as a treatment for posttraumatic stress disorder (PTSD).
A moderate-size body of low-quality evidence has consistently found that ketamine reduces symptoms of severe treatment-resistant unipolar depression, symptoms of PTSD, or suicidal ideation at short-term follow-up of 1 to 3 days posttreatment; however, the findings at longer-term follow-up of 1 to 4 weeks are mixed. The majority of the studies administered only a single dose of ketamine; the safety and effectiveness of repeated administration of ketamine for treatment of depression or PTSD is unknown. The evidence suggests that ketamine is reasonably safe if complications are properly managed. Additional large, well-designed studies with adequate follow-up are needed to evaluate the long-term effects of prolonged ketamine treatment, to assess simplified ketamine administration via intranasal or subcutaneous routes, to determine the efficacy and safety of ketamine for PTSD treatment, and to evaluate the efficacy and safety of ketamine relative to ECT for unipolar depression.
Insights
- The low oral bioavailability and potential for abuse makes ketamine an unlikely first- or second-line therapy for treatment-resistant unipolar depression or PTSD.
- The reviewed studies found that ketamine is consistently beneficial for 24 hours posttreatment; however, the durability of results at 1 to 4 weeks posttreatment are mixed. Thus, it is unclear whether ketamine provides durable relief of depression or PTSD symptoms.
- As the beneficial effects of ketamine may be limited to 24 hours posttreatment, it is important to establish the safety and effectiveness of repeated administration of ketamine. There is currently a paucity of studies investigating repeated administration of ketamine for unipolar depression or PTSD.
- Several representative payer organizations do not have coverage policies for ketamine monotherapy for unipolar depression or PTSD.

Applicable Codes

Considered Not Medically Necessary - experimental, investigational or unproven:

CPT® or HCPCS Codes	Description
J3490	Unclassified drugs
Commonly submitted with CPT code(s) 96365, 96366, 96367, or 96368	
ICD-10 Codes	**Description**
F01-F09	Mental disorders due to known physiological conditions
F10-F19	Mental and behavioral disorders due to psychoactive substance use
F20-F29	Schizophrenia, schizotypal, delusional, and other non-mood psychotic disorders
F30-F39	Mood [affective] disorders
F40-F48	Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders

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F50-F59	Behavioral syndromes associated with physiological disturbances and physical factors
F60-F69	Disorders of adult personality and behavior
F70-F79	Intellectual disabilities
F80-F89	Pervasive and specific developmental disorders
F90-F98	Behavioral and emotional disorders with onset usually occurring in childhood and adolescence
F99-F99	Unspecified mental disorder
T14.91XA	Suicidal behavior with attempted self-injury
R45.89	Suicidal behavior without attempted self-injury
T65.92XA	Suicidal deliberate poisoning
R45.851	Suicidal ideation
R45.851	Suicidal ideations
R45.851	Suicidal intent
T50.902A	Suicidal overdose
T50.902A	Suicidal overdose, initial encounter
T50.902S	Suicidal overdose, sequela
T50.902D	Suicidal overdose, subsequent encounter
R45.89	Suicidal risk
R45.851	Suicidal thoughts
R45.851	Feeling suicidal
T40.602A	Narcosis due to narcotic, purposeful, non-suicidal
Z71.1	Concern about becoming suicidal without diagnosis
F32.A, R45.851	Depression with suicidal ideation
Z91.52	History of non-suicidal self-harm
Z91.51	History of suicidal behavior

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Date Created	Date Reviewed	Date Last Revised
11/10/2021	12/07/2021[MPC],	12/07/2021

[MPC] Medical Policy Committee

Revision History	Description
12/07/2021	MPC approved to adopt a policy of non-coverage for IV Ketamine for mental diagnoses including chronic pain, depression, generalized anxiety and social anxiety disorders, substance use disorder and suicidal ideation.
06/21/2022	Updated the 60-day notice to 12/1/2022 and removed “oral” per Pharmacy

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PATIENT REFERRAL GUIDELINES
Kidney Transplant

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Criteria

For Medicare Members

Source	Policy
Chapter Manual	Medicare Benefits Manual Chapter 11 – End Stage Renal Disease Section 140 - Transplantation
National Coverage Determination (NCD)	Thoracic Duct Drainage (TDD) in Renal Transplants (20.3) Dental Examination Prior to Kidney Transplantation (260.6) Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation 110.16
Local Coverage Determination (LCD)	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. Kidney transplantation is the preferred renal replacement therapy for almost all patients with chronic kidney disease. Most patients with chronic kidney disease or end stage renal disease should be considered for kidney transplant evaluation. However, the patient must have adequate social support systems and a proven record of adherence to medical treatment. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. Referral to a regionally contracted transplant center for kidney transplant does not guarantee that the patient will be listed or transplanted. These are decisions made at the Transplant Center's discretion.

1. **GENERAL PRINCIPLES**
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection is a contraindication to transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low.[1,2,3] Exceptions may be made on a case-by-case basis.
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
   g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

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h. Patients must have a care giver or care givers who are physically and cognitively able to assist the patient with self- care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
i. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
j. Evidence of such nonadherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
k. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR KIDNEY TRANSPLANT

Most patients with kidney failure can be considered for transplantation. It is important to note that these are guidelines and should be applied together with careful clinical judgment. The aim is to perform pre-emptive renal transplantation without initiation of standard kidney replacement therapy (hemodialysis/peritoneal dialysis).

a. All pediatric and adult patients who require dialysis or are expected to require dialysis within the next 12 months can be considered candidates. If possible, patients should be evaluated prior to this time to discuss options for renal replacement therapy.
   1. Patients with an estimated GFR ≤ 30 should be informed of, educated about, and considered for potential referral for transplantation.[4]
b. Known Type 2 diabetes patients, sometimes referred to as type 1.5 diabetes, with BMI <28, who require low-dose insulin, may be considered for SPK. Input from endocrinology may be needed.
c. Patients cannot be listed on the UNOS waiting list for a deceased donor kidney until their estimated GFR, calculated by the CKD-EPI creatinine equation (2021) that are refitted without race or the CKD-EPI creatinine-cystatin equation (2012) that are refitted without race, is less than 20ml/min.[5,6,7]
d. Estimated GFR for the pediatric population using the Schwartz formula of 10 – 15, or sooner if symptomatic. Symptomology is defined as poor growth/failure to thrive and suboptimal energy level despite adequate caloric support. Patients with estimated GFR <30 may be referred early.

CONTRAINDICATIONS FOR KIDNEY TRANSPLANT

a. Significant irreversible coronary artery disease and/or left ventricular dysfunction, and irreversible pulmonary disease.
b. Irreversible peripheral vascular disease, including carotid vascular disease. (Amputation alone is not a contraindication)
c. Uncontrolled hypertension.

RELATIVE CONTRAINDICATIONS FOR KIDNEY TRANSPLANT

a. Patients with a BMI ≥ 40 may be referred to the COE for individual consideration and concurrently referred for weight loss intervention.
b. Active nicotine abuse.
c. Age: There is no firm upper limit cut-off for kidney transplantation.
d. When considering candidacy, close attention should be paid to concurrent conditions, such as frailty, that would increase the risk of morbidity and mortality.
e. Presence of other significant, permanent, irreversible organ failure.

Footnotes

1. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
2. *Liver Transplant Surg*. 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
4. KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. Transplantation. 2020;104: S1 – S103.
5. Inker, Lesley A., et al., "New Creatinine- and Cystatin C–Based Equations to Estimate GFR without Race." N Engl J Med 2021; DOI: 10.1056/NEJMoa2102953
6. Hsu, Chi-yuan, et.al., "Race, Genetic Ancestry, and Estimating Kidney Function in CKD." N Engl J Med 2021; DOI: 10.1056/NEJMoa2103753
7. National Kidney Foundation, eGFR Calculator: https://www.kidney.org/professionals/kdoqi/gfr_calculator

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If requesting this service, please send the following documentation to support medical necessity:

- Copy of final summary report from multidisciplinary transplant team

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Background

Kidney transplant is a surgical procedure to implant a healthy kidney into a patient with kidney disease or kidney failure. The kidney transplant may be taken from a living donor or from a recently deceased donor.

The transplant is conducted when the patient has non-reversible, end stage renal failure with a glomerular filtration rate 20 mL/min/1.73m2 (0.33 mL/sec/1.73m2) or less. There are several causes for renal failure, but the most common cause is diabetes or hypertension.

Evidence and Source Documents

See evidence document for HIV patients: Organ Transplant for HIV Positive Patients

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

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Date Created	Date Revised	Date Last Revised
05/1996	10/05/2010 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC,	01/10/2022

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	06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt KP National criteria for Kidney transplant.
03/03/2020	MPC approved the proposed changes from KP National Transplant Services.
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”
01/10/2022	MPC approved the proposed changes from KP National Transplant Services. 60-day notice is not required.

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PATIENT REFERRAL GUIDELINES
Kidney/Pancreas Transplant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefits Manual Chapter 11 – End Stage Renal Disease Section 140 - Transplantation
National Coverage Determinations (NCD)	Pancreas Transplants (260.3)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Note: Simultaneous Pancreas Kidney Transplantation (SPK)[1]

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. It is important to note that these are guidelines and should be applied together with careful clinical judgment. Patient and treating physician should understand the uncertain benefits of successful pancreas transplantation beyond glucose control.

1. **GENERAL PRINCIPLES**
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection is a contraindication to transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low[2,3,4]. Exceptions may be made on a case-by-case basis.
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
   g. Patient must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
   h. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
   i. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

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j. Evidence of such non adherence may be: failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
k. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation

2. INDICATIONS FOR SPK TRANSPLANT

a. Type 1 (as verified by stimulated C-peptide testing or presence of antibodies to glutamic acid decarboxylase, islet cell, insulin, etc.) diabetes mellitus with or approaching end stage renal disease. A diagnosis of Type 1.5 diabetes mellitus may be needed by endocrinology.
    1. In selective situations, known Type 2 Diabetes Mellitus patients (also referred to as Type 1.5 DM) with low C peptide and a low BMI (<28), requiring low dose insulin with end stage renal disease or advanced CKD may be considered for SPK.
b. Optimally and intensively managed by an endocrinologist for at least 12 months for Type 1 diabetes mellitus.[5]
c. Age 18-55, except under special clinical circumstances.
d. Must be a candidate for kidney transplantation. Patients cannot be listed on the UNOS waiting list for a deceased donor kidney until their estimated GFR, calculated by the CKD-EPI creatinine equation (2021) that are refitted without race or the CKD-EPI creatinine-cystatin equation (2012) that are refitted without race, is less than 20ml/min.[6,7,8]

CONTRAINDICATIONS FOR SPK TRANSPLANT

a. Significant irreversible coronary artery disease and/or left ventricular dysfunction, and irreversible pulmonary disease.
b. Irreversible peripheral vascular disease, including carotid vascular disease. (Amputation alone is not a contraindication)
c. Uncontrolled hypertension.

RELATIVE CONTRAINDICATIONS FOR SPK TRANSPLANT

a. BMI ≥ 35. Patients may be referred to the COE for individual consideration
    i. May be concurrently referred for weight loss intervention.
b. Cachexia and/or malnourishment

Footnotes

1. In certain situations where the NTS COE recommends, in discussion with the patient, to proceed with a staged transplant procedure (living donor kidney followed by cadaveric pancreas transplant) due to organ availability, the patient will need to meet the indications for a SPK transplant.
2. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
3. *Liver Transplant Surg*. 1997, Vol 3, 304 – 310.The natural history of alcoholism and its relationship to liver transplantation.
4. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
5. National Coverage Determination (NCD) for Pancreas Transplants (260.3) version 3. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?
6. Inker, Lesley A., et al., "New Creatinine- and Cystatin C–Based Equations to Estimate GFR without Race." N Engl J Med 2021; DOI: 10.1056/NEJMoa2102953
7. Hsu, Chi-yuan, et.al., "Race, Genetic Ancestry, and Estimating Kidney Function in CKD." N Engl J Med 2021; DOI: 10.1056/NEJMoa2103753
8. National Kidney Foundation, eGFR Calculator: https://www.kidney.org/professionals/kdoqi/gfr_calculator

If requesting this service, please send the following documentation to support medical necessity:

- Copy of final summary report from multidisciplinary transplant team

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

This service is covered when it is medically necessary and identified as a benefit in the consumer's coverage contract. The Kaiser Permanente Nephrologists in collaboration with the Kaiser Permanente Transplant Committee and the Transplant Centers define the Kaiser Permanente patient referral guidelines.

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Evidence and Source Documents

Kaiser Permanente Committee on Emerging Technology
Transplant, simultaneous Pancreas/Kidney (SPK) - 7/11/1990
Simultaneous pancreas/kidney transplantation is approved for diabetic patients who otherwise would be candidates for a kidney transplant, subject to review in six months.

The University of Washington transplant criteria set are used as a source document and updated when new efficacy data becomes available by the Kaiser Permanente Nephrology section with approval by the Kaiser Permanente Transplant Committee.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
HCPC Codes	**Description**
S2065	Simultaneous pancreas kidney transplantation ***S codes not covered by Medicare***

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date	Date Reviewed	Date Last

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Date Sent: 6/28/23
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Created		Revised
07/11/1997	04/05/2010[MDCRPC], 08/02/2011[MDCRPC], 06/05/2012[MDCRPC], 04/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	01/10/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt Kaiser Permanente National coverage policy
06/12/2020	Added “Patient Referral Guidelines” to title; changed background from patient selection criteria to patient referral guidelines
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”
01/10/2022	MPC approved the proposed changes from KP National Transplant Services. 60-day notice is not required.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Vertebroplasty + Kyphoplasty

- Percutaneous Vertebroplasty with Polymethylmethacrylate
- Radiofrequency Ablation with Vertebral Augmentation for Painful Spinal Metastases

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34106)
Local Coverage Article	Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56573)

For Non-Medicare Members

Effective until October 1, 2022

Kyphoplasty

I. Percutaneous balloon kyphoplasty may be considered medically necessary for the treatment of no more than 3 symptomatic vertebral fractures of the **T5-L5** spine when **ALL of the following criteria are met:**
   A. Appropriate imaging (plain film x-ray or MRI) has been performed preoperatively and the findings of such imaging correlate unequivocally with the patient's pain; **and**
   B. There is documentation in the medical record that the member's pain is predominantly, if not solely, related to the demonstrated fracture(s); **and**
   C. The member has failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks; **and**
   D. Prior to the procedure a documented assessment confirms the absence of the following contraindications:
      1. Chronic (>12 months) fracture at the same vertebral level
      2. Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators
      3. Bone fragment retropulsion
      4. Symptoms that cannot be related to a fracture
      5. Unstable fracture or requirement for stabilization procedure in same or adjacent spinal region
      6. Active osteomyelitis whether fungal, bacterial or mycobacterial, or any other active infection, including urinary tract infection (UTI)
      7. Uncorrected coagulation disorders
      8. Known allergy to any of the materials used in these procedures

II. Percutaneous kyphoplasty with a balloon device is not covered for all other indications, including but not limited to the following:
   A. Acute vertebral fractures due to osteoporosis or trauma (before 6 weeks of conservative therapy as noted above)
   B. Vertebrae of the cervical spine and thoracic levels T1-5

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C. Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty)
D. Prophylactic treatment for osteoporosis of the spine or for chronic back pain of long-standing duration, even if associated with old compression fracture(s).
E. Absence of a confirmed acute or subacute fracture
F. Symptoms that cannot be related to a fracture;
G. Radicular symptoms that are explained by bone impinging on nerves or another anatomic lesion;
H. Unstable fracture;
I. Asymptomatic vertebral compression fracture;
J. Active osteomyelitis, whether fungal, bacterial or mycobacterial;
K. Burst fracture with retropulsed fragments demonstrated by imaging study;
L. Uncorrected coagulation disorders; and
M. Known allergy to any of the materials used in either procedure
N. Compression fractures shown by the medical record to be more than one year old.

III. Percutaneous vertebral augmentation by any technique other than inflatable balloon is not covered which includes but not limited to the following:
A. Vertebroplasty – See separate criteria for vertebroplasty
B. Radiofrequency-assisted vertebral augmentation with ultrahigh viscosity cement, including but not limited to Radiofrequency-Targeted Vertebral Augmentation™ (RF-TVA™) with the StabiliT® System
C. Mechanical vertebral augmentation using any device other than a balloon device, including but not limited to use of the following:
1. Use of the Kiva® system

Vertebroplasty

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Effective October 1, 2022

Kaiser Permanente has elected to use coverage guidance from the Noridian Local Coverage Determination (LCD) L34106 *Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)* for medical necessity determinations for non-Medicare members.

*Note: Provisions in the LCD and related coding article only address Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (VCF). Coverage will remain available for medically necessary procedures for other conditions not included in the LCD, such as other pathologic vertebral compression fractures.

Percutaneous vertebral augmentation is not covered if the procedure includes the following:
A. Radiofrequency-assisted vertebral augmentation with ultrahigh viscosity cement, including but not limited to Radiofrequency-Targeted Vertebral Augmentation™ (RF-TVA™) with the StabiliT® System
B. Mechanical vertebral augmentation using any device other than a balloon device, including but not limited to use of the following:
1. Use of the Kiva®

Percutaneous Sacroplasty – there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Vertebral compression fractures (VCFs) occur when the bones of the spine become compressed and break. It is

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estimated that about five million new vertebral fractures occur worldwide each year. Most common in elderly populations and females, osteoporosis is responsible for more than 1.5 million fractures annually, the majority of which are vertebral. Other potential causes of VCFs include trauma, steroid use, malignancy in the vertebrae, and haemangioma. In any case, VCFs can be asymptomatic and resolve without treatment, however, they are frequently associated with pain, disability, and reduced quality of life (QoL). To add to this, VCFs are a risk factor for subsequent fractures which can lead to additional complications such as kyphosis, impairment of mobility or balance, and increased mortality to name a few (Chitale and Prasad 2013).

The majority of patients with VCFs are successfully treated with conservative management aimed to alleviate symptoms via external bracing, decreased activity and analgesics. Some patients, however, will experience persistent pain and symptoms refractory to medical therapy and may require additional intervention.

Over the last twenty years, two minimally invasive techniques to augment the vertebral bodies and reduce pain have been developed as a treatment option for refractory VCFs. The first technique, percutaneous vertebroplasty, was first introduced in France by Deramond and colleagues in 1984 and later, in 1993, was introduced into clinical practice in the United States (US). The procedure, initially performed to strengthen vertebrae weakened by angiomas, involved injection of polymethylmethacrylate (PMMA) into a collapsed vertebral body under fluoroscopic guidance (Deramond, Depriester et al. 1998). Since then, however, indications for vertebroplasty have expanded to include metastatic vertebral cancer, multiple myeloma, as well as, osteoporotic VCFs that have not responded to conservative therapy. The second procedure, kyphoplasty, was devised in 1998 after mounting concerns over flaws in the vertebroplasty technique. With the same aims and desired outcomes as vertebroplasty, kyphoplasty employs the use of inflatable balloon tamps to restore vertebral height and reduce kyphotic deformity before stabilization with PMMA. It is believed that the cavity formation and the use of more viscous cement introduced with less pressure, compared to vertebroplasty leads to lower risk of cement extravasation (Atalay, Caner et al. 2005; Wardlaw, Cummings et al. 2009).

Medical Technology Assessment Committee (MTAC)

06/07/2001: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: The published evidence consists of one poorly described case series that is insufficient to draw conclusions about the safety and efficacy of kyphoplasty.
Articles: The literature search yielded one published article. The article reported on a study using cadavers and does not have data appropriate for MTAC review. One other published article was received from Kyphon. This was largely a review article; it included one paragraph about the use of the kyphoplasty procedures. No details on study methodology were given so that this study also could not be evaluated. There is also one article documented to be in-press in Spine. An evidence table was created for this case series. Lieberman IH, Dudeney S, Reinhardt M-K, Bell G. Initial outcome and efficacy of “kyphoplasty” in the treatment of painful osteoporotic vertebral compression fractures. Spine 2001; in-press. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/14/2004: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: The evidence is insufficient to draw conclusions about the safety and efficacy of kyphoplasty. It consists of two small (fewer than 30 patients) case series, one published in 2001 and one with the abstract published electronically in April 2004 ahead of the print version.
Articles: The search yielded 41 articles, most of which were discussion pieces and technical reports. The single new empirical study was an “electronic publication ahead of print” and was not yet available. An inspection of the abstract showed that this was a case series with 27 patients.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/06/2005: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: There are no randomized controlled studies that compared the short and long-term outcomes of kyphoplasty with those of the more conservative standard therapies. The Grohs’ study compared

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kyphoplasty head to head with vertebroplasty however, it was small, nonrandomized and unblinded. Postoperative comparison was made versus baseline condition for each intervention with no direct comparison between the two techniques. The results of the study show that both procedures offered significant pain relief, which was maintained at a lower level with the kyphoplasty. The functional disability on the other hand was significantly improved only with kyphoplasty and not vertebroplasty. The observed improvement was statistically significant for the first year only. The results of the study also indicate that the rate of fracture of an adjacent vertebra seems to be higher with the kyphoplasty vs. vertebroplasty (21% vs. 4%). The other article reviewed was a case series with some advantages: it was relatively large, had inclusion/exclusion criteria, and had objective outcomes. However, like all case series it lacks a control or comparison group and has potential selection and observation bias. Overall its results showed that the pain was completely relieved in 78% of the patients, and, that the vertebral height significantly improved after kyphoplasty. There were no long-term follow-up data to determine the long-lasting effects or late complications of the intervention. In conclusion, the published literature does not provide sufficient evidence to determine the effects of the procedure on the spine, or its long-lasting effect on pain relief. A European multicenter prospective randomized controlled trial comparing kyphoplasty with the standard pharmacological therapy is underway (Ohlin 2004).
Articles: The search yielded 70 articles, most of which were review articles, discussion pieces and technical reports. There was no randomized controlled trial that compared the short and long-term outcomes with conservative therapies. The search revealed a recent nonrandomized study that compared kyphoplasty head-to head with percutaneous vertebroplasty, as well as several small prospective case series, and retrospective reviews of cases that underwent the procedure. *The following controlled study, as well as the largest case series (N=222), were selected for critical appraisal:* Grohs JG, Matzner M, Trieb K, et al. Minimal invasive stabilization of osteoporotic vertebral fractures. A prospective nonrandomized comparison of vertebroplasty and balloon kyphoplasty. *J Spinal Disord Tech* 2005; 18:238-242. See Evidence Table. Majd ME, Farley S, and Holt RT. Preliminary outcomes and efficacy of the first 360 consecutive kyphoplasties for the treatment of painful osteoporotic vertebral compression fractures. *Spine J.* 2005; 5:244-255. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/04/2008: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: The body of evidence on the safety and efficacy of balloon kyphoplasty (BKP) in the treatment of vertebral compression fractures consisted of multiple case series and few non-randomized studies that compared BKP to either vertebroplasty or the standard conservative therapy. Several authors pooled the results of these comparative and non-comparative series in a number of meta-analyses. However, the quality of meta-analyses and the strength of their conclusions depend on the quality of the included studies. The studies included in the published meta-analyses for BKP were too small, and had their methodological flaws and potential selection and observation bias. The comparative studies were non-randomized and the authors did not discuss how and why patients were selected for each of the procedures. There was evidence of publication bias as well as significant heterogeneity between the studies included in the meta-analyses. The studies differed their inclusion/exclusion criteria, outcome measures, scales used, and scoring systems, as well as duration and completeness of follow-up. Moreover, the results were unblinded and many of the outcomes were subjective.
The comparative studies published after the meta-analyses were also too small, non- randomized, unblinded, with relatively short follow-up duration, as well as other validity threats and do not allow making conclusions as regard the efficacy and safety of the procedure. In conclusion, the published literature does not provide sufficient evidence to determine the benefit of the procedure in relieving pain, improving function, and reducing rate of vertebral fractures. There is also insufficient evidence to determine its long-lasting effect on pain relief or its adverse effects on the spine. Large well conducted randomized controlled trials, with long term follow-up duration are needed to objectively compare balloon kyphoplasty to conventional treatment and other percutaneous techniques, and to determine its long-term safety and efficacy in improving function and reducing pain, disability, and complications associated with vertebral compression fractures.
Articles: The search yielded over 90 articles on balloon kyphoplasty. Many were reviews and technical reports. No randomized controlled trials that compared the procedure with vertebroplasty or conservative therapy were identified. There were four meta-analyses of non-randomized controlled studies and case series. All four included almost the same studies, and two were performed by the same group of authors. The search also revealed two non-randomized comparative studies published after the meta-analyses. One (N=21) compared kyphoplasty to vertebroplasty for the treatment of painful osteoporotic or traumatic VCFs, and the other (N=60) compared kyphoplasty with standard medical treatment of osteoporotic or traumatic VCF. The studies on the use of kyphoplasty for severe back pain due to metastatic disease were small case series with no control or comparison

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groups. The most recent meta-analysis and the two comparative studies were critically appraised. Taylor RS, Fritzell P, Taylor RJ. Balloon kyphoplasty in the management of vertebral compression fractures: an updated systematic review and meta-analysis. *Eur Spine J* 2007; 16:1085-1100. See Evidence Table. De Negri P, Tirri T, paternoster G, et al. Treatment of painful osteoporotic or traumatic vertebral compression fractures by percutaneous vertebral augmentation procedures. *Clin J Pain.* 2007; 5:425-430. See Evidence Table. Grafe IA, Fonseca KD, Hillmeier J, et al. Reduction of pain and fracture incidence after kyphoplasty: 1-year outcomes of a prospective controlled trial of patients with osteoporosis. *Osteoporos Int* 2005; 16:2005-2012. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/07/2009: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: A recently published RCT (Wardlaw et al 2009) compared kyphoplasty plus standard medical therapy to medical therapy alone in 300 patients from 21 sites in eight countries. The trial was randomized and controlled, however kyphoplasty was not compared to a sham procedure or an alternative invasive or noninvasive surgical procedure. The medical therapy was not standardized and varied according to the standard practices of the participating centers, and neither the patients nor the investigators were blinded to the treatment received. Medtronic Spine LLC, the manufacturer of the kyphoplasty balloon technology was involved in the study design, data monitoring, analysis, and reporting of the results. The results of the trial shows that patients in the kyphoplasty group experienced greater reduction in pain and improved function at one month compared to the control group. The significant improvement observed at one month in the short form -36 physical component summary (SF-36 PCS) scale, the primary outcome the trial, declined along the following months and was statistically insignificant by the 12th months, when the controls showed improvement. The results also show a higher rate of vertebral fractures and/or worsening of fractures among the patients in the kyphoplasty group vs. the controls. The difference was not statistically significant, but the study was not powered to detect significant differences in fracture rates. The authors did not report on any cement leakage associated with kyphoplasty.
In conclusion, the published literature does not provide sufficient evidence to determine that kyphoplasty is a safe and an appropriate procedure for relieving pain, improving function, reducing rate of vertebral fractures and disability in patients with vertebral compression fractures.
Articles: The search identified one recent randomized controlled trial (Wardlaw et al 2009) that compared balloon kyphoplasty with non-surgical care for vertebral compression fracture No randomized controlled trials that compared the procedure with a sham treatment were identified. A relatively small RCT with only 6 months of follow-up compared the kyphoplasty to vertebroplasty in patients with osteoporotic vertebral fractures. Wardlaw et al's RCT was selected for critically appraised. Wardlaw D, Cummings SR, Van Meirhaeghe J. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomized controlled trial. Lancet. 2009; 373:1016-24. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/09/2015: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: *Effectiveness* In 2009, Wardlaw and colleagues reported results from an RCT comparing kyphoplasty to non-surgical management (NSM) in 300 patients from 21 sites in eight countries. The results of the trial indicate that patients in the kyphoplasty group experienced greater reduction in pain and improved function at one month compared to the control group. The significant improvement observed at one month in the short form- 36 (SF-36) physical component summary (PCS) scale, the primary outcome the trial, declined along the following months and was statistically insignificant by 12 months. The kyphoplasty group also experienced statistically significant reductions in back pain and improvement in both back function and quality of life scales early on, however, this effect diminished over time (Wardlaw, Van Meirhaeghe et al. 2012). In 2010, Boonen and colleagues expand on the results of the FREE-trial including an additional 12 months of follow-up. With the exception of pain and QoL, most criteria were no longer statistically significant at 24 months indicating that any benefit for both groups occurs within the first year. The investigators do note that averaged scores, across the 24 month period, did show significance when compared with NSM in physical symptoms, as assessed by the SF-36 PCS (3.24 points, 95% CI 1.47-5.01, p=0.0004), and on the QoL scale as assessed by the Euro quality-of-life questionnaire (EQ-5D) (0.12 points, 95% CI, 0.06 to 0.18, p=0.0002). The investigators concluded that, compared with NSM, kyphoplasty rapidly reduces pain and improves function, disability, and QoL over the course of two years (Boonen, Van Meirhaeghe et

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al. 2011). [Evidence Table 1] *Safety* At 24 months, the investigators report that the overall frequency of patient with adverse events (AE) and serious adverse events (SAE) was similar between treatment groups. With that said, the investigators did report two serious adverse events, hematoma and urinary tract infection (UTI), that were considered to be related to the procedure. In addition, the investigators identified cement leakage in one patient who had undergone kyphoplasty. Finally, the kyphoplasty group had a higher rate of subsequent vertebral fractures when compared with the NSM group (47.5% vs. 44.1%; 3.4% difference, 95% CI -16.5 to 9.9, p=0.68), however, this difference was not statistically significant, and the study was not powered to detect significant differences in fracture rates. The FREE-trial has the advantage of being multi-centered, randomized and controlled. In addition, the analysis was based on intention-to-treat (ITT) and the study was adequately powered. Limitations of the study, however, include an inadequate comparator. Ideally, kyphoplasty should have been compared with a sham procedure or an alternative surgical procedure. Instead, the investigators compare the procedure to conservative management which, with 21 sites spanning eight different countries, was variable and not standardized. To add to this limitation, the differences in the treatment of the control and the intervention groups did not allow for blinding of both patients and the investigators opening the study up to selection and information bias. A further limitation of the study includes the investigators failure to stratify the data in analysis according to indication (osteoporosis vs. myeloma vs. metastasis) limiting the applicability of the results. Finally, it should be noted that the manufacturer of the kyphoplasty balloon technology, Medtronic Spine LLC, was involved in the study design, data monitoring, analysis, and reporting of results. For these reasons, the results of the study should be interpreted with caution and does not provide sufficient evidence to determine safety and effectiveness of kyphoplasty for treating VCF. *Conclusions:* There is insufficient evidence to support the effectiveness of kyphoplasty over non-surgical management for the treatment of VCF caused by osteoporosis, myeloma or malignancy. There is insufficient evidence to support the safety of kyphoplasty for the treatment of VCF caused by osteoporosis, myeloma or malignancy.
Articles: The literature search sought to update the evidence from the end date of the last MTAC review. The search revealed a large quantity of publications including a variety of systematic reviews and retrospective observational studies. No RCTs were identified that compared kyphoplasty to sham treatment. The largest RCT to date, the fracture reduction evaluation (FREE), included 300 patients with 12 months follow-up and was critically appraised by MTAC in 2009 (Wardlaw, Van Meirhaeghe et al. 2012). Since then, Boonen and colleagues have published a follow-up analysis reporting the 24-month outcomes of the FREE trial. The following articles were selected for critical appraisal: Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomized controlled trial. Lancet. 2009; 373(9668):1016-1024. Evidence Table 1. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon Kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. JBMR. 2011; 26(7):1627-1637. Evidence Table 1.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Percutaneous Vertebroplasty of Low Back Pain
02/09/2000: MTAC REVIEW
Evidence Conclusion: Efficacy of vertebroplasty in patients with osteoporotic compression fractures cannot be determined from these studies because of the likelihood of selection bias, observation bias, confounding and chance as explanations for some of, or all of, the studies' findings.
Articles: Articles were selected on the basis of study type. Because the literature revealed no randomized control trials or meta-analyses, the 14 cohort studies or case series were reviewed by abstract. The largest case series were selected for critical appraisal and evidence tables were created (Weill A, Chrias J, Simon J, et al. Spinal Metastases: Indications for Results of Percutaneous Injection of Acrylic Surgical Cement. Radiology. 1996; 199:241-247. Cortet B, Cotton A, Boutry N, et al. Percutaneous Vertebroplasty in the Treatment of Osteoporotic Vertebral Compression Fractures: An Open Prospective Study. J Rheumatol. 1999;26:2222-8.) Weill A, Chrias J, Simon J, et al. Spinal Metastases: Indications for and Results of Percutaneous Injection of Acrylic Surgical Cement. Radiology 1996; 199;241-247. See Evidence Table. Cortet B, Cotten A, Boutry N, et al. Percutaneous vertebroplasty in the treatment of osteoporotic vertebral compression fractures: An open prospective study. J Rheumatol. 1999;26:2222-8. See Evidence Table. Deramond H, Depriester C, Galibert P, et al. Percutaneous Vertebroplasty with Polymethylmethacrylate: Techniques, Indications, and Results. Radiologic Clinics of North America, Vol 36(3); May 1998:533-546. See Evidence Table.

The use of percutaneous vertebroplasty of low back pain has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria*.

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Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture
06/06/2005: MTAC REVIEW
Evidence Conclusion: The studies reviewed do not provide sufficient evidence to determine the efficacy of the procedure, its long-term benefits, or late complications. No direct randomized studies comparing the intervention with standard, non-operative care are available.
Diamond et als study had the advantage of comparing the intervention with conservative therapy. However, it was not randomized, and conservative therapy was offered to those who denied percutaneous vertebroplasty, which might be a potential source of selection bias. The study was also subject to observation bias as it was not blinded, and all outcomes were subjective. Moreover, the follow-up duration might be insufficient to determine the long- term effects of the vertebroplasty. The Grohs' study compared kyphoplasty head to head with vertebroplasty.
However, it was small, nonrandomized and unblinded. Postoperative comparison was made vs. baseline condition for each intervention with no direct comparison between the two techniques. The results of the study show that both procedures offered significant pain relief, which was maintained at a lower level with the kyphoplasty. The functional disability on the other hand was significantly improved only with kyphoplasty and not vertebroplasty. The results of the study also indicate that the rate of fracture of an adjacent vertebra seems to be higher with the kyphoplasty vs. vertebroplasty (21% vs. 4%). Gangi's study was a case series with potential selection and observation bias, with no control or comparison group, and the authors did not provide sufficient data on patient selection for the intervention, their characteristics, and follow-up, or long-term outcomes.
Articles: The search yielded 179 articles, most of which were review articles, discussion pieces and technical reports. A nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy, and another comparing it to kyphoplasty were identified, as well as several case series. *The two studies with comparison groups, as well as the largest case series (N=868), were selected for critical appraisal:* Diamond T, Champion B, and Clark W. Management of acute osteoporotic vertebral fractures: A nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy. Am J Med. 2003;114:257-265. See Evidence Table.

Grohs JG, Matzner M, Trieb K, et al. Minimal invasive stabilization of osteoporotic vertebral fractures. A prospective nonrandomized comparison of vertebroplasty and balloon kyphoplasty. J Spinal Disord Tech 2005;18:238-242. See Evidence Table. Gangi A, Guth S, Imbert JP, et al. Percutaneous vertebroplasty: Indications, technique, and results. Radiographics. 2003;23:e10-e10. See Evidence Table.

The use of Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

09/04/2009: MTAC REVIEW
Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture
Evidence Conclusion: There is fair evidence from two randomized controlled trials that vertebroplasty does not have a significant benefit over sham treatment in reducing pain and pain-related disability in patients with osteoporotic vertebral fractures. Kallmes, et al 2009 trial: Kallmes and colleagues randomly assigned 131 patients with 1-3 painful osteoporotic compression vertebral fractures (between T4 and L5), that was <1 year old and not responding to standard medical therapy, to undergo vertebroplasty or a sham treatment that simulated the procedure but without PMMA infusion. The primary outcomes were scores on the modified Roland-Morris Disability Questionnaire (RDQ) and patient's rating of average pain intensity during the preceding 24 hours at 1 month. Patients were allowed to cross over to the other study group after one month. The results of the trial show no significant differences in the primary outcome between the two groups (difference in RDQ score 0.7; 95%CI, -1.3 to 2.8, p=0.49, and difference in pain rating 0.7; 95% CI, -0.3 to 1.7, p=0.19). One serious adverse event occurred in each of the 2 study groups (injury to the thecal sac in the vertebroplasty procedure, and tachycardia and rigors in the control group) At 3 moths there was a higher rate of cross over in the control group (43%) than the vertebroplasty group (12%), p<0.001. The study had generally valid methodology, bur not without limitations. It was randomized, controlled, blinded, multicenter, with well defined inclusion/ exclusion criteria, sufficient statistical power to detect differences between the study groups, and analysis was based on ITT. The limitations of the trial included allowing cross-over between the two treatment groups after 1 month which did not allow evaluating the long-term efficacy of the procedure. Moreover, no adjustments were made for other medical treatments received, or other causes of pain all of which are potential confounders. Buchbinder, et al 2009: Buchbinder and colleagues randomized 78 patients with one or two painful. MRI confirmed unhealed osteoporotic vertebral fractures. <12 months duration to undergo vertebroplasty or a sham procedure. Patients were followed up for 6 months, and the primary outcome was overall pain at 3 months. Secondary outcomes included functional status and QoL at 1week, 1, 3, and 6 months after the procedures. The trial had generally valid methodology but was relatively small. It was randomized, controlled, blinded, multicenter, with sufficient statistical power to detect significant differences between the study groups, and analysis was based on ITT. The results show no significant difference between the

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vertebroplasty and sham treatment in any of the outcomes. The mean reduction in pain was 2.6 +2.9 and 1.9+3.3 respectively with an adjusted difference between the two groups of 0.6; 95% CI, -0.7 to 1.8. Both groups showed a significant reduction of pain at three months vs. baseline. 7 new of clinical vertebral fractures occurred during the 6-month follow-up (three in the vertebroplasty group and 4 in the control group. Conclusion: The published literature provides fair evidence that vertebroplasty has no significant benefit over a sham procedure in the treatment of patients with osteoporotic vertebral fractures.
Articles: Two trials on vertebroplasty for osteoporotic spinal fractures were recently published: Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009;36:557-568. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009;36:569-579.

The use of Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

02/09/2015: MTAC REVIEW
Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture
Evidence Conclusion: *Effectiveness:* In the first RCT, detailed in evidence table one, Buchbinder and colleagues included 78 subjects with back pain, ≤12 months in duration, who had up to two VCF evidenced by the presence of vertebral collapse, edema and/or a fracture line on MRI. Patients were randomized into either the vertebroplasty treatment group or a group that received sham procedure. Outcomes were measured at baseline and several points in time up to six months following the procedure. The primary endpoint was overall pain at three months, however, the study also included QoL measures and a survey specific to osteoporotic vertebral fractures.
Ultimately the study found no beneficial effect of vertebroplasty over the sham procedure at any time. In fact, the only significant between-group difference was seen on the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) total score at one week, favoring the sham group [-4.0 (95%CI -7.8 to -0.2)] (Buchbinder, Osborne et al. 2009). Evidence Table . The second study, by Kallmes and colleagues, also randomized osteoporotic patients with up to three painful VCFs (n=131) to vertebroplasty or sham procedures. After one month, if patients did not achieve adequate pain relief, the investigators allowed cross-over to the alternate therapy. The primary outcomes, pain and disability, were assessed at one month, however, investigators also describe outcomes up to three months to assess the effects of cross-over. At one month, both the vertebroplasty and sham groups demonstrated substantial improvements, however, no significant differences were seen between groups in either of the primary outcomes. The mean Roland-Morris Disability Questionnaire (RDQ) in the vertebroplasty group was 12.0±6.3 and 13.0±6.4 in the sham group (adjusted treatment effect, 0.7; 95% CI, -1.3 to 2.8; P=0.49). Similarly, the mean pain-intensity rating was 3.9±2.9 in the vertebroplasty group and 4.6±3.0 in the sham group (adjusted treatment effect, 0.7; 95% CI, -0.3 to 1.7; P=0.19). The investigators note, however, that the control group saw a higher rate of cross-over than the vertebroplasty group (51% vs. 13%, P<0.001). Despite this significance, the investigators concluded that improvements in pain and pain-related disability associated with osteoporotic VCF in patients treated with vertebroplasty were similar to the improvements seen in the sham group (Kallmes, Comstock et al. 2009). Evidence Table. *Safety:* Adverse events were documented in both studies and included hospitalizations from the procedure, as well as, subsequent fractures. Cement leakage was not reported by Kallmes and colleagues, however, Buchbinder et al. reported 37% cement leakage rate with no symptomatic events. Neither of the studies provided extended follow-up of safety and adverse events with the longest follow-up limited to six months following procedure. Previous reviews of vertebroplasty failed MTAC criteria with the available evidence offering little value due to methodological limitations such as a lack of randomization, inappropriate comparators and the likelihood of selection bias, observation bias, confounding and chance as explanations for study findings. Currently, however, the literature is more robust with two RCTs that compare vertebroplasty to sham procedures. The design of both studies was strengthened by the use of a sham procedure replicating verbal and visual cues allowing for the blinding of patients. With that said, an additional control group receiving no treatment would have benefited the outcome comparisons. Other limitations include sample size. Despite relatively lax inclusion criteria, both of the studies experienced difficulties recruiting patients resulting in a modification of sample size in the study by Kallmes et al. and the inability to assess two year follow-up in the Buchbinder study. Ultimately, the studies provide adequate evidence to suggest that vertebroplasty is no better than sham treatment for treating patients with VCF due to osteoporosis.
Conclusions: There is evidence to suggest that vertebroplasty is no more effective than sham therapy for the treatment of vertebral compression fractures in osteoporotic patients. There is insufficient evidence to assess the safety of vertebroplasty for the treatment of vertebral compression fractures in osteoporotic patients.
Articles: The search yielded a large quantity of publications relating to vertebroplasty. The majority of the literature was comprised of non-randomized, observational studies, many of which sought to compare vertebroplasty with

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kyphoplasty. A supplemental search of the clinical trials database revealed several studies relating to vertebroplasty that are currently recruiting or on-going. Since the last MTAC review, two randomized trials comparing percutaneous vertebroplasty with a sham procedure therapy were published and selected for critical appraisal. The following articles were selected for critical appraisal: Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. NEJM. 2009; 361(6):557-568.
Evidence Table 1. Kallmes DF, Cornstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. NEJM. 2009;261(6):569-571. Evidence Table 2.

The use of Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Radiofrequency Ablation with Vertebral Augmentation for Painful Metastases
BACKGROUND
The number of patients living with cancer in the United States (US) is estimated to be 4.86 million. Virtually all cancers have the potential to spread, or metastasize, with bone being one of the more common sites of metastasis. Generally speaking, skeletal metastases are associated with debilitating symptoms such as intolerable pain and hypercalcemia compromising the quality of life. Occurrence in the vertebral column, as does with a third of all cancer patients, contributes the additional complexity of complications such as vertebral compression factors (VCF) and spinal cord or nerve root compression that can cause potentially irreversible loss of neurologic function (Coleman 2000).

Depending on the primary tumor, prognosis is variable with five-year survival ranging from 2% in patients with lung cancer to 44% in those with thyroid cancer. Treatment presents a challenge in that there is no currently available cure, nor has there been any established treatment proven to increase life expectancy. Instead, the goals of treatment aim to control pain, limit complications and preserve function. Depending on individual patient factors, management options range from medications and systemic therapy all the way to surgical resection (Dunning, Butler et al. 2012).

Due to the advanced nature of metastatic cancer and its accompanying comorbidities, populations with skeletal metastases are usually at a higher surgical risk, making minimally invasive techniques an attractive option. Vertebral augmentation (VA) techniques, aimed at stabilizing vertebral compression fractures (VCF), have been documented to provide immediate and sustained relief (Weill, Chiras et al. 1996). In the same way, radiofrequency ablation (RFA), a technique that utilizes thermal energy to destroy cancer cells, has also been demonstrated to reduce pain (Goldberg and Dupuy 2001; Kassamali, Ganeshan et al. 2011). Most recently, RFA and VA, in combination, have been considered a promising treatment option for treating metastatic lesions of the spine (Grönemeyer, Schirp et al. 2002; Schaefer, Lohrmann et al. 2002; Schaefer, Lohrmann et al. 2003).

The STAR™ Tumor Ablation System was developed by DFINE, Inc. (San Jose, CA) specifically for metastatic spinal lesions. The system itself consists of the SpineSTAR™ Ablation Instrument and the corresponding MetaSTAR™ RF Generator which work in unison to deliver energy and provide access and navigation to the tumor within the vertebrae. Subsequent to tumor ablation, stabilization is carried out with the StabiliT® Vertebral Augmentation System, also developed by DFINE, Inc. Put simply, the StabiliT® System allows for the delivery of highly viscous bone cement to the tumor bed. In combination, the procedures require a small incision under local anesthesia with conscious sedation and offer the advantages of unipedicular access, and real-time monitoring of ablation zone allowing for the targeting of tumor cells and controlled cement delivery.

04/20/2015: MTAC REVIEW
Radiofrequency Ablation with Vertebral Augmentation for Painful Metastases
Evidence Conclusion: *Effectiveness:* In a small RCT, Orgera and colleagues, sought to compare the combined techniques of RFA and VA with VA alone. Following baseline assessment, the investigators randomized 36 patients into the two treatment groups and followed them up for six weeks. Outcomes of interest included surgery success, pain relief and the amount of analgesia administered. The investigators reported a 100% technical success rate in both groups with no significant differences noted between treatment groups with regard to pain as measured on a Visual Analogue Scale (VAS) or Roland Morris Questionnaire (RMQ). In addition, medication use decreased significantly in both groups but the investigators found no significant difference between groups.
Ultimately, the results led the investigators to conclude that the addition of RFA did not offer any additional benefit (Orgera, Krokidis et al. 2014). [Evidence Table 1] A retrospective review of 128 metastatic lesions in 92 patients who underwent 96 procedures was carried out by Anchala and colleagues. The studies intent was to assess the safety

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and efficacy of RFA of malignant spinal lesions using the SpineSTAR ablation instrument. The investigators determined that RFA was 'technically successful' in all metastatic lesions. Post-operative pain rated on a Visual Analogue Scale (VAS) demonstrated significant changes at all time points when compared to baseline. The investigators also reported that within the largest institution, 54% of patients reported a decrease in pain medication. Ultimately, the investigators concluded that the STAR system was safely and effectively used in the treatment of spine metastatic osseous lesions (Anchala, Irving et al. 2014). [Evidence Table 2]
Safety Although the follow-up period was limited, Orgera and colleagues reported several complications such as cement leakage (11%), death (5%) and opioid toxicity (8%). Anchala and colleagues, on the other hand, did not explicitly report safety details, but did note asymptomatic cement extravasation in two patients. Although Orgera's study was randomized and blinded, the population size was small and the follow-up period short. Limitations of Anchala's study include the lack of an adequate comparator and retrospective design. The investigators also highlight limitations such as a heterogeneous population and variable availability of data collected from each treatment center. Finally, it should be noted that at least two of the investigators from the retrospective review disclosed financial relationships with the device manufacturer. Collectively, the body of evidence is limited in nature and should be interpreted with caution.
Conclusions: There is insufficient evidence to support the effectiveness of the combination of RFA and VA, compared with VA alone, for the management of pain in metastatic spinal tumors. There is insufficient evidence to support the safety of RFA and VA, compared with VA alone, for the management of pain in metastatic spinal tumors.
Articles: A search of the literature returned a variety of publications relating to both RFA and VA, in general. The majority of publications returned were case studies/series. One study was identified comparing the combination of RFA and VA with balloon kyphoplasty, however, this study was performed in cadaveric models (Dalton, Kohm et al. 2012). A recent study identified in the search, by Song and colleagues, investigated the use of RFA and vertebral augmentation in 12 patients, however, this study was not selected for critical appraisal due to the small sample size and lack of a comparator (Song, Gu et al. 2014). The best evidence identified was a small randomized controlled trial (RCT) comparing RFA+VA with VA alone in patients with multiple myeloma (Orgera, Krokidis et al. 2014). In addition, a retrospective analysis, by Anchala and colleagues, evaluating the combination of RFA with VA for treating metastatic spinal lesions was also included (Anchala, Irving et al. 2014). An additional search of the clinical trials database identified a few prospective observational studies sponsored by DFINE, Inc. currently in the recruitment phase. The following articles were selected for critical appraisal: Orgera G, Krokidis M, Matteoli M, et al. Percutaneous vertebroplasty for pain management in patients with multiple myeloma: is radiofrequency necessary? 2014;37:203-210. See Evidence Table. Anchala PR, Irving WD, Hillen TJ, et al. Treatment of metastatic lesions with a navigational bipolar radiofrequency ablation device: a multicenter retrospective study. Pain Physician. 2014;17:317-327. See Evidence Table.

The use of Radiofrequency Ablation with Vertebral Augmentation for Painful Spinal Metastases does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Kyphoplasty - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or

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	bilateral cannulation, inclusive of all imaging guidance; lumbar
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

Sacroplasty - Considered Not Medically Necessary:

CPT® Codes	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
06/07/2001	04/02/2013[MDCRPC], 02/04/2014[MPC], 05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	05/03/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD for Percutaneous Vertebral Augmentation (L34106).
08/04/2020	Added Medicare LCA A56573
05/03/2022	MPC approved to adopt Medicare criteria for Non-Commercial members for Vertebroplasty; merged Kyphoplasty and Vertebroplasty into one policy

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Laser Treatments for Snoring and Sleep Apnea

- Cautery-Assisted Palatal Stiffening Operation (CAPSO)
- Laser-Assisted Uvulopalatoplasty (LAUP)
- Repose Procedure
- Somnoplasty

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**Laser Treatments for Snoring & Sleep Apnea**", for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe and/or provides better long-term outcomes than current standard services/therapies. These treatments are found to be effective in the treatment of snoring; however, no Kaiser Permanente or Kaiser Permanente Options, Inc. plan covers interventions for the treatment of snoring.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive Sleep Apnea Syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also have mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone.

Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, or tracheostomy when all other treatments fail. Surgical treatment approach varies, and the results are affected by age, cause of obstruction, and severity of the disease. The best method of treatment remains controversial.

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Evidence and Source Documents

Sleep Apnea – Cautery-Assisted Palatal Stiffening Operation (CAPSO)
Sleep Apnea – Repose Procedure
Somnoplasty for Treating Obstructive Sleep Apnea

Medical Technology Assessment Committee (MTAC)

Sleep Apnea – Cautery-Assisted Palatal Stiffening Operation (CAPSO)

BACKGROUND

Obstructive sleep apnea has been treated with uvulopalatopharyngoplasty (UPPP), a surgical procedure on the soft palate using a scalpel. Cautery-assisted palatal stiffening operation (CAPSO) is a procedure that was first used to treat palatal snoring and is proposed as a new treatment for obstructive sleep apnea. With CAPSO, a midline strip of soft palate mucosa is removed, and the wound is allowed to heal by secondary intention. This procedure stiffens the flaccid palate and causes a cessation of palatal snoring (Wassmuth, 2000). Other possible alternatives to UPPP are laser-assisted uvulopalatoplasty (LAUP) and somnoplasty (which uses radiofrequency energy). Possible advantages of CAPSO, LAUP and somnoplasty compared to UPPP are that it is performed under local anesthetic and can be done as an outpatient procedure (Laube, 1999).

08/08/2001: MTAC REVIEW
Cautery-Assisted Palatal Stiffening Operation (CAPSO)
Evidence Conclusion: Only a single small case series is available to evaluate CAPSO for treating obstructive sleep apnea. This represents insufficient evidence to draw conclusions about the effect of CAPSO on health outcomes related to sleep apnea.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There were two empirical articles on CAPSO, both were case series. One of the case series (n=25) included patients with obstructive sleep apnea, while the other, report (n=206) included patients who complained of excessive habitual snoring, no attempt was made to diagnose sleep apnea. An evidence table was created for the case series with sleep apnea patients. Wassmuth Z, Mair E, Loube D, Leonard D. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2000; 123: 55-60. See Evidence Table.

The use of cautery-assisted palatal stiffening operation (CAPSO) in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Sleep Apnea: Repose Procedure

BACKGROUND

The Repose system is one of several new treatments of obstructive sleep apnea (OSA). The Repose is a disposable surgical kit manufactured by Influence Medical Technologies, San Francisco. The kit contains: 1) a self-tapping screw with pre-attached double polypropylene No. 1 sutures; 2) a battery-operated screwdriver and; 3) a suture passer that aids passage of the suture through the tongue. The Repose procedure consists of anchoring the bone to soft-tissue to stabilize the base of the tongue (deRowe et al., 2000).
The Repose system is used under general anesthesia. A screw with pre-attached sutures is inserted at the base of the mandible. The sutures are passed through the tongue base; the two ends are tied together below the tongue mucosa and placed in the mouth floor that supports the tongue base. Tightness of the suspension is determined digitally.

08/08/2001: MTAC REVIEW
Repose Procedure
Evidence Conclusion: The existing scientific evidence does not permit conclusions about the efficacy of the Repose procedure on health outcomes. The best evidence is a case series of 16 individuals with data available on 14 of these. This report is subject to the limitations of case series (selection and observation bias likely).
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There were three articles on the Repose procedure, one review/discussion piece and two small case series (n=9 and n=15). Because it was the best available evidence, an evidence table was created for the larger case series. DeRowe A, Gunther E, Fibbi A, Lehtimake K, Valatalo K., Maurer J, Ophir D. Tongue-based suspension with a soft tissue-to-bone anchor for obstructive sleep apnea: Preliminary clinical results of a new minimally invasive technique. Otolaryngol Head Neck Surg 2000; 122: 100-3. See Evidence Table.

The use of repose procedure in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Somnoplasty for Treating Obstructive Sleep Apnea

BACKGROUND

Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive Sleep Apnea Syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also have mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone. Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, or tracheostomy when all other treatments fail. Surgical treatment approach varies, and the results are affected by age, cause of obstruction, and severity of the disease. The best method of treatment remains controversial. Temperature-controlled radiofrequency tissue ablation (Somnoplasty) may be a less morbid alternative to other invasive surgical procedures. Somnoplasty is performed under local anesthesia in an outpatient setting. The commercially available device made by Gyrus Medical delivers 460 kHz using a radiofrequency generator. Radiofrequency energy is delivered via 22-gauge electrodes with a 10-mm active tip. High frequency alternating current flows into the tissue, creating ionic agitation. This agitation heats the tissue and, when the temperature rises above 47oC, protein coagulation and tissue necrosis take place. The target temperature is between 80oC and 85oC, with a maximum of less than 90oC. The maximum lesion size is two-thirds the diameter of the radiofrequency electrode, or approximately 7mm. During the three weeks following the procedure, there is inflammation, fibrosis and tissue volume reduction (Troell, 2003). The Gyrus Somnoplasty system was cleared by the FDA in 1998 for treating obstructive sleep apnea. Single-level radiofrequency ablation refers to creation of lesions in one area only (base of tongue, soft palate or turbinates). Multi-level radiofrequency ablation refers to its use in more than one area.

04/14/1999: MTAC REVIEW

Somnus Somnoplasty System

Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1990 to February 1999 using the terms: somnoplasty, sleep apnea and radiofrequency. The Somnus Company was aware of only one published article related to the use of the Somnoplasty system for obstructive sleep apnea. This article (summarized below) reports data from a single case series of 22 patients treated for snoring, daytime sleepiness and mild obstructive sleep apnea. Results from this study show no changes in Respiratory Distress Index (RDI*) following somnoplasty, statistically significant improvements in partner report of snoring and an improvement of 3.3 points (24-point scale) in self-report of sleepiness.

Articles: Powell, NB, et al *Chest,* 1998:113:1163-74. See Evidence Table

The use of the Somnus Somnoplasty System for the treatment of obstructive sleep apnea has been approved by the FDA and therefore meets Kaiser Permanente *Medical Technology Assessment Criteria.*

08/08/2001: MTAC REVIEW

Base of Tongue Somnoplasty in the Treatment of Sleep Apnea

Evidence Conclusion: The evaluated study does not provide sufficient evidence to determine the efficacy of base of tongue somnoplasty, in the treatment of sleep apnea, due to its small sample size, together with the other limitations of case series.

Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There was a pilot study done for base of tongue somnoplasty on humans, and another study made on animals. *The best available article for critical appraisal was the pilot study:* Powell N B, Riley R W, et al. Radiofrequency Tongue Base Reduction In Sleep- Disordered Breathing: A Pilot Study. *Otolaryngol Head Neck Surg* 1999: 120: 656-64. See Evidence Table.

The use of base of tongue somnoplasty in the treatment of sleep apnea does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

12/05/2005: MTAC REVIEW

Radiofrequency Tissue Ablation (Somnoplasty)

Evidence Conclusion: *Efficacy of Multi-Level Base of Tongue and Soft Palate Procedure*: The best evidence is from a randomized controlled trial comparing radiofrequency ablation of the tongue and soft palate to CPAP and sham ablation (Woodson et al., 2003; Stewart et al., 2005). The three primary outcomes were slowest reaction time (SRT) and two quality of life (QOL) variables. There were no significant differences in the change in SRT in the radiofrequency ablation versus the placebo group, the CPAP group versus the placebo group or the radiofrequency ablation group vs. CPAP group. One of the two QOL variables improved significantly in the radiofrequency ablation group compared to placebo, but there was not a significant difference in QOL change in

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the radiofrequency ablation group versus the CPAP group. Among patients in the radiofrequency ablation group, those who had long-term follow-up had significant improvement in SRT, but not QOL compared to baseline. The 2005 publication did not report long-term findings for the CPAP or placebo groups.
Efficacy of Single-Level Base of Tongue Procedure: There were no randomized controlled trials. The best evidence is from a prospective non-randomized study comparing a group of patients who received base of tongue Somnoplasty and peri-operative use of CPAP to a group of patients receiving CPAP only (Woodson et al., 2001). There were no significant between-group differences in the change in subjective self-report outcomes (e.g. sleepiness, SF-36. Objective outcomes were only reported for the radiofrequency ablation group. In the group of 73 patients receiving radiofrequency ablation, the apnea-hypopnea index decreased significantly pre- to post-treatment. This study is subject to selection bias since patients were not randomized to treatment group; there was no between-group comparison for the objective outcomes. Complications: Single and Multi-level: Two single-center case series were reviewed; one included 136 patients and was conducted at Stanford University (Kerzirian et al., 2005) and the other included 322 patients and was conducted in Mannheim, Germany (Stuck et al., 2003). Both studies found relatively low complications rates. The Kerzirian study did not identify any moderate or severe complications. The Stuck study found four moderate severity complications and one severe complication. Both of the studies included a combination of patients who received single-level and multi-level radiofrequency ablation, and both included patients who received treatment of the turbinates, as well as those with base of tongue or palate procedures. A limitation of both studies was that they were conducted at centers with extensive experience in somnoplasty and findings may not be generalizable to other institutions. Overall Conclusions: There is insufficient evidence on single level base of tongue somnoplasty to draw conclusions about the efficacy of the procedure compared to placebo or the standard treatment, CPAP. There were no RCTs on single level somnoplasty. One non-randomized comparative study did not find significant between-group differences on subjective outcomes. There is evidence from one RCT that multilevel (base of tongue and soft palate) does not improve outcomes compared to sham treatment or placebo. The RCT did not identify significant between-group differences in two of three primary outcomes including the objective outcome, slowest reaction time. Findings from case series suggest that there is a relatively low complication rate, at least in institutions with extensive experience with the technology.
Articles: One randomized controlled trial was identified in the literature search, a comparison of multilevel radiofrequency ablation, sham treatment, and CPAP. There were two publications on the RCT, initial outcomes (Woodson et al., 2003) and long-term follow-up of the active treatment group (Stewart et al., 2005). Both articles were critically appraised in the same evidence table. One other comparative study was identified and critically appraised. This was a non-randomized comparison of a patients receiving single-level base of tongue Somnoplasty and CPAP (Woodson et al., 2001). Several small case series (n<25) on the efficacy of Somnoplasty were identified, but not reviewed further. Two relatively large case series (n>100) on complications of Somnoplasty were identified; both were critically appraised (Kezirian et al., 2005; Stuck et al., 2003).*The articles critically appraised were:* Woodson BT, Steward DL, Weaver EM et al. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2003; 128: 848-861. See Evidence Table. Stewart DL, Weaver EM, Woodson BT. Multilevel temperature-controlled radiofrequency for obstructive sleep apnea: Extended follow-up. Otolaryngol Head Neck Surg 2005; 132; 630-635. Woodson BT, Nelson L, Mickelson S et al. A multi-institutional study of radiofrequency volumetric tissue reduction for OSAS. Otolaryngol Head Neck Surg 2001; 125: 303-311. See Evidence Table. Kezirian EJ, Powell NB, Riley RW, Hester JE. Incidence of complications in radiofrequency treatment of the upper airway. Laryngoscope 2005; 115: 1298-1304. See Evidence Table. Stuck BA, Starzak K, Verse T et al. Complications of temperature-controlled radiofrequency volumetric tissue reduction for sleep-disordered breathing. Acta Otolaryngol 2003; 123: 532-535. See Evidence Table.

The use of Radiofrequency tissue ablation (somnoplasty) in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary-
Repose

CPT® or HCPC Codes	Description
41512	Tongue base suspension, permanent suture technique

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Somnoplasty

CPT® or HCPC Codes	Description
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session

LAUP

CPT® or HCPC Codes	Description
42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)
42890	Limited pharyngectomy
S2080	Laser-assisted uvulopalatoplasty (LAUP)

CAPSO

CPT® or HCPC Codes	Description
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)

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Date Created	Date Reviewed	Date Last Revised
03/1999	05/04/2010[MDCRPC], 03/01/2011[MDCRPC], 05/03/2011[MDCRPC], 08/2/2011[MDCRPC], 03/6/2012[MDCRPC], 06/5/2012 [MDCRPC], 01/08/2013 [MDCRPC], 11/05/2013 [MDCRPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	06/08/2009

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Director Clinical Review and Policy Committee

Revision History	Description
01/09/2018	Adopted Kaiser Permanente criteria for MA members

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Clinical Review Criteria
Leadless Pacemakers

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Leadless Pacemakers (20.8.4)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Cardiac arrhythmias occur when there is interruption of the normal sinus rhythm. Symptoms include palpitations, dizziness, lightheadedness, syncope, dyspnea, anxiety, weakness, and chest discomfort. One therapeutic option is the implantation of pacemaker which provides electrical impulses to the heart. Conventional pacemakers consist of a pulse generator, which provides electrical impulses, and leads delivering electrical impulses from the generator to the heart. The pulse generator is the battery and is placed in the anterior part of the chest (pre-pectoral) while the leads are placed transvenously.

However, there are several complications associated with traditional pacemakers. Complications due to the pulse generator include hematoma, skin breakdown, and pocket infection (Udo et al., 2012). Complications due to the leads include venous obstruction, lead dislodgement, lead malfunction, lead fractures, and infection (Cheng, Wang, Curtis, & Varosy, 2010; Kirkfeldt et al., 2011; Udo et al., 2012).

Leadless pacemakers have been the center of attention due to its ability to address the limitations of traditional transvenous pacemakers. Two leadless pacemakers have been assessed for single-chamber right ventricular pacing. These include Nanostim LP (Abbott, formerly St. Jude, Lake Bluff, IL) and Micra Transcatheter Pacing System (Medtronic, Minneapolis, MN). Nevertheless, Nanostim is out of the market due to premature battery depletion (Yarlagadda et al., 2018). Leadless pacemakers are composed of a pulse generator, battery, and electrode in the same device (Reddy et al., 2015). It is placed through a catheter and is directly implanted into the right ventricle (Yarlagadda et al., 2018).

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The leadless pacemaker's (Nanostim) length is 42 mm and a maximum diameter of 5.99 mm with a battery life ranging from 8.4 to of 12.4 years (Reddy et al., 2015). A sheath is placed in the femoral vein, and with a sleeve-based catheter, the device is delivered to the right ventricle. The sleeve is then withdrawn, and the pacemaker is implanted into the endocardium while the device remains docked. The device is then undocked from the catheter but is still connected to the catheter through tether connections. This allows for device measurements and evaluation of stability without the catheter. Repositioning can be performed if the device is not well positioned. Once positioning is assured and the pacemaker parameters are optimal [(R wave amplitude ≥5.0 mV) and pacing threshold (≤2.0 V at 0.4 ms)] (Yarlagadda et al., 2018), the device is untethered from the catheter resulting in the final implant position (Reddy et al., 2015). The procedure is performed under fluoroscopy. After the procedure, patients are observed over a period of 24 hours and discharged (CADTH 2015). An external programmer is used to program Micra transcatheter pacing system.
Some differences are worth noted. The Nanostim pacemaker is smaller than the traditional pacemaker (<10%), with a battery life ranging between 8.4 years and 12.4 years. The Micra Transcatheter Pacing System pacemaker is 30% smaller than the Nanostim and its estimated battery life ranges from 10 to 15 years. Micra transcatheter pacing is 93% smaller than conventional pacemakers, about the size of a large vitamin capsule (https://www.medtronic.com/us-en/patients/treatments-therapies/pacemakers/our/micra.html). The insertion of these devices takes 20 to 45 minutes compared to 60 minutes for the conventional pacemaker (CADTH 2015).

Medical Technology Assessment Committee (MTAC)

Leadless Pacemakers for the treatment of cardiac arrhythmias

Date: 04/21/2019

Evidence Conclusion:

- In patients with cardiac arrhythmias who require single-chamber ventricular pacing, there is insufficient evidence to compare leadless pacemakers with conventional pacemakers. However, serious complications are non-negligible.
- Randomized controlled trials with longer-term follow-up and direct comparisons are warranted.

Articles: PubMed was searched through March 8, 2019 with the search terms ((Nanostim Leadless Pacemaker OR Micra Transcatheter Pacing System OR leadless pacemaker)) AND (traditional pacemakers OR conventional pacemakers). Other search terms included (Nanostim Leadless Pacemaker OR Micra Transcatheter Pacing System OR leadless pacemaker) filters: observational study. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Randomized controlled trials, and observational studies were included in the search. Clinicaltrials.gov was also searched. Three studies were retained and reviewed. See Evidence Table**.**

The use of Leadless Pacemakers for the treatment of cardiac arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

Micra Transcatheter Pacing System (Medtronic Inc.) for Single Chamber Pacemaker Indications

Date: July 3, 2022

The Micra TPS is a single-chamber right ventricular pacing device. The device senses electrical activity of the heart via electrodes within the device's titanium capsule. Heart rhythm is monitored for bradycardia. Rate-adaptive pacing therapy is provided based on programmed pacing parameters. The Micra TPS is self-contained and does not require a surgical incision in the chest or intravascular leads. It is inserted via a 23-French catheter placed in the femoral vein and held in place within the right ventricle of the heart via nitinol tines that attach to the myocardium.

Conclusion

A low-quality body of evidence suggests that Micra TPS is associated with a high rate of procedural success and that pacing capture thresholds remained low and stable after implantation for up to 36 months. Major complications are comparable with and perhaps lower for Micra TPS versus TVPM, and revision and retrieval rates are lower for Micra TPS than TVPM. However, the clinical significance of any benefits introduced by use of the Micra TPS is uncertain due to the small body of evidence directly evaluating patient-centered outcomes.

Hayes Rating: C

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Hayes. Hayes Technology Assessment. Micra Transcatheter Pacing System(Medtronic Inc.) for Single-Chamber Pacemaker Indications. Dallas, TX: Hayes; July 3, 2022. Retrieved May 15, 2023, from https:// https://evidence.hayesinc.com/report/htb.micrapacing4178

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

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Date Created	Date Reviewed	Date Last Revised
05/07/2019	05/07/2019[MPC], 05/05/2020[MPC] , 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/15/2023

[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt a non-coverage policy for leadless pacemakers
05/05/2020	Added applicable CPT codes 33274 and 33275 to policy
05/15/2023	Updated References to include Hayes Technology assessment

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Clinical Review Criteria
Peanut Challenge for Sensitized Infants

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Criteria

For Medicare Members

None

For Non-Medicare Members

Medical necessity review no longer required.

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Background

Food allergy affects 1-3% of children in developing countries, and the prevalence of food allergy has increased dramatically in the past several decades. For many years' scientists believed that delaying the introduction of allergenic foods into an infant's diet was beneficial, though more recent evidence has questioned this assumption. The "Learning Early About Peanut Allergy" (LEAP) Study, sponsored in part by FARE (Food Allergy Research and Education) and the National Institute of Allergy and Infectious Disease, hypothesized that the early introduction of peanuts into the diet of high-risk infants may prevent peanut allergy. LEAP Study design: The LEAP study enrolled 640 "high risk" infants between age 4 months and 11 months. High risk was defined as having moderate to severe eczema (persistent rash affecting > 75% of skin) and/or egg allergy since children with these problems are more likely to develop peanut allergy. All of the infants were skin tested to peanut. Those who had a strongly positive skin test (> 4 mm welt from prick test) were not allowed to continue in the study because they were assumed to have peanut allergy. The rest of the infants were randomly assigned to either consume peanut at least 3 days a week until age 5 (equivalent of 6 tsp peanut butter per week) or to avoid peanuts until age 5. Importantly, all these high-risk infants randomized to consume peanut underwent supervised oral challenge to peanut in the allergy clinic before feeding peanut at home.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing
95079	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)
with dx of peanut allergy	

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Date Created	Date Reviewed	Date Last Revised
09/01/2015	09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	09/01/2015

[MPC] Medical Policy Committee

Revision History	Description
04/04/2017	Medical necessity review no longer required.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Light Therapy, for Seasonal Affective Disorder (SAD)

- Bright Light Therapy
- Dawn Simulation Therapy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	See the Noridian Non-Covered Items for HCPC code E0203

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

The term 'seasonal affective disorder' (SAD) was first introduced by Rosenthal and colleagues in 1984 who described a series of patients with a history or recurrent depressions that occurred in the fall or winter and spontaneously remitted in the following spring or summer. Two seasonal patterns of SAD have been described; the summer-onset SAD and the fall-onset SAD. The latter, also known as "winter depression", is the most common pattern of the disorder. SAD affects about 5-6% of the population in the U.S. and its prevalence increases with latitude. This ranges from 1.4% in Florida to 9.7% in New Hampshire and 9.9% in Alaska. It is reported that SAD affects patients in their 20s, and that women are more likely than men to develop the disorder.

SAD was previously classified as a mood disorder in which people with normal mental health throughout most of the year experience depressive symptoms in the winter or summer. The Diagnostic and Statistical Manual of Mental Disorders DSM-IV and DSM-5 no longer classifies SAD as a unique mood disorder but describes it as a "specifier" or a subtype that can occur as part of unipolar major depression, bipolar I disorder, or bipolar II disorder. SAD is characterized by typical symptoms of major depression such as low mood, lack of drive, lack of concentration, and decrease in interest. In addition, patients exhibit more atypical depressive symptoms such as hypersomnia, increased appetite with carbohydrate craving, weight gain, irritability, and anger attacks. Symptoms usually resolve in the summer, and rarely progress to manic episodes of bipolar disorder.

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The exact mechanism of SAD is still under investigation, but it is hypothesized that it is related to natural seasonal variations in light levels. According to this hypothesis "the phase shift hypothesis" fewer daylight hours in the winter causes a circadian misalignment between the biological clock and solar cycle leading to disturbances in the melatonin levels and longer periods of its synthesis at night. Melatonin, also called circadian hormone, peeks in the darkness and promotes sleep. It is believed that its increased daytime levels contribute to the depressive symptoms of SAD. Other neurotransmitters under circadian control e.g. serotonin, norepinephrine, and dopamine are also believed to have a role in the SAD mood alterations. However, no studies have established a causal relationship between decreasing daylight and the winter SAD.

Three types of treatment are being used for patients with SAD: pharmacological therapy, cognitive behavioral therapy (CBT), and light therapy. Antidepressant medication is an accepted treatment for depression in general, and three SSRIs have shown favorable results with SAD. CBT may help reduce the risk of relapse of major depression, but only few small studies evaluated its effectiveness for SAD.

Light therapy using light boxes was introduced as a treatment for SAD when the disorder was first described in 1984, based on the phase shift hypothesis. Early studies examined the effect of bright white light on circadian rhythm. Other research investigated less intense light and showed that it may have a larger capacity to regulate the biological clock than higher intensity light. A small study showed that blue light with an intensity of about 460 m may have a significant effect on melatonin suppression and circadian phase shifting.

Currently there are a number of commercially available light therapy products. These include bright light boxes, lamps, light visors, and dawn simulators. Light boxes come in different shapes and sizes, and with varied features and intensities of light. There is no well-accepted standard protocol for light therapy. Commonly bright-light therapy (BLT) is applied using a light box containing fluorescent lamps, a reflector and a diffusing screen. For adequate treatment light intensities of 5,000-10,000 lux measured at the level of the eyes, and at a therapeutic distance of 60-80 cm from the light box is considered as a standard requirement. Patients do not need to look directly into the light source as long as the light meets the eye at an angle of 30-60o. Treatment is usually started with using a light intensity of 10,000 lux for 30 minutes. The duration of treatment may be increased in case of insufficient response or when using less powerful light boxes. It is reported that morning administration of BLT offers greater chance of remission, that compliance is the primary factor for success of the therapy, and that the therapeutic effect is demonstrated in 3-7 days and disappears shortly after the treatment is discontinued.

Light boxes are designed to be safe and effective but are not regulated as devices by the Food and Drug Administration (FDA). A number of side effects of light therapy for SAD have been reported but are generally mild and/or transient. These include headache, nausea, agitation, eye strain and blurred vision. Evening light therapy may lead to sleep disturbances. Suicidality, menstrual irregularity, and hypomania in bipolar patients have also been reported. Retinal degeneration after prolonged exposure to intensive light has been noticed in rodents but was not confirmed in humans. However, it is recommended that caution must be used with patients at higher risk of retinal damage or those who need photosensitizing medication.

Medical Technology Assessment Committee (MTAC)

Light Therapy in the Treatment of Seasonal Affective Disorder (SAD)

06/02/2008: MTAC REVIEW

Evidence Conclusion: There is evidence from a meta-analysis of placebo-controlled RCTs (Golden et al., 2005) that bright light therapy and dawn simulation are both effective for treating SAD in non-geriatric adults. Strength of the meta-analysis was that the investigators used strict criteria to ensure that studies had a valid placebo control. Limitations are that studies tended to be small (all had <100 participants) and the minimum treatment duration was 4 days. Moreover, studies had different treatment protocols and thus conclusions cannot be drawn about the effectiveness of a particular approach to light therapy (e.g. lux, frequency of sessions, length of treatment). There is currently no generally accepted protocol for light therapy. When the two RCTs in the meta-analysis with the longest treatment durations and largest sample sizes were examined closely, bright light therapy did not clearly appear to be effective. Avery et al. (2001) did not find that bright light was significantly superior to placebo. Eastman et al. (2005) did not find a significant benefit to light therapy versus placebo for the outcomes change in SIGH-SAD score and response rate. They did find a significant benefit when examining the proportion of participants classified as near complete or complete responders. All of the studies on dawn simulation in the Golden et al. meta-analysis were conducted by the same research group. As the authors pointed out, the evidence would be strengthened if their findings could be replicated by different researchers in other locations. The largest study, Avery et al., (2001) found that dawn simulation was superior to both bright light and placebo for remission of SAD. The RCTs identified that compared light therapy to medication or cognitive-behavioral therapy did not have true placebo control groups and thus, intervention effectiveness beyond the placebo effect cannot be

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determined. The Rohan et al. 2007 study found a lower post-treatment SAD score in patients receiving light therapy, CBT or their combination compared to a wait-list control. However, being on a wait-list could have a 'reverse placebo effect' since patients are not expecting to improve before receiving treatment. The Lam et al. (2006) studies did not find significant differences in response rates in groups assigned to light therapy or fluoxetine treatment.
Conclusion: A valid placebo group is important in RCTs of light therapy for SAD. A meta-analysis of placebo-controlled RCTs found a significant benefit of bright light and dawn simulation therapy. The meta-analysis was limited because studies tended to be small and of short duration. The largest RCTs in the meta-analysis did not find a significant benefit to bright light therapy. The evidence on dawn simulation is limited because all studies were done by the same research group and it is not known whether findings are generalizable. RCTs comparing light therapy to antidepressant treatment or psychotherapy did not include true placebo groups.
Articles: The ideal study would be a randomized controlled trial (RCT) or meta-analysis of RCTs that include a placebo or sham intervention. Studies comparing light therapy to medication therapy and/or psychotherapy should also have a placebo group. There was a protocol for a Cochrane review on light therapy for SAD. The protocol was published in 2003, and its status remains unchanged in Cochrane Library 2008, Issue 2. An estimated date for completion of the review is not available. One published meta-analysis was identified (Golden et al., 2005). The Golden study searched the literature to July 2003 and included only placebo-controlled studies. Golden et al. and the two RCTs in the meta-analysis with the largest sample sizes per treatment group and the longest trial duration (Avery et al., 2001; Eastman et al., 1998) were critically appraised. No large placebo-controlled RCTs published after the Golden meta-analysis was identified. There was one newer RCT comparing light therapy to fluoxetine treatment (Lam et al., 2006) and another comparing light therapy to cognitive-behavioral therapy (Rohan et al. 2007). These two new RCTs were also critically appraised. References for studies reviewed are as follows:
Golden RN, Gaynes BN, Ekstrom RD et al. The efficacy of light therapy in the treatment of mood disorders: A review and meta-analysis of the evidence. Am J Psychiatry 2005; 162: 656-662. See Evidence Table. Avery DH, Eder DN, Bolte MA et al. Dawn simulation and bright light in the treatment of SAD: A controlled study. Biol Psychiatr 2001; 50: 205-216. See Evidence Table. Eastman CI, Young MA, Fogg LF et al. Bright light treatment of winter depression. Arch Gen Psychiatr 1998; 55: 883-889. See Evidence Table. Lam RW, Levitt AJ, Levitan RD et al. The Can-SAD study: A randomized controlled trial of the effectiveness of light therapy and fluoxetine in patients with winter seasonal affective disorder. Am J Psychiatry 2006; 163: 805-812. See Evidence Table. Rohan KJ et al. A randomized controlled trial of cognitive-behavioral therapy, light therapy and their combination for seasonal affective disorder. J Consult Clin Psych 2007; 75: 489-500. See Evidence Table.

The use of light therapy in the treatment of Seasonal Affective Disorder (SAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/21/2015: MTAC REVIEW
Light Therapy for SAD
Evidence Conclusion: The ideal study for examining the effect of bright light therapy for SAD would be a double-blind randomized controlled trial that compares light therapy to a placebo or sham intervention. Studies comparing light therapy to pharmacological therapy or psychotherapy should also have a placebo group since there is limited evidence from placebo-controlled trials on the effectiveness of antidepressants or cognitive behavioral therapy on SAD. *Light therapy versus placebo* Martensson et al's meta-analysis, 2015 (Evidence table 1), pooled the results of 8 RCTs that compared light therapy to placebo (low negative air ions, dim red light, and dawn simulator placebo) to determine the effect bright white light (BWL) therapy on SAD. The authors performed two separate sets of meta-analyses; the first analyzed the results week-by-week, and the second analyzed the final results only. The pooled results suggest that BWL had a moderate effect on SAD symptoms compared to the controls (standardized mean difference [SMD] -0.54 (95% CI -0.95, -0.03), and that it reached statistical significance at week two and week three of treatment. The authors concluded that the BWL therapy seems to be effective, but they questioned the validity of the results due to the heterogeneity of the studies, lack of an appropriate placebo or sham light therapy control group, and other methodological limitations including the small sizes, short duration, and complex design of the trials. The results of Martensson et al's meta-analysis show a smaller effect size than that found in the Golden et al's meta-analysis reviewed earlier in MTAC (effect size 0.84, 95% CI 0.60, 1.08). As noted in the 2008 MTAC report, Golden et al's meta-analysis had the advantage of using strict criteria to ensure that studies had a valid placebo control, but was limited by the inclusion of very small studies with large treatment effect, short treatment durations, and the use different treatment protocols, which makes it difficult to draw any conclusion on the effectiveness of a particular approach to light therapy. When the two RCTs in the meta-analysis with the longest treatment durations and largest sample sizes were examined closely, bright light therapy did not clearly appear to be effective. *Light therapy versus antidepressants* In a Cochrane review on second-generation antidepressants for SAD, Thaler, et al (2011), pooled the results of two small trials (total N=136 participants) that

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compared light therapy to fluoxetine and found no significant difference between the two therapies in response or remission of SAD. The trials were small, with limitations and high dropout rates, and the overall response rate (>50% improvement on 24-item HAM-D SIGH-SAD) was 68/100 in the light therapy group and 67/100 in the fluoxetine group. The authors concluded that the overall quality of evidence is a low and insufficient to draw any conclusion on the use of second-generation antidepressants for SAD. The only available RCT of fluoxetine vs. placebo showed a nonsignificant effect in favor of fluoxetine, and the two small trials that compared fluoxetine to light therapy showed no significant differences between the two therapies in the treatment of SAD. *Light therapy versus cognitive behavioral therapy (evidence table 2)* In a recent RCT, Rohan et al, 2015, compared the treatment outcomes of light therapy versus cognitive behavioral therapy for SAD. The trial randomised 177 participants to receive light therapy (using 23x15.5x3.25 in. SunRay that emits 10,000 lux of cool-white fluorescent light) immediately upon awakening, or to receive cognitive behavioral therapy (CBT-SAD) for 6 weeks. The primary endpoints of the trial were the change in depression severity SIGH-SAD during 6 weeks of therapy, and remission status after treatment. Overall, the results showed improvement in SAD symptoms in the two study groups with no significant differences between them at 6 weeks of treatment. There was no long-term follow-up to examine recurrence rates with each therapy. The trial was a relatively small, single center, RCT conducted mainly among white women. The participants were not blinded to the treatment allocation, which is a potential source of bias, and according to the authors, the primary investigator was the developer of CBT-SAD which is another potential source of bias. More importantly, light therapy was compared to CBT-SAD which has not been thoroughly investigated as a treatment for SAD. Ideally the trial would include a sham light therapy and /or a placebo group to determine the placebo effect of each of the two therapies.
Conclusion: There is insufficient evidence to determine the effectiveness of light therapy for the treatment of SAD. Several national and international guidelines recommend light therapy for SAD giving it a level 1 evidence (Canadian guideline, 2009) or level 2 evidence (AAFP, 2013), others like the British NICE guideline (2009) and the World Federation of Societies of Biological Psychiatry (WFSBP, 2013) are uncertain about the evidence supporting light therapy for SAD.
Articles: The literature search for studies on light therapy for SAD published after the last MTAC review revealed a recent systematic review with meta-analyses on bright light therapy for depression including SAD, a Cochrane review on second-generation antidepressants for SAD, a randomized controlled trial of CBT vs. light therapy for SAD, a crossover RCT investigating the rapid effects of light therapy on SAD, and a retrospective study investigating the appropriate duration of light therapy. The search also identified three small to relatively small RCTs that compared standard bright light vs. dawn simulation, low-intensity blue-enriched white light, or negative air ions, as well as a more recent trial on different intensities of transcranial bright light treatment delivered via the ear canals for SAD. The meta-analysis and the RCT comparing bright light therapy to CBT were selected for critical appraisal. The pooled results of studies comparing antidepressants vs. light therapy in the Cochrane review were included. Mårtensson B, Pettersson A, Berglund L, et al. Bright white light therapy in depression: A critical review of the evidence. *J Affect Disord*. 2015 Aug 15; 182:1-7. See Evidence Table 1**.** Rohan KJ, Mahon JN, Evans M, et al. Randomized Trial of Cognitive-Behavioral Therapy versus Light Therapy for Seasonal Affective Disorder: Acute Outcomes. *Am J Psychiatry*. 2015 Sep 1; 172(9):862-869. See Evidence Table 2.

The use of light therapy in the treatment of Seasonal Affective Disorder (SAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/08/2019: MTAC REVIEW
Light Therapy for SAD
Conclusion:
- The search identified one study which is a follow-up of one of the studies assessed in the last review in 2015. The study is of low quality and suggests that CBT may be comparable to LT in terms of recurrence and remission status at next winter. In addition, CBT might be more effective than light therapy two winters later. Studies with higher quality are needed to draw firm conclusions on light therapy and unipolar depression with seasonal pattern in the long-term. There is insufficient (high-quality) evidence for or against the use of light therapy in patients with unipolar major depression with seasonal pattern in the long-term.
- There is insufficient evidence for or against the effectiveness of light therapy as preventive treatment for patients with a history of SAD.

Articles: The search yielded 242 items; but one RCT and one meta-analysis were retained.

The use of light therapy in the treatment of Seasonal Affective Disorder (SAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered not covered:

HCPC Codes	Description
E0203	Therapeutic lightbox, minimum 10,000 lux, table top model
A4634	Replacement bulb for therapeutic light box, tabletop model

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/16/2008	05/03/2011[MDCRPC], 08/02/2011[MDCRPC], 06/05/2012 [MDCRPC], 04/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	08/06/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/20/2015	Changed Medicare link
01/06/2016	MPC approved to retain a policy of insufficient evidence
08/06/2019	Added July 8, 2019 MTAC review

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PATIENT REFERRAL GUIDELINES

Liver Transplant

- Liver Transplant: Adult/Pediatric
- Living-Donor Liver Transplant: Adult – Adult
- Organ Transplantation in Members with HIV/AIDS

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Adult Liver Transplantation (260.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Liver transplantation may be considered for patients with end-stage liver diseases who have no prospect for prolonged survival, or whose quality of life is severely impaired. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral.

1. **GENERAL PRINCIPLES**
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection outside of the hepatobiliary tree is a contraindication to liver transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low. [1,2,3] Exceptions may be made on a case-by-case basis.
      i. For patients with a first alcohol-related / liver decompensating event, whose severity of liver disease suggests they are unlikely to survive to reach 6 months alcohol abstinence, see appendix for the "Kaiser Permanente Protocol: Reduced Duration Alcohol Sobriety Pathway to Liver Transplant Listing" (Appendix I).
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
   g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
   h. Patients must have a caregiver or caregivers, who are physically and cognitively able to assist the patient with self-care activities and are able to travel within short notice to the KP approved transplant Center of Excellence.

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i. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
j. Evidence of such non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
k. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. **INDICATIONS FOR LIVER TRANSPLANT**
   a. Acute Fulminant Hepatic Failure. Refer patient as soon as diagnosis is made.
      i. Progressive Coagulopathy
      ii. Hepatic Encephalopathy
      iii. Progressive Hyperbilirubinemia
   b. Chronic Liver Disease – referral is generally not advised until there is a MELD or PELD score of 15, with exceptions for the indications listed below: There is evidence that there is no survival benefit for patients transplanted with a MELD score <15. [4]
      i. Hepatocellular Carcinoma
         1. Patients who meet Milan/UCSF criteria for hepatocellular carcinoma may be referred to transplant centers for transplant evaluation.
         2. Patients with hepatoblastoma who exceed Milan/UCSF criteria may be considered as liver transplant candidates on a case by case basis. [5]
         3. Pediatric patients with nonmetastatic and unresectable hepatoblastoma (PRETEXT IV and complex pretext III) should be referred for LT evaluation at the time of diagnosis or no later than after 2 rounds of chemotherapy.
         4. Pediatric patients with hepatoblastoma and pulmonary metastases can be considered for liver transplant if, following chemotherapy, a chest CT is clear of metastases or, if a tumor is identified, the pulmonary wedge resection reveal the margins are free of the tumor (AASLD/NASPGHAN guidelines 2014)
      ii. Intractable Encephalopathy
      iii. Intractable Ascites/ hepatic hydrothorax
      iv. Intractable Variceal Bleeding
      v. Cholestatic Liver Disease:
         1. Intractable Pruritis
         2. Recurrent Cholangitis
         3. Intractable Bone Disease
      vi. Progressive Hepatopulmonary Syndrome
      vii. Hepatorenal Syndrome
      viii. Additional indications for liver transplant for the pediatric population: Urea cycle defects, organic acidemia and other metabolic disorder

3. **CONTRAINDICATIONS FOR LIVER TRANSPLANT**
   a. Advanced cardiopulmonary disease or any other life limiting disorder not corrected by liver transplantation. All patients should be evaluated for coronary artery disease (CAD) and occult cardiomyopathy. Hepatopulmonary syndrome and hepatorenal syndrome are not contraindications as they are correctable by transplantation.
   b. Patient whose HCC exceeds Milan criteria or whose alpha fetoprotein (AFP) level is greater than 1000 ng/ml should not be referred for transplant until they have been down staged successfully to within Milan criteria and/or an AFP level of less than 500 ng/ml. Exceptions may be made on a case by case basis for hepatoblastoma. [6, 7]
   c. Absolute contraindication of liver transplant in pediatric patients - Severe multisystem mitochondrial disease

4. **RELATIVE CONTRAINDICATIONS FOR LIVER TRANSPLANT**
   a. Pulmonary hypertension with pulmonary artery systolic pressure 50 mmHg or mean >35 mmHg (despite optimal medical management).
   b. Renal failure (excluding hepatorenal syndrome)
   c. Active infection outside the hepatobiliary system
   d. Advanced malnutrition
   e. Severe diabetic complications
   f. Inability to control HbA1C <8
   g. Massive obesity
   h. Multiple abdominal surgeries

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i. Significant irreversible neurologic dysfunction.
j. Highly selected patients with only intra-ductal cholangiocarcinoma may be considered for transplant on a case-by-case basis, at a transplant center with an established cholangiocarcinoma program. [8, 9]

5. MULTIPLE ORGAN TRANSPLANTS INCLUDING LIVER

Liver transplantation combined with another organ transplant is indicated in special circumstances in pediatric and adult patients. Examples include, but are not limited to, liver/kidney, liver/lung and liver/heart. These combined organ transplants require case by case evaluation.

6. SPECIAL CONSIDERATIONS FOR LIVING DONOR LIVER TRANSPLANT

In addition to the current KP cadaveric donor patient referral guidelines for adults, the following should be considered when presented with a potential living donor liver transplant.

a. No recipient should be considered for living donor liver transplant if in status 1 fulminant liver failure.
b. Patients with MELD < 15 but with complications of liver disease that are uncorrectable and not reflected in the MELD score may be considered for living donor liver transplantation on a case by case basis after consultation with a hepatologist.
c. Recipients with hepatocellular carcinoma (HCC) should meet the same guidelines as listed for cadaveric donor patient referral guidelines.
d. Living donor liver transplant is not contraindicated for pediatric patients with acute liver failure if patient is a candidate for liver transplant.

7. ADDITIONAL INFORMATION ON LIVER TRANSPLANTATION

For additional information about UNOS policies on organ allocation and candidate criteria, please visit **https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_09**

APPENDIX I:

Reduced Duration Alcohol Sobriety Pathway to Liver Transplant Listing - Kaiser Permanente Protocol

(For Northern California, please consult the "**Reduced Duration Alcohol Sobriety Pathway to Liver Transplant Listing Kaiser Permanente Northern California Protocol**", available on the Clinical Library under Northern California)

BACKGROUND / PURPOSE:

- There is data suggesting that the currently utilized 6-month alcohol sobriety rule needed for liver transplant listing may not be the best predictor of relapse on a liver transplant list or post-transplant
- Some liver transplant programs in the United States and Europe accept a reduced duration alcohol sobriety pathway to liver transplant listing
- This protocol is designed to evaluate and qualify Kaiser Permanente patients for liver transplant listing who have not reached 6-months of alcohol sobriety

WHO THIS PATHWAY APPLIES TO:

- This protocol applies to patients with a first alcohol-related / liver decompensating event (as defined below) and whose severity of liver disease suggests they are unlikely to survive to reach 6 months alcohol abstinence (see suggested scenarios below)
- Patient must be without incapacitating hepatic encephalopathy and/or cannot be intubated when evaluated by addiction medicine and supporting gastroenterology and hepatology physician
  - Family/family friends or significant others will not be used as sole historians in the event the candidate is incapacitated with hepatic encephalopathy and/or intubated
- This protocol does not apply to patients who are not presenting with a first liver-decompensating event or who have already reached 6 months alcohol abstinence. Standard criteria for liver transplant listing should be applied to those patients.

Protocol Flow Diagram:

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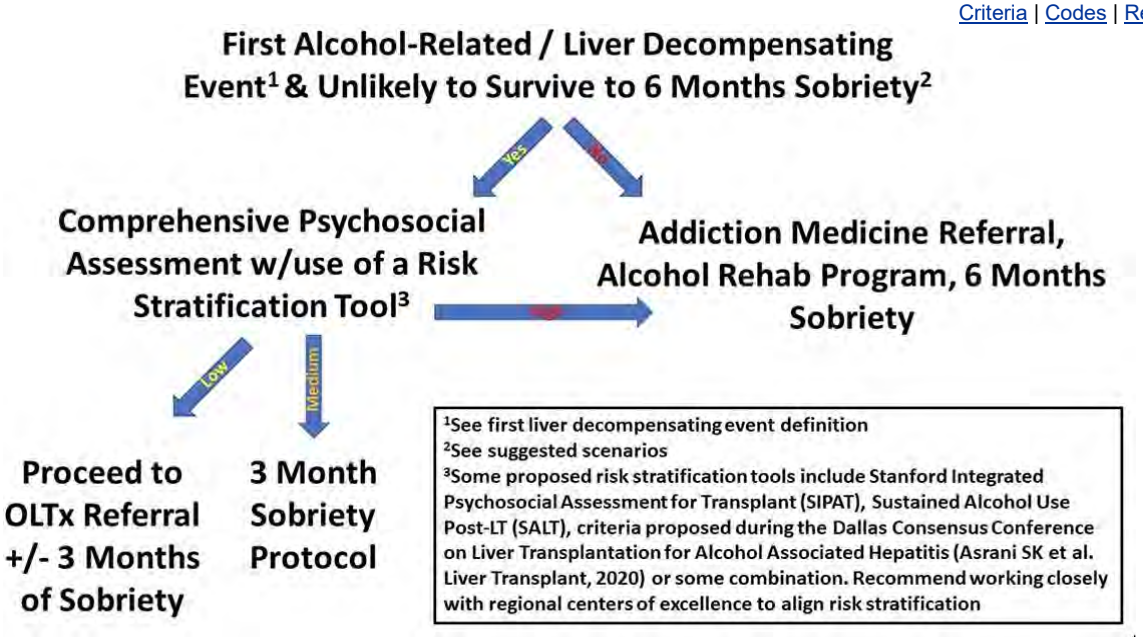

DEFINITION OF FIRST ALCOHOL-RELATED / LIVER DECOMPENSATION

To help define a potential first alcohol-related / liver decompensating event, try to answer this question: When faced with the knowledge that their alcohol use was linked to a negative effect on their legal status or medical health, did the candidate stop drinking? If no, then the candidate's presentation with severe alcoholic hepatitis or acute on chronic liver failure is not considered their first decompensating event, as it demonstrated poor insight and decision-making. These criteria represent relatively easy to find information within the medical chart that represent exclusion criteria.

- Exclusion of patients with history of hospital admission due to the following complication of alcohol abuse within *the last 2 years*:
  - Alcohol-related hepatitis
  - Alcohol-related pancreatitis
  - Alcohol-related cardiomyopathy
  - Alcohol withdrawal (including delirium tremens and/or seizures)
  - Alcohol psychosis
- Exclusion of patients with history of an emergency room visit due to the following complication of alcohol abuse within *the last 2 years:*
  - Alcohol-related hepatitis
  - Alcohol-related pancreatitis
  - Alcohol-related cardiomyopathy
  - Alcohol withdrawal (including delirium tremens and/or seizures)
  - Alcohol psychosis
  - Alcohol intoxication with or without a complication (like fall or altercation)
- Exclusion of patients with *more than one* failed alcohol rehabilitation attempt within *the last 2 years*
- Exclusion of patients with any previous diagnosis in problem list of the following complications of alcohol abuse within *the last 2 years*:

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- Alcohol-related hepatitis
- Alcohol-related pancreatitis
- Alcohol-related cardiomyopathy
- Severe alcohol use disorder

➢ Exclusion of patients with any previous diagnosis in problem list of alcohol-related cirrhosis at *any time*.
➢ Exclusion of patients with active polysubstance abuse (any co-substance except for marijuana and/or nicotine) within *the last 2 years*.

UNLIKELY TO SURVIVE TO REACH 6 MONTHS ALCOHOL ABSTINENCE

No comprehensive definition of patients with severe acute alcohol related hepatitis or alcohol related acute on chronic liver failure can be provided. Ultimately, this assessment is left to patient's treating hepatologist and larger treatment team. Some suggested scenarios include:

- Patient with severe acute alcoholic hepatitis (Maddrey's Discriminant Function >32) who is not a candidate for or has failed medical management (including use of prednisolone with or without N-acetylcysteine infusion with resultant 7-day Lille Score > 0.45)
- Inpatient with persistent MELD score > 30 (see 3-month predicted survival based on MELD score below) Inpatient with dialysis dependent hepatorenal syndrome type 1

3-Month Mortality Based on MELD Scores

The estimated 3-month mortality is based on the MELD score highlighted in yellow above.

MELD Score	Mortality Probability
40	71.3% mortality
30-39	52.6% mortality
20-29	19.6% mortality
10-19	6.0% mortality
9 or less	1.9% mortality

Footnotes

1. Liver Transplantation 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
2. Liver Transplant Surg. 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), TPMG New Medical Technology
4. American Journal of Transplantation 5 (2) 203-205, February 2005.
5. Hepatoblastoma (HB) is the most common type of liver cancer in children. The gold standard treatment of HB is perioperative chemotherapy followed by complete resection of tumor. Liver transplantation (LT) for children with HB should be considered (even if beyond Milan criteria) if the tumors are nonresectable or show chemotherapy resistance. LT for children with HB should be considered even with very high AFP levels. LT may be considered even if there is a history of pulmonary metastasis (after thoracotomy and resection +/- chemotherapy). Contraindications to LT for HB: Vascular invasion (including tumor clot).
6. The Milan Criteria for liver patients with HCC is 1 tumor: 5 cm or 2 – 3 lesions, none >3 cm and no vascular invasion. Source: NEJM 1996, 334; 693-699.
7. The UCSF/Region 5 Criteria for liver patients with HCC is 1 tumor: 6.5 cm, or 2 – 3 lesions, none >4.5 cm and total tumor diameter ::8 cm, and no vascular invasion. Hepatology, 2001, 33; 1394-1403.

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8. Transplantation for Hilar Cholangiocarcinoma. Liver Transplantation, Vol. 10, (10); Supplement II (October) 2004:pp 565-568
9. Goldberg, et. Al. (2014), Hepatology, 60 (5), 1717-1726.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Liver transplantation or hepatic transplantation is the replacement of a diseased liver with a healthy liver from another person (allograft). Liver transplantation is a viable treatment option for end-stage liver disease and acute liver failure.

Medical Technology and Assessment Committee (MTAC)

Living-Donor Liver Transplant – Adult-to-Adult

BACKGROUND

Living donor liver transplantation (LDLT) was developed as an alternative to cadaveric liver transplantations due to the dramatic shortage of available livers. LDLT to pediatric recipients was introduced into clinical practice in 1989 and the procedures are now performed worldwide. Adult-to-adult LDLT was initiated in the United States in the late 1990s. In 1997, one adult-to-adult LDLT was performed at one center in the U.S. and this grew to 266 procedures at 38 centers in 2000 (Brown et at, 2003). Left lateral segmentectomy, which uses approximately 20% of the hepatic mass, is generally used for LDLT to pediatric donors. However, these grafts provide insufficient liver mass for an average sized adult recipient. With adult recipients, a larger portion of the donor's liver must be taken which poses increased risks to the donor. Adult-to-adult liver transplantation involves either a full left or right hepatic lobe. Initially, all adult LDLT used the smaller left hepatic lobe. The hepatic mass was sufficient for some Asian recipients, but not for the average U.S. patient. Currently, adult-to-adult LDLTs in the U.S. use donation of the right hepatic lobe, which represents about 60% of the hepatic mass. Risks to the donor in adult-to-adult LDLT include the possibility that the donor will not be left with sufficient hepatic function, the possibility of biliary complications, risks associated with blood transfusion, risks associated with surgery and unknown, long-term risks associated with major hepatic resection. (American Society of Transplant Surgeons: Ethics Committee, 2000; Renz and Roberts, 2000; Hayashi & Trotter, 2002).There is an ethical debate on adult-to-adult LDLT centering on the question of whether or not it is acceptable for a consenting healthy individual to undergo this surgery and take the risk of complication or death in order to potentially save the life of a loved one. LDLT programs conduct extensive physical and psychological examinations of donors. Related ethical issues are how to select adult recipients of LDLT (i.e. to what extent are they at risk of dying), how successful LDLT is in adult recipients (i.e. increased life expectancy in recipient vs. risk to donor) and how to allocate cadaveric livers.

04/12/2000: MTAC REVIEW

Living-Donor Liver Transplant – Adult-to-Adult

Evidence Conclusion: The limited amount of evidence available is not sufficient to determine the safety and efficacy of LRLT. Case series reports were the best available evidence. The published case studies have small sample sizes and were not rigorously performed (i.e. did not specify inclusion/exclusion criteria or outcome measurement, had variable and relatively short length of follow-up). In addition, the published studies report on different clinical techniques for performing LRLT and these individual techniques have not been systematically evaluated.

Articles: There were no randomized control trials, meta-analyses or cohort studies. Case series for adult-to-adult transplants all had small sample sizes (<50). Several larger case series included both adults and children as recipients and did not present results separately. Evidence tables were created for those with the largest sample sizes: (n=33) Hashikura, Y, Kawasaki, S, Miyagawa, S, Terada, M, Ikegami, T, Miwa, S, Kubota, T, Mita, A. Living-related donor liver transplantation in adults: Experience at Shinshu University Hospital. Transplantation Proceedings 1999; 31: 1953-4; (N=25) Marcos, A, Fisher, RA, Ham, JA, Shiffman, ML, Sanyal, AJ, Luketic, VAC, Sterling, RK, Posner, MP. Right lobe living donor liver transplantation. Transplantation 1999; 68: 798-803. Hashikura, Y, Kawasaki, S, Miyagawa, S, Terada, M, Ikegami, T, Miwa, S, Kubota, T, Mita, A. Living-related donor liver transplantation in adults: Experience at Shinshu University Hospital. Transplantation Proceedings 1999; 31: 1953-4. See Evidence Table. Marcos, A, Fisher, RA, Ham, JA, Shiffman, ML, Sanyal, AJ, Luketic, VAC, Sterling, RK, Posner, MP. Right lobe living donor liver transplantation. Transplantation 1999; 68: 798-803. See Evidence Table.

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The use of Adult to Adult Living Related Donor Liver Transplant treatment of Liver Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/11/2003: MTAC REVIEW
Living-Donor Liver Transplant – Adult-to-Adult

Evidence Conclusion: There is a lack of evidence on the effectiveness of adult-to-adult living-donor liver transplantation compared to cadaveric whole or split-liver transplantation and one small study (Liu) that addresses the effectiveness of LDLT compared to remaining on a wait list for cadaveric transplantation. Liu found a higher survival rate with right lobe LDLT than no transplantation among patients with acute liver failure; however, findings do not necessarily generalize to patients with other indications for transplantation.
The remaining studies are case series. One-year recipient survival rates were 72% in the case series of 308 adults from Japan (Todo) in which 71% of the operations were left-lobe transplantations and 85% for 50 right-lobe operations in the U.S. (Miller). No peri-operative donor mortality was reported in the recent case series articles. Brown identified one donor death among 449 right-lobe adult-to-adult living-donor transplantations performed in the U.S. between 1997 and 2000. Brown's survey found a 14.5% donor complication rate including 6% experiencing biliary leakage and 4.5% needing re-operation. A limitation of the case series data and the Brown survey data is variability in the eligibility criteria and interventions across centers and within centers over time. There are no quality long-term data on outcomes among recipients or donors.
Articles: The search yielded 206 articles, many of which were reviews, opinion pieces or dealt with technical aspects of the procedure. There were no randomized controlled trials. The next preference was given to non-randomized comparative trials. There was one study that compared patients with acute liver failure who did and did not opt for LDLT; this study was reviewed. The remaining studies were case series. Other articles selected were the largest case series (conducted in Japan), the largest case series in the United States and a survey of transplantation programs focusing on donor outcomes. The following four articles were critically appraised:
Liu CL, Fan ST, Lo CM et al. Right-lobe live donor liver transplantation improves survival of patients with acute liver failure. *Br J Surg* 2002; 89: 317-322. See Evidence Table. Todo S, Furukawa H, BonJin M et al. Living donor liver transplantation in adults: Outcome in Japan. *Liver Transplantation* 2000; 6 (Suppl 2): S66-S72. See Evidence Table. Miller CM, Gondolesi CE, Florman S. et al. One hundred nine living donor liver transplants in adults and children: A single-center experience. *Ann Surg* 2001; 234: 301-012. Brown RS, Russo MW, Lai M. et al. A survey of liver transplantation from living adult donors in the United States. *N Engl J Med* 2003; 348: 818-825. See Evidence Table.

The use of Adult to Adult Living Related Donor Liver Transplant treatment of Liver Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Kidney Transplantation in the treatment of HIV+

BACKGROUND
HIV infected patients are at risk for end-stage renal disease caused by HIV-related disease such as HIV-associated nephropathy and hepatitis C infection. HIV-positive patients co-infected with hepatitis B or hepatitis C are also at risk of progression of liver disease (Roland & Stock; Fishman). Until recently, HIV-positive patients have been excluded from organ transplantation programs. A primary reason for this exclusion has been the belief that patients in an immuno-compromised state would be adversely affected by the immunosuppression required for transplantation. Several changes have occurred that have caused some transplant centers to question the exclusion based on HIV infection. Highly active anti-retroviral therapy (HAART) became available in the mid to late 1990s. HAART can prolong survival in HIV-positive patients, thereby increasing the number of patients with stable HIV infection who progress to end-stage organ failure. In addition, there have been improvements in immunosuppressive drug regimens and surgical techniques associated with transplantation. This review will evaluate the evidence published to date on the safety and efficacy of organ transplantation among HIV-positive patients in the HAART era. Kidney transplantation in HIV positive patients was previously reviewed by MTAC in December 2001. At that time, the evidence consisted of several case series with five or fewer HIV-positive patients and the item failed MTAC evaluation criteria. Other types of organ transplantation (liver, lung, heart) have not been reviewed by MTAC.

12/12/2001: MTAC REVIEW
Kidney Transplantation in the treatment of HIV+

Evidence Conclusion: There is insufficient published evidence on which to base a conclusion about the effect of kidney transplant in HIV-positive patients on health outcomes. Although recent changes in the prognosis of HIV-positive individuals suggest that some may benefit from kidney transplant, there are no direct empirical data to support this claim.

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Articles: The search yielded 64 articles, many of which dealt with other related procedures or populations or were review articles or opinion pieces. No articles with empirical data were included in the search. Three older case series were identified in the reference list of the Gow review article. Each of these case series included 5 or fewer HIV-positive patients receiving kidney transplants. None of the articles was suitable for critical appraisal.

The use of Kidney Transplantation in the treatment of HIV+ patients with renal failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/11/2004: MTAC REVIEW
Heart, Lung, Kidney, & Liver Transplantation in the treatment of HIV+
Evidence Conclusion: There were two primary issues addressed in this review: 1) evidence on the safety and effectiveness of organ transplantation for HIV-positive individuals and; 2) evidence on whether survival among HIV-positive individuals who receive organ transplants is lower than among HIV-negative individuals. There is no published evidence on the safety and effectiveness of lung transplantation in HIV-positive individuals and only two case reports of heart transplants. There were no articles comparing transplantation to another intervention in HIV-positive patients with end-stage liver or kidney disease. The best published evidence on kidney and liver transplants in HIV-positive individuals is from cohort studies conducted in the HAART era. Abbott did a retrospective study comparing outcomes in HIV-positive and HIV-negative individuals, all of whom were identified in a national database of kidney transplants. Ragni compared survival in a prospective series of HIV-positive patients and a retrospective analysis of selected HIV-negative patients from the UNOS Scientific Registry for Liver Transplantation. In both studies, three-year survival rates did not differ significantly in the HIV-positive and HIV-negative groups. Limitations of both studies include: The relatively small sample sizes of HIV-positive patients, 24 in the Ragni study and 47 in the Abbott study. The HIV-positive and HIV-negative groups may have differed in ways that affected outcomes (despite statistical adjustment for confounding in the Abbott study). The authors commented that clinicians may have selected the healthiest HIV-positive patients for transplantation which might increase the likelihood of a successful outcome compared with the HIV-negative patients. The Abbott study was retrospective and the Ragni study included a prospective group of HIV-positive patients but did a retrospective analysis of the HIV-negative control group. Prospective designs are preferred. A prospective, multi-center uncontrolled study to evaluate the safety and efficacy of kidney and liver transplants performed in HIV-positive patients is currently in its early phases. The study is being coordinated by UCSF. The investigators anticipate enrolling up to 275 transplant recipients and following them for 2-5 years.
Articles: The search yielded 217 articles. Most were opinion pieces, on technical aspects of transplantation in HIV-positive patients and articles on related clinical topics. Empirical studies on specific types of organ transplantation were as follows: Lung There were no studies with empirical data. Heart There were two case reports, each reporting on a single case. The articles were ineligible for critical appraisal. Kidney and Liver There was one study on kidney transplants (Abbott et al., 2004) and one study on liver transplants (Ragni et al., 2003) that compared outcomes in HIV-positive patients to outcomes in HIV-negative patients. Data from HIV-negative patients were taken from national transplantation databases in both studies. These two studies were critically appraised. The largest published series from UCSF included 14 patients, 10 received kidney transplants and 3 received liver transplants (Stock et al. 2003). Newer reports with additional patients have been presented at conferences and discussed in review articles, but the data have not been published in empirical articles. The case series was not critically appraised due to the small sample and availability of comparative studies. There was also a retrospective cohort study evaluating data on kidney transplants from 1987-1997; this study was not critically appraised because it primarily included cases from the pre-HAART era.
The studies reviewed were Abbott KC, Swanson SJ, Agodoa LYC et al. Human immunodeficiency virus infection and kidney transplantation in the era of highly active antiretroviral therapy and modern immunosuppression. *J Am Soc Nephrol* 2004; 15: 1633-1639. See Evidence Table. Ragni MV, Belle SH, Im K et al. Survival of human immunodeficiency virus-infected liver transplant recipients. *J of Infect Dis* 2003; 188: 1412-1420. See Evidence Table.

The use of Heart Transplantation in the treatment of HIV+ patients with heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of Lung Transplantation in the treatment of HIV+ patients with lung failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of Kidney Transplantation in the treatment of HIV+ patients with renal failure evidence is not sufficient to determine whether HIV infection should or should not be an exclusion for kidney transplantation.

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The use of Liver Transplantation in the treatment of HIV+ patients with renal failure the evidence is not sufficient to determine whether HIV infection should or should not be an exclusion for liver transplantation.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
47135	Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
05/1996	07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 08/02/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC],11/05/2013[MPC], 02/04/2014[MPC], 09/02/2014[MPC], 10/07/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	01/10/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/06/2015	Merged Living Donor Related criteria to Liver Transplant criteria
11/03/2015	Merged Organ Transplantation for HIV+ Patients for Liver and Kidney
03/05/2019	MPC approved to adopt KP National Criteria for Liver Transplant
09/03/2019	MPC approved to change General Principles 1.3 to *Uncontrollable infection is a contraindication to transplant* as recommended by KP National Transplant Services.
03/03/2020	MPC approved proposed changes from KP National Transplant Services
04/06/2021	MPC approved proposed changes from KP National Transplant Services. Requires 60-day notice, effective date September 1, 2021.
01/10/2022	MPC approved proposed changes from KP National Transplant Services. 60-day notice is not required.

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Clinical Review Criteria
Localization System for External Beam Radiation

- Calypso 4D Localization
- Electromagnetic Localization System
- GPS for the Body
- Tracking with Beacon Transponders during External Beam Radiation Therapy (Calypso Medical)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Localization System for External Beam Radiation" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Prostate cancer is the most commonly diagnosed cancer and second leading cause of death in men in the United States. The treatment options for early-stage prostate cancer include radical prostatectomy, high dose brachytherapy, and high dose external beam radiation therapy (EBRT). Several studies showed improvement in biochemical progression free survival with radiation dose escalation. However, this comes at the cost of higher bladder and bowel toxicity. Investigators found that toxicity due to radiation therapy can be reduced by the use of intensity modulated radiotherapy (IMRT) techniques that focus a high dose radiation to the prostate while decreasing the dose to the bladder and rectum. With the higher doses being delivered with increased conformity,

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it is critical that the isocenter of the prostate treatment volume be placed with precision (Kuban 2008, Quigley 2009, Rajendran 2010).

The prostate gland is known to have some movement during the day as the bladder and rectum are filled at different volumes. Two types of motion have been described and may be an issue for treatment planning: 1. Interfraction motion from day-to-day, and 2. Intrafraction movement that is motion occurring while the patient is on the treatment table during radiation delivery. This is thought to be caused by breathing or other biological factors as contraction/relaxation of the pelvic floor and by rectal gas. Target localization during radiation therapy for prostate cancer has two aspects: the initial setup before delivering the radiation, and the subsequent real-time target position monitoring during the actual delivery of radiation. The interfraction position has been addressed by various techniques including ultrasound, infrared cameras, diagnostic CT imaging, and x-ray imaging. The use of implanted markers as gold is accepted as an accurate, reliable, and reproducible method to establish the position of the prostate gland during EBRT treatment. Other techniques used to estimate the motion of prostate during delivery of radiation include transabdominal ultrasound, X-rays, MRI, CT, and fluoroscopy. The use of these technologies may be limited as they may not be available in the treatment room or usable during radiation delivery, provide only a snapshot of the prostate position, result into additional radiation dose, are labor intensive and /or require user skill for image acquisition or interpretation (Kupelian 2006, Rajendran 2010).

In the last few years, the use of an implantable radiofrequency emitting device has been proposed as an alternative to radiopaque fiducial markers and radiographic localization to provide an objective, accurate real-time method of localizing and monitoring prostate position. The Calypso 4D Localization System is based on electromagnetic detection of implanted Beacon transponders that allows the three-dimensional position of the implanted transponders and target isocenter to be tracked at a frequency of 10Hz. This provides continuous real-time localization and monitoring of the prostate. The Calypso System (Calypso Medical, Seattle, WA) consists of three implantable wireless Beacon transponders approximately 8 mm in length and 2mm in diameter, an electromagnetic array, an infrared camera system, and a tracking station. Typically, three transponders are implanted in the right and left base and the apex of the prostate gland under transrectal ultrasound guidance in a manner similar to needle biopsy. The coordinates of the Beacons and the isocenter are identified on the treatment planning CT and entered into the calypso tracking station. Similar to ultrasound localization, the initial localization with the Calypso System is performed using skin marks to align with room lasers. Calypso is used to localize the prostate and the system calculates the initial offset. The couch is shifted until the three offsets are zero. During treatment Calypso monitors and reports the offset between the actual and planned isocenter position (Santanam 2009, Foster 2010, Rajendran 2010).

Potential benefits of the Calypso system include its ability to continuously monitor target position during treatment, with no exposure to ionizing radiation to perform the localization, and without using complicated procedures of acquiring X-ray images. Potential disadvantaged on the other hand, are the need for implantation, transponders stability within the implanted tissues, and the absence of any associated image of the targeted areas.
The Calypso System has received 510 (K) clearance from the FDA in 2006.

Medical Technology Assessment Committee (MTAC)

Calypso 4D Localization System

12/20/2010: MTAC REVIEW

Evidence Conclusion: The published literature on the Calypso system is very limited and do not provide sufficient evidence to determine the safety of the technology or its effect on patients with localized prostate cancer treated with radiation therapy. The published studies were small case series the majority of which were conducted by the same group of authors many of whom had financial interest with the manufacturer of the technology. The safety of the Calypso system and its effect on improving health outcomes were not examined in randomized controlled trials. Assessing the Impact of Margin Reduction (AIM) study was the largest case series on the Calypso System published to date, and the first with clinical outcomes. However, it was not randomized and used a historical comparison group. It had several other limitations including the significant baseline differences between study participants and the comparison groups, difference in the time of treatment, and variations in the radiation therapy received by the two groups, as well as the absence of long-term follow-up to determine the effect of the technology on the incidence of late complications. Moreover only 83% of the participants were included in the analysis, and the study was funded by the manufacturer.
Articles: The published literature on the Calypso 4D localization system for the prostate is very limited. There are no published randomized controlled trials that compared the effect of the Calypso system versus other localization technologies on reducing radiation toxicity or improving quality of life (QoL) in patients with prostate cancer. The

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literature search identified the 'Assessing the Impact of Margin Reduction (AIM)' study that assessed the effect of reducing the planning target volume margins while using real-time tumor tracking on the quality of life of patients with prostate cancer treated with radiation therapy. It did not include a comparison or control group. No trials on the safety of the technology were identified.
The AIM study was selected for critical appraisal: Sandler M, Liu P-Y, Dunn RL, et al. Reduction in patient-reported acute morbidity in prostate cancer patients treated with 81-Gy Intensity-modulated radiotherapy using reduced planning target volume margins and electromagnetic tracking: assessing the impact of margin reduction study. *Urology.* 2010 May;75(5):1004-8. Epub 2010 Feb 13. See Evidence Table

The use of Calypso 4D localization system (Calypso 4D localization and Tracking with Beacon transponders during external beam radiation therapy [Calypso Medical], GPS for the Body, electromagnetic localization system) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® / HCPC Codes	Description
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

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Creation Date	Review Dates	Date Last Revised
12/20/2010	02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/16/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/01/2020	Added KPWA Medical Policy statement under Medicare section
09/16/2020	Added HCPC code G6017

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KAISER PERMANENTE®

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Clinical Review Criteria
Low-Dose CT Screening for Lung Cancer

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (210.14)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

For Non-Medicare Members

Low-dose CT screening for lung cancer will be covered when the patient meets the following criteria:

Ages 50 through 79: Annual screening for lung cancer with low dose computed tomography is recommended for patients who:

- Have at least a 20 pack-year smoking history,
- Currently smoke or quit less than 15 years ago, and
- Have no significant comorbidities that would preclude surgical treatment or limit life expectancy.

Ages 80 and over: Annual lung cancer screening with LDCT is not recommended.

Discontinuation

Discontinuation of lung cancer screening is recommended at 15 years following the patient's quit date, or as appropriate for health status.

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Background

Lung cancer is the third most common cancer and the leading cause of cancer death in the United States. According to the U.S. Preventive Services Task Force (USPSTF), nearly 90% of individuals with lung cancer die of the disease. However, when detected at an early stage, non–small cell lung cancer (NSCLC) has a better prognosis and can be treated with surgical resection. (The majority of lung cancer cases are NSCLC.)

The most important risk factor for lung cancer is smoking, which results in approximately 85% of all U.S. lung cancer cases. The incidence of lung cancer increases with age, occurring most commonly in individuals aged 55 years or older. Increasing age and cumulative exposure to tobacco smoke are the two factors most strongly associated with the occurrence of lung cancer.

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The USPSTF found adequate evidence that annual screening with low-dose computed tomography (LDCT) in current and former smokers aged 55 to 79 years who have significant cumulative tobacco smoke exposure can prevent a substantial number of lung cancer deaths. LDCT has greater sensitivity for detecting early-stage cancer than chest X-ray and sputum cytology; however, it also has a very high rate of false positives (about 95%). For the benefits to outweigh the harms, screening needs to be limited those who are at the highest risk for lung cancer.

Medical Technology Assessment Committee (MTAC)

Low-Dose CT Screening for Lung Cancer

12/12/2001: MTAC REVIEW

Evidence Conclusion: There is no evidence on the diagnostic accuracy of the low-dose CT test for lung cancer screening. That is, an independent, blind, comparison of the low-dose CT tests with a gold standard (e.g. high-dose CT) for an appropriate group of patients. In the Henschke study, only patients with certain findings on low-dose CT were recommended to have high-dose CT. There are also no studies comparing the diagnostic accuracy of low-dose CT screening to the current standard, chest radiography. The only available evidence on low-dose CT screening for lung cancer is prospective reports of screening programs. Henschke set up a protocol to screen individuals at increased risk of lung cancer. They found that more non-calcified nodules, malignant nodules and stage I malignant disease was found using low-dose CT than could be detected by chest radiography. These data suggest that low-dose CT may be useful for lung cancer screening. The data presented in the Henschke study are insufficient for evaluating the question of whether screening with low-dose CT reduces disease-specific mortality. Even though more nodules and more stage I nodules were identified than with chest radiography, it is not known whether this early identification will lead to decreased mortality from lung cancer. (Previous randomized controlled trials evaluating the effectiveness of chest radiography for lung cancer screening did not find a difference in mortality in the screened and unscreened groups). Alternatively, CT screening may not increase disease-specific survival due to lead-time bias and over diagnosis bias. Randomized controlled trials comparing CT screening to no screening would provide more rigorous information about its effectiveness as a screening strategy.

Articles: The search yielded 54 articles, many of which were review articles, opinion pieces or dealt with technical aspects of the procedure. There were no randomized controlled trials or meta-analyses. Five case series with relevant clinical outcomes were identified. Four were studies conducted in Japan and one was a study conducted at Cornell University. Of the four Japanese studies, there were two studies by Sone al. and two studies by Kaneko et al. The Sone articles were an earlier and later report on the same project, as were the Kaneko articles. Neither of the Japanese screening projects had specific clinical inclusion and exclusion criteria. The Sone study screened the general population and the Kaneko study screened people who were members of a non-profit organization, the Anti-Lung Cancer Association (ACLA). In addition, neither Japanese screening project appeared to have a consistent protocol that was followed. The Cornell University study by Henschke et al. screened only individuals at high-risk of lung cancer and had clear eligibility criteria as well as screening and follow-up protocols. None of the articles were designed to evaluate the diagnostic characteristics of the low-dose CT test (e.g. sensitivity, specificity). *An evidence table was created for the Henschke study:* Henschke CI, McCauley DI, Yankelevitz DF, Naidich DP, McGuinness G, Miettingen OS, Libby DM, Pasmantier MW et al. Early Lung Cancer Action Project: Overall design and findings from baseline screening. Lancet 1999; 354: 99-105. See Evidence Table

The use of CT Scanning in the screening of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* 2 for effectiveness of diagnostic test.

Low-Dose CT Screening for Lung Cancer

8/15/2011: MTAC REVIEW

Evidence Conclusion: The National Lung Screening Trial (NLST), a large RCT that included 53,454 participants, examined whether screening high-risk individuals for lung cancer annually for three years with either LDCT or chest x-ray would reduce lung cancer mortality. Results from the NLST suggest that in high-risk patient's annual lung cancer screening for three years using LDCT reduced lung-cancer mortality with a number needed to screen to prevent one cancer death of 320. However, before recommending a screening test there are other factors to consider such as overdiagnosis, cost-effectiveness, false positive results, and other potential harms such as radiation-induced cancer. The effect of overdiagnosis and radiation-induced cancer could not be directly measured in this trial and cost-effectiveness analyses are currently underway. With regard to false positive results, across the three rounds of screening, 96.4% of the positive results in the LDCT and 94.5% in the x-ray group were false positive results. Additionally, 39.1% of subjects in the LDCT group and 16.0% in the x-ray group had at least one positive screening test during the screening phase of the trial (NSLT 2011). A recent interim analysis from a RCT that included 2,472 men who were at high-risk for lung cancer examined whether yearly lung

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cancer screening using LDCT in combination with a medical interview and physical exam would reduce lung cancer mortality compared to yearly medical interview and physical exam alone. After approximately 3 years of follow-up, significantly more men in the intervention group were diagnosed with lung cancer [intervention 60 (4.7%) vs. control 34 (2.8%), P=0.02]. However, there was no significant difference in lung cancer mortality between the two groups [intervention 20 (1.6%) vs. control 20 (1.7%), P=0.84]. Conclusion: Results from the NLST suggest that screening high-risk patients with LDCT annually for three years may reduce lung-cancer mortality; however, despite these positive results there are many other questions that still need to be answered such as screening frequency and duration. In 2007, the California Technology Assessment Forum evaluated the use of low-dose spiral computed tomography (LDCT) screening for lung cancer. They concluded that while the use of LDCT to screen for lung cancer in high-risk populations appeared promising, there was insufficient published evidence to recommend the use of LDCT outside of the investigational setting. Since the 2007 technology assessment, two randomized controlled trials (RCTs) were selected for review that examined the effectiveness of screening high-risk individuals for lung cancer using LDCT compared to chest x-ray.
Articles: The following studies were critically appraised: National Lung Screening Tral (NLST). Reduced lung-cancer mortality with computed tomographic screening. *N Engl J Med 2011.* [Epub ahead of print] See Evidence Table Infante M, Cavuto S, Lutman FR, et al. A randomized study of lung cancer screening with spiral computed tomography: three-year results from the DANTE trial. *Am J Respir Crit Care Med 2009;* 180:445. See Evidence Table

The use of CT Scanning in the screening of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* 2 for effectiveness of diagnostic test.

Low-Dose CT Screening for Lung Cancer
10/15/2012: MTAC REVIEW
Evidence Conclusion: The Danish Lung Cancer Screening (DLCST), a RCT that included 4,104 participants, examined whether screening high-risk individuals yearly with LDCT would reduce lung cancer mortality compared to usual care (no screening). Results from this trial suggest that after 5 years of screening, LDCT did not reduce lung cancer mortality or all-cause mortality compared to usual care. Significantly more lung cancers were diagnosed in the screening group compared to the control group (69 vs. 24, P<0.001), and more were early stage (48 vs. 21, P=0.002). There was no significant difference in the number of late stage lung cancer (21 vs. 16, P=0.51). The diagnostic false positive rate was 7.9% at baseline, 1.7% at year 1, 2.0% at year 2, 1.6% year 3, and 1.9% year 4. One limitation of this trial is that the sample size may be insufficient and the duration of follow-up may not be long enough to detect a reduction in mortality (Saghir 2012) The Multicentric Italian Lung Detection (MILD), a RCT that included 4,099 participants, examined whether screening high-risk individuals yearly or every two years with LDCT would reduce lung cancer mortality compared to usual care (no screening). Results from this trial suggest that after 5 years of follow-up, annual or biennial screening with LDCT did not reduce lung cancer mortality compared to usual care. The incidence of lung cancer was significantly higher in LDCT screening groups compared to the control group (P=0.025), but not in the annual versus the biennial groups (P=0.24). Due to recruitment issues the trial may be underpowered to detect differences in mortality. Additionally, at baseline more subjects in the control group were current smokers (Pastorino 2012). Conclusion: Results from the NLST suggest that screening high-risk patients with LDCT annually for three years may reduce lung-cancer mortality; however, despite these positive results there are many other questions that still need to be answered such as screening frequency and duration, and the effects of cumulative radiation exposure. Results from other RCTs have not shown a mortality benefit; however, these trials may be underpowered.
Articles: Low-dose CT screening for lung cancer was previously reviewed in 2001 and 2011. Since the 2011 review, two randomized controlled trial were identified that assessed the benefits and harms of screening for lung cancer using low-dose CT in high risk patients. The following studies were critically appraised: Saghir Z, Dirksen A, Ashraf H, et al. CT screening for lung cancer brings forward early disease. The randomized Danish Lung Cancer Screening Trial: status after five annual screening rounds with low-dose CT. *Thorax.* 2012; 67:296-301. See Evidence Table Pastorino U, Rossi M, Rosato V, et al. Annual or biennial CT screening versus observation in heavy smokers: 5-year results of the MILD trial. *Eur J Cancer Prev.* 2012; 21:308-315. See Evidence Table

The use of CT Scanning in the screening of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* 2 for effectiveness of diagnostic test.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT® or HCPC Codes	Description
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)
Diagnosis Codes	**Description**
Z87.891	Personal history of nicotine dependence
F17.210	Nicotine dependence, cigarettes, uncomplicated
F17.211	Nicotine dependence, cigarettes, in remission
F17.213	Nicotine dependence, cigarettes, with withdrawal
F17.218	Nicotine dependence, cigarettes, with other nicotine-induced disorders
F17.219	Nicotine dependence, cigarettes, with unspecified nicotine-induced disorders

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Date Created	Date Reviewed	Date Last Revised
12/28/2001	05/03/2011[MDCRPC], 08/02/2011[MDCRPC], 09/06/2011[MDCRPC], 07/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013 [MPC], 07/01/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC] , 02/02/2021[MPC],02/01/2022[MPC],02/07/2023[MPC]	12/07/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
11/04/2014	MPC adopted the USPSTF guidelines for lung cancer screening
05/05/2015	Age limits were changed to align with Medicare: • Ages 75 through 77 • Ages 78 and over
11/17/2015	Changed Medicare link
08/26/2021	Updated link under Medicare Local Coverage Article section
12/07/2021	MPC approved to adopt the modifications to the current Low Dose CT Cancer Screening to align with updated recommendations from the USPSTF. Requires 60-day notice, effective 03/01/2022.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Low Level Laser Therapy for Pain

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Laser Procedures (140.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Low level laser therapy (LLLT) is a non-invasive therapeutic option which uses low intensity light at a wavelength ranging from 540 to 830 nm. LLLT produces photochemical reactions and enhance the metabolism of cells. The photochemical reactions change the permeability of cell membrane, increase accumulation of mRNA and result in cell proliferation. After the light is applied, there is activation of photoacceptors, located in the mitochondria, followed by protein synthesis (through several mechanisms). The process reduces pain, causes anti-inflammatory effects, cell proliferation, neovascularization, and balancing immune system. LLLT uses photons at a non-thermal radiation and does not produce heat. In addition, no destruction of the surrounding tissue is reported. Since the density of LLLT is inferior to 5.0 W/cm2, the technique is also called cold laser. (Rayegani, Raeissadat, Heidari, & Moradi-Joo, 2017).

Low-level light with different wavelengths is applied to a specific site. This is followed by absorption of the light by the tissue. The red or infrared light causes the photochemical response and regeneration described above. The wavelengths vary between 600 to 700 nm for small penetration and 780 to 950 nm for more profound penetration. The procedure is short, and no pain, sound, vibration or heat is generated. (https://www.healthline.com/health/cold-laser-therapy#procedure).

The clinical application of low-level laser therapy is broad, but it's mainly used for pain reduction. The current review will focus on knee pain (osteoarthritis/musculoskeletal disorders), painful diabetic neuropathy, and carpal tunnel syndrome.

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The incidence and prevalence of osteoarthritis vary and depend on its definition. In the United States, its incidence is lower in African Americans than Caucasians (Nelson, 2018). Based on United States data ranging from 2007 to 2008, 7% of adults over age 25 had symptomatic knee osteoarthritis (Nelson, 2018). Knee osteoarthritis (KOA) is a degenerative disease characterized by gradual loss of cartilage.
Symptoms of KOA include pain, limited range of motion, bony swelling, deformity, instability, disability, and reduced quality of life. The diagnosis is clinical; imaging can be performed if the diagnosis is not clear. Conservative therapy includes exercise therapy, non-steroidal anti-inflammatory drugs (NSAIDs), and low-level laser therapy (LLLT) (Stausholm et al., 2019).

Carpal tunnel syndrome is characterized by tingling, pain, even numbness in the wrist/hand. It is the result of compression of the median nerve.

Medical Technology Assessment Committee (MTAC)

12/20/2010: MTAC Review

Lower Level Laser Therapy for Pain

Evidence Conclusion: *Back pain* **-** A meta-analysis of 7 RCTs that included 384 participants assessed the effects of LLLT in patients with non-specific low-back. Because the studies included in the meta-analysis were heterogeneous with respect to population, intervention, and comparison group, it is difficult to draw conclusions on the clinical effect of LLLT for low back pain (Yousefi-Nooraie 2008). A double-blind RCT that included 80 participants was conducted after the meta-analysis and compared the effectiveness of LLLT on pain and functional capacity in patients with acute and chronic low back pain caused by lumbar disc herniation (LDH). Patients were randomized to one of four treatment groups: LLLT + hot pack (acute back pain), placebo LLLT + hot pack (acute back pain), LLLT + hot pack (chronic back pain), and placebo LLLT + hot pack (chronic back pain). After treatment, there were statistically significant improvements in pain, range of motion, and disability in all groups with respect to all outcome parameters. However, there was no statistically significant difference between the four treatment groups for any of the treatment parameters. This study had several limitations. The sample size may have been too small to detect between group differences and the follow-up duration was only 3 weeks (Ay 2010). *Neck pain* - A recent meta-analysis of 16 RCTs that included 820 participants assessed the safety and efficacy of LLLT in treating acute and chronic neck pain. Subjects with acute neck pain who were treated with LLLT were significantly more likely to experience an improvement in pain compared to subjects treated with placebo (RR 1.69, 95% CI 1.22 to 2.33). Patients with chronic neck pain treated with LLLT also experienced greater reductions in pain compared to patients receiving placebo (WMD 19.86, 95% CI 10.04 to 29.68). Results from this analysis also suggest that the effects of treatment may last as long as 22 weeks. Side-effects included tiredness, nausea, headache, and increased pain. Side-effects were generally mild and did not differ from those in the placebo group. Trials included in the meta-analysis were small RCTs that were heterogeneous with respect to laser parameters, application technique, and intended rationale for treatment (Chow 2009).A small double-blind RCT that included 60 participants investigated the clinical effects of LLLT in patients with acute neck pain with radiculopathy. Results from this study suggest that compared to placebo, patients treated with LLLT experienced significantly greater improvements in arm pain, disability, and neck mobility. There was no significant difference in neck pain between the two groups. All adverse events occurred in the LLLT group and included: transitional worsening of pain (6/30), persistent nausea (1/30), and increased blood pressure (1/30). Results from this study are generalizable to patients with acute neck pain with radiculopathy with severe levels of pain and moderate to severe levels of disability (Konstantinovic 2010). *Carpal tunnel syndrome* **- LLLT vs. placebo** A double-blind RCT that included 36 patients with mild to moderate carpal tunnel syndrome (CTS) evaluated the therapeutic effects of LLLT versus placebo for the treatment of CTS. The primary outcome measures included: pain, grip strength, symptom severity, functional status, and motor and sensory peak latency. After treatment there was no significant differences between LLLT and placebo for any of the outcomes except for pain. Patients who were treated with LLLT experienced a greater reduction in pain compared to patients treated with placebo. However, after 2 weeks of follow-up, patients who received LLLT showed significant improvement in pain, symptom severity, functional status, and grip strength. There was no significant difference in sensory peak latency or motor latency between the groups after treatment or after 2 weeks of follow-up. This was a small trial with a short duration of follow-up (Chang 2008). Another RCT that included 81 patients and compared LLLT to placebo found no significant difference with regard to pain and functional capacity between the two treatment groups after 12 weeks of follow-up (Evcik 2007). **LLLT vs. ultrasound** An RCT that included 50 patients with mild to moderate CTS (90 wrists) compared the efficacy of LLLT and ultrasound for the treatment of CTS. Results from this study suggest that compared to patients treated with LLLT, patients treated with ultrasound showed significant improvements in pain, pinch strength, grip strength, and electroneurographic measurements (Bakhtiary 2004). **Splinting vs. splinting + ultrasound vs. splinting + LLLT** A recent RCT that included 100 wrists of patients with mild to moderate CTS investigated the effectiveness of splinting, ultrasound, and LLLT for the management of CTS. The primary outcome measures were symptom severity, functional status, pain, median

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nerve sensory velocity, and median nerve motor distal latency. For all measurements, the combination of a splint plus ultrasound or LLLT was significantly better than the use of a splint alone. Patients who were treated with a splint plus LLLT experience significantly greater reductions in pain and symptom severity compared to patients treated with a splint plus ultrasound. Results from this study should be interpreted with caution as power was not addressed, it was not stated if an ITT analysis was performed, 4 patients did not finish therapy, 6 patients were lost to follow-up, and splint compliance was not addressed (Dincer 2009). *Conclusion:* There is insufficient evidence to determine the safety and efficacy of LLLT for the treatment of: Low back pain, Neck pain, and Carpal tunnel syndrome

Articles: A meta-analysis of RCT and an RCT published after the meta-analysis were identified that addressed the safety and efficacy of LLLT for the treatment of low back pain. The literature search also revealed a meta-analysis and RCT that looked at LLLT for the treatment of neck pain. Several RCT were identified that addressed the efficacy of LLLT for the treatment of carpal tunnel syndrome. Trials were selected for review if they had more than 25 participants and compared LLLT alone or in combination with another therapy to placebo or another active treatment. The following studies were critically appraised: Ay S, Doğan SK, and Evcik D. Is low-level laser therapy effective in acute or chronic low back pain? *Clin Rheumatol 2010;* 29:905-910. See Evidence Table**.** Bakhtiary AH and Rashidy-Pour A. Ultrasound and laser therapy in the treatment of carpal tunnel syndrome. *Aust J Physiother 2004;* 50:147-151. See Evidence Table**.** Chang WD, Wu JH, Jiang JA, et al. Carpal tunnel syndrome treated with a diode laser: a controlled treatment of the transverse carpal ligament. *Photomed Laser Surg 2008;* 26:551-557. See Evidence Table**.** Chow RT, Johnson MI, Lopes-Martins RAB, et al. Efficacy of low-level laser therapy in the management of neck pain: a systematic review and meta-analysis of randomized placebo controlled, or active-treatment controlled trials. *Lancet 2009;* 374:1894-1908. See Evidence Table**.** Dincer U, Cakar E, Kiralp MZ, et al. The effectiveness of conservative treatments of carpal tunnel syndrome: splinting, ultrasound, and low-level laser therapies. *Photomed Laser Surg 2009;* 27:119-125. See Evidence Table**.** Konstantinovic LM, Cutovic MR, Milovanovic AN, et al. Low-level laser therapy for acute neck pain with radiculopathy: a double-blind placebo-controlled randomized study. *Pain Med 2010;* 11:1169-1178. See Evidence Table**.** Yousefi-Nooraie R, Schonstein E, Heidari K, et al. Low-level laser therapy for nonspecific low-back pain. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No. CD005107.DOI: 10.1002/14651858. CD005107.pub4. See Evidence Table.

The use of low-level laser therapy for pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

01/13/2020: MTAC Review
Lower Level Laser Therapy for Pain
Evidence Conclusion:

- Low evidence supports the effectiveness (reduction of pain and disability) of LLLT (with or without exercise therapy) in patients with knee osteoarthritis compared to placebo/sham.
- There is insufficient evidence to assess the safety of LLLT in patients with knee osteoarthritis or musculoskeletal disorders.
- There is also insufficient evidence to compare LLLT versus physical therapy or NSAIDs.
- The evidence is insufficient to assess quality of life.
- There is insufficient evidence to assess the effectiveness and safety of LLLT in patients with painful diabetic neuropathy.
- Low evidence indicates that LLLT may be more effective than placebo on the short-term, but there is insufficient evidence to compare LLLT vs ultrasound or as adjunct to other treatment for patients with carpal tunnel syndrome.

Articles: PubMed was searched through January 3, 2020. Search terms included Low level laser therapy OR LightForce OR Cold laser treatment OR cold laser therapy OR LLLT AND with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Filters included meta-analysis and randomized controlled trials. The search yielded several articles. The following articles (under summary) were reviewed. See Evidence Table.

The use of low-level laser therapy for pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/20/2010	02/10/2011[MDCRPC] ,12/06/2011[MDCRPC],10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/04/2019	Removed MCG A-0511 for clinical guidelines
03/03/2020	Added January 2020 MTAC review; MPC approved to retain existing non-coverage policy for LLT.
09/01/2020	Added CPT code 0552T

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KAISER PERMANENTE®

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Clinical Review Criteria
Lower Limb Prosthesis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Lower Limb Prosthesis (L33787)
Local Coverage Article	Lower Limb Prostheses (A52496)

For Non-Medicare Members

Kaiser Permanente has elected to use the Lower Limb Prosthesis (KP-0487) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist, including the Prosthetics & Orthotics practitioner

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A large number of lower limb prosthetic designs are now available. The choice of the most appropriate prosthetic depends on factors such as amputation level, height, weight, and activity level of the amputee. Prosthetics fall mainly under two broad functional groups: non-microprocessor-controlled prosthetics and microprocessor-controlled prosthetics. The normal gait cycle is comprised of the stance phase, the period when the leg is on the ground, and the swing phase, the period when the leg is off the ground. Non-microprocessor-controlled prosthetics incorporate friction, pneumatic, or hydraulics in the joint to control the swing and stance phases of gait. While they have helped amputees gain mobility these prosthetics have limitations. Prosthetics that utilize friction to control the swing phase can only be adjusted for one walking speed. Pneumatic and hydraulics prosthetics allow amputees to change their walking speed; however, these prosthetics do not incorporate adaptive stance phase control. The lack of adaptive stance phase control requires the amputee to lock the knee mechanism in full extension during stance to avoid buckling. The limitations of the non-microprocessor-controlled prosthetics result in gait asymmetries which may contribute to problems such as increased energy expenditure and secondary disabilities.

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Microprocessor-controlled prosthetics incorporate sensors that measure angles and movement every 20 millisecond and alter the damping of the hydraulic unit for each phase of gait. This technology is intended to normalize the swing and stance phase of gait over a wide range of walking speeds. Potential benefits of this technology include: decreased effort in walking, improved gait symmetry, reduced need for muscular compensation on the contralateral limb, fewer falls, and more stable gait on uneven terrain, ramps, inclines, and stairs (Berry 2009, Segal 2006).

C-leg® is a microprocessor-controlled knee joint system with hydraulic stance and swing phase control. In 1999, C-Leg® (Otto Block Healthcare, Duderstadt, Germany) received FDA approval.

Medical Technology Assessment Committee (MTAC)

Lower Limb Prosthesis

08/11/2004: MTAC REVIEW

Evidence Conclusion: The few studies published in peer-reviewed journals, included a small number of selected active participants, and do not provide sufficient evidence on effectiveness of the microprocessor-controlled lower limb prosthesis.

Articles: The search yielded 32 articles. The majority dealt with the technical aspects and mechanisms of action of the prostheses. The search did not reveal any randomized controlled trials. There was a pilot study (N=10) that compared the cognitive demand of walking using the intelligent prosthesis with the conventional damped knees. Another open crossover study of six amputees that compared the gait symmetry, energy expenditure, and patient impressions of the intelligent prosthesis to the standard pneumatic swing-phase control knee was also identified. The other reports/studies revealed by the search were small descriptive case series with less than 25 participants. None of the articles was selected for critical appraisal.

The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/07/2006: MTAC REVIEW

Lower Limb Prosthesis

Evidence Conclusion: The few studies published in peer-reviewed journals, included small numbers of participants, and do not provide sufficient evidence to determine the effectiveness and benefit of the microprocessor-controlled lower limb prosthesis.

Articles: The search yielded 43 articles. The majority dealt with the technical aspects and mechanisms of action of the prostheses. The search identified one recent (Klute 2006) * small randomized controlled that compared the functional mobility and daily activity level of microprocessor-controlled hydraulic knee vs. the non-microprocessor hydraulic knee. Eighteen transfemoral amputees agreed to enroll in the study, but the majority withdrew before randomization. Eight amputees were randomized, and only five completed the trial. The other reports/studies revealed by the search were small comparative non-randomized studies or case series with less than 10 participants each. *None of the articles were selected for critical appraisal.*

The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW

Lower Limb Prostheses

Evidence Conclusion: *Energy expenditure* - Two studies investigated the use of microprocessor-controlled prosthetics and non-microprocessor-controlled prosthetics with respect to energy expenditure. Both studies used a non-randomized, non-blinded cross-over design. The first study found no significant difference in energy efficiency; however, there was an increase in physical activity related energy expenditure when subjects used the microprocessor-controlled prosthetic (Kaufman 2008). The second study compared energy expenditure at self-selected typical and fast walking paces on a motorized treadmill. There was no significant difference in heart rate at either pace; however, when subjects used the microprocessor-controlled prosthetic there was a small, but statistically significant decrease in energy expenditure (Seymour 2007). *Walking speed and dynamics* - Seymour and colleagues also found that on a standardized walking obstacle course when subjects wore the microprocessor-controlled prosthetic they were significantly faster, took less steps, and had less step-offs than when they used the non-microprocessor-controlled prosthetic (Seymour 2007). Another study found that when subjects wore the microprocessor-controlled prosthetic walking speeds on a variety of surfaces improved and self-reported falls and stumbles decreased (Kahle 2008). Significant improvements in stair decent, hill decent time, hill affected side step length, and falls/stumbles were also found when subjects used a microprocessor-controlled prosthetic compared to when they used a mechanical prosthetic (Hafner 2007). Additionally, after

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receiving the microprocessor-controlled limb, subjects demonstrated significant improvements in gait and balance (Kaufman 2007). *Preference* - In a survey of 368 amputees, the majority of participants reported improvements with the microprocessor-controlled prosthetic compared to the non-microprocessor-controlled prosthetic with regard to comfort, security, maneuverability, cosmetic attributes, adverse events, and safety (Berry 2009). The prosthesis evaluation questionnaire (PEQ) measures subjective prosthesis function and prosthesis-related quality of life. Three studies found improvement in PEQ scores when subjects used the microprocessor-controlled prosthetic (Hafner 2007, Kahle 2008, Kaufman 2008).
Conclusion: As the majority of the published studies to date are small and non-randomized it is hard to draw firm conclusions regarding the superiority of microprocessor-controlled prosthetics compared to non-microprocessor-controlled prosthetics; however, results from the above studies suggest that the microprocessor-controlled prosthetics decreased energy expenditure, improved walking speed and dynamics, and improved PEQ scores.
Articles: The literature search revealed several studies that compared non-microprocessor-controlled prosthetics and microprocessor-controlled prosthetics. The majority of the studies were small comparative non-randomized studies or case series with less than 20 participants. Studies with more than 10 participants were reviewed. One randomized trial was identified; however, it was not selected for review as it included only 8 participants.
The following studies were critically appraised: Berry D, Olson MD, and Larntz K. Perceived stability, function, and satisfaction among transfemoral amputees using microprocessor and non-microprocessor-controlled knees: a multicenter survey. *J Prosthet Orthot 2009;* 21:32-42. See Evidence Table. Hafner BJ, Willingham LL, Buell NC, et al. Evaluation of function, performance, and preference as transfemoral amputees' transition from mechanical to microprocessor control of the prosthetic knee. *Arch Phys Med Rehabil 2007;* 88:207-217. See Evidence Table. Kahle JT, Highsmith MJ, and Hubbard SL. Comparison of non-microprocessor knee mechanism versus C-Leg® on prosthesis evaluation questionnaire, stumbles, falls, walking tests, stair descent, and knee performance. *J Rehabil Res Dev 2008;* 45:1-14. See Evidence Table. Kaufman KR, Levine JA, Brey RH, et al. Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. *Gait Posture 2007;* 26:489-493. See Evidence Table. Kaufman KR, Levine JA, Brey RH, et al. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. *Arch Phys Med Rehabil 2008;* 89:1380-1385. See Evidence Table. Seymour R, Engbreston B, Kott K, et al. Comparison between C-Leg® microprocessor-controlled prosthetic knee and non-microprocessor controlled prosthetic knees: a preliminary study of energy expenditure, obstacle course performance, and quality of life survey. *Prosthet Orthot Int 2007;* 31:51-61. See Evidence Table.

The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
L5010	Partial foot, molded socket, ankle height, with toe filler
L5020	Partial foot, molded socket, tibial tubercle height, with toe filler
L5050	Ankle, Symes, molded socket, SACH foot
L5060	Ankle, Symes, metal frame, molded leather socket, articulated ankle/foot
L5100	Below knee (BK), molded socket, shin, SACH foot
L5105	Below knee (BK), plastic socket, joints and thigh lacer, SACH foot
L5150	Knee disarticulation (or through knee), molded socket, external knee joints, shin, SACH foot
L5160	Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee joints, shin, SACH foot
L5200	Above knee (AK), molded socket, single axis constant friction knee, shin, SACH foot
L5210	Above knee (AK), short prosthesis, no knee joint (stubbies), with foot blocks, no ankle joints, each
L5220	Above knee (AK), short prosthesis, no knee joint (stubbies), with articulated ankle/foot, dynamically aligned, each
L5230	Above knee (AK), for proximal femoral focal deficiency, constant friction knee, shin, SACH foot
L5250	Hip disarticulation, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
L5270	Hip disarticulation, tilt table type; molded socket, locking hip joint, single axis constant friction knee, shin, SACH foot
L5280	Hemipelvectomy, Canadian type; molded socket, hip joint, single axis constant friction knee, shin,

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	SACH foot
L5301	Below knee (BK), molded socket, shin, SACH foot, endoskeletal system
L5312	Knee disarticulation (or through knee), molded socket, single axis knee, pylon, SACH foot, endoskeletal system
L5321	Above knee (AK), molded socket, open end, SACH foot, endoskeletal system, single axis knee
L5331	Hip disarticulation, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
L5341	Hemipelvectomy, Canadian type, molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
L5400	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment, suspension, and one cast change, below knee (BK)
L5410	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, below knee (BK), each additional cast change and realignment
L5420	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast change above knee (AK) or knee disarticulation
L5430	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, above knee (AK) or knee disarticulation, each additional cast change and realignment
L5500	Initial, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, direct formed
L5505	Initial, above knee (AK), knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, direct formed
L5510	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5520	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5530	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5535	Preparatory, below knee (BK) PTB type socket, nonalignable system, no cover, SACH foot, prefabricated, adjustable open end socket
L5540	Preparatory, below knee (BK) PTB type socket, nonalignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5560	Preparatory, above knee (AK), knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5570	Preparatory, above knee (AK), knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5580	Preparatory, above knee (AK), knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5585	Preparatory, above knee (AK), knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, prefabricated adjustable open end socket
L5590	Preparatory, above knee (AK), knee disarticulation, ischial level socket, nonalignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5595	Preparatory, hip disarticulation/hemipelvectomy, pylon, no cover, SACH foot, thermoplastic or equal, molded to patient model
L5600	Preparatory, hip disarticulation/hemipelvectomy, pylon, no cover, SACH foot, laminated socket, molded to patient model
L5610	Addition to lower extremity, endoskeletal system, above knee (AK), hydracadence system
L5611	Addition to lower extremity, endoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with friction swing phase control
L5613	Addition to lower extremity, endoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with hydraulic swing phase control
L5614	Addition to lower extremity, exoskeletal system, above knee (AK), knee disarticulation, four-bar linkage, with pneumatic swing phase control
L5616	Addition to lower extremity, endoskeletal system, above knee (AK), universal multiplex system, friction swing phase control
L5617	Addition to lower extremity, quick change self-aligning unit, above knee (AK) or below knee (BK), each
L5618	Addition to lower extremity, test socket, Symes
L5620	Addition to lower extremity, test socket, below knee (BK)

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L5622	Addition to lower extremity, test socket, knee disarticulation
L5624	Addition to lower extremity, test socket, above knee (AK)
L5626	Addition to lower extremity, test socket, hip disarticulation
L5628	Addition to lower extremity, test socket, hemipelvectomy
L5629	Addition to lower extremity, below knee, acrylic socket
L5630	Addition to lower extremity, Symes type, expandable wall socket
L5631	Addition to lower extremity, above knee (AK) or knee disarticulation, acrylic socket
L5632	Addition to lower extremity, Symes type, PTB brim design socket
L5634	Addition to lower extremity, Symes type, posterior opening (Canadian) socket
L5636	Addition to lower extremity, Symes type, medial opening socket
L5637	Addition to lower extremity, below knee (BK), total contact
L5638	Addition to lower extremity, below knee (BK), leather socket
L5639	Addition to lower extremity, below knee (BK), wood socket
L5640	Addition to lower extremity, knee disarticulation, leather socket
L5642	Addition to lower extremity, above knee (AK), leather socket
L5643	Addition to lower extremity, hip disarticulation, flexible inner socket, external frame
L5644	Addition to lower extremity, above knee (AK), wood socket
L5645	Addition to lower extremity, below knee (BK), flexible inner socket, external frame
L5646	Addition to lower extremity, below knee (BK), air, fluid, gel or equal, cushion socket
L5647	Addition to lower extremity, below knee (BK), suction socket
L5648	Addition to lower extremity, above knee (AK), air, fluid, gel or equal, cushion socket
L5649	Addition to lower extremity, ischial containment/narrow M-L socket
L5650	Additions to lower extremity, total contact, above knee (AK) or knee disarticulation socket
L5651	Addition to lower extremity, above knee (AK), flexible inner socket, external frame
L5652	Addition to lower extremity, suction suspension, above knee (AK) or knee disarticulation socket
L5653	Addition to lower extremity, knee disarticulation, expandable wall socket
L5654	Addition to lower extremity, socket insert, Symes, (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5655	Addition to lower extremity, socket insert, below knee (BK) (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5656	Addition to lower extremity, socket insert, knee disarticulation (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5658	Addition to lower extremity, socket insert, above knee (AK) (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5661	Addition to lower extremity, socket insert, multidurometer Symes
L5665	Addition to lower extremity, socket insert, multidurometer, below knee (BK)
L5666	Addition to lower extremity, below knee (BK), cuff suspension
L5668	Addition to lower extremity, below knee (BK), molded distal cushion
L5670	Addition to lower extremity, below knee (BK), molded supracondylar suspension (PTS or similar)
L5671	Addition to lower extremity, below knee (BK)/above knee (AK) suspension locking mechanism (shuttle, lanyard, or equal), excludes socket insert
L5672	Addition to lower extremity, below knee (BK), removable medial brim suspension
L5673	Addition to lower extremity, below knee (BK)/above knee (AK), custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L5676	Additions to lower extremity, below knee (BK), knee joints, single axis, pair
L5677	Additions to lower extremity, below knee (BK), knee joints, polycentric, pair
L5678	Additions to lower extremity, below knee (BK), joint covers, pair
L5679	Addition to lower extremity, below knee (BK)/above knee (AK), custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L5680	Addition to lower extremity, below knee (BK), thigh lacer, nonmolded
L5681	Addition to lower extremity, below knee (BK)/above knee (AK), custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)
L5682	Addition to lower extremity, below knee (BK), thigh lacer, gluteal/ischial, molded
L5683	Addition to lower extremity, below knee (BK)/above knee (AK), custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L5673 or L5679)

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L5684	Addition to lower extremity, below knee, fork strap
L5686	Addition to lower extremity, below knee (BK), back check (extension control)
L5688	Addition to lower extremity, below knee (BK), waist belt, webbing
L5690	Addition to lower extremity, below knee (BK), waist belt, padded and lined
L5692	Addition to lower extremity, above knee (AK), pelvic control belt, light
L5694	Addition to lower extremity, above knee (AK), pelvic control belt, padded and lined
L5695	Addition to lower extremity, above knee (AK), pelvic control, sleeve suspension, neoprene or equal, each
L5696	Addition to lower extremity, above knee (AK) or knee disarticulation, pelvic joint
L5697	Addition to lower extremity, above knee (AK) or knee disarticulation, pelvic band
L5698	Addition to lower extremity, above knee (AK) or knee disarticulation, Silesian bandage
L5699	All lower extremity prostheses, shoulder harness
L5700	Replacement, socket, below knee (BK), molded to patient model
L5701	Replacement, socket, above knee (AK)/knee disarticulation, including attachment plate, molded to patient model
L5702	Replacement, socket, hip disarticulation, including hip joint, molded to patient model
L5703	Ankle, Symes, molded to patient model, socket without solid ankle cushion heel (SACH) foot, replacement only
L5704	Custom shaped protective cover, below knee (BK)
L5705	Custom shaped protective cover, above knee (AK)
L5706	Custom shaped protective cover, knee disarticulation
L5707	Custom shaped protective cover, hip disarticulation
L5710	Addition, exoskeletal knee-shin system, single axis, manual lock
L5711	Additions exoskeletal knee-shin system, single axis, manual lock, ultra-light material
L5712	Addition, exoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
L5714	Addition, exoskeletal knee-shin system, single axis, variable friction swing phase control
L5716	Addition, exoskeletal knee-shin system, polycentric, mechanical stance phase lock
L5718	Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control
L5722	Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5724	Addition, exoskeletal knee-shin system, single axis, fluid swing phase control
L5726	Addition, exoskeletal knee-shin system, single axis, external joints, fluid swing phase control
L5728	Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5780	Addition, exoskeletal knee-shin system, single axis, pneumatic/hydra pneumatic swing phase control
L5781	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system
L5782	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy-duty
L5785	Addition, exoskeletal system, below knee (BK), ultra-light material (titanium, carbon fiber or equal)
L5790	Addition, exoskeletal system, above knee (AK), ultra-light material (titanium, carbon fiber or equal)
L5795	Addition, exoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5810	Addition, endoskeletal knee-shin system, single axis, manual lock
L5811	Addition, endoskeletal knee-shin system, single axis, manual lock, ultra-light material
L5812	Addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
L5814	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock
L5816	Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock
L5818	Addition, endoskeletal knee-shin system, polycentric, friction swing and stance phase control
L5822	Addition, endoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5824	Addition, endoskeletal knee-shin system, single axis, fluid swing phase control
L5826	Addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5830	Addition, endoskeletal knee-shin system, single axis, pneumatic/swing phase control

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L5840	Addition, endoskeletal knee-shin system, four-bar linkage or multiaxial, pneumatic swing phase control
L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5850	Addition, endoskeletal system, above knee (AK) or hip disarticulation, knee extension assist
L5855	Addition, endoskeletal system, hip disarticulation, mechanical hip extension assist
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5910	Addition, endoskeletal system, below knee (BK), alignable system
L5920	Addition, endoskeletal system, above knee (AK) or hip disarticulation, alignable system
L5925	Addition, endoskeletal system, above knee (AK), knee disarticulation or hip disarticulation, manual lock
L5930	Addition, endoskeletal system, high activity knee control frame
L5940	Addition, endoskeletal system, below knee (BK), ultra-light material (titanium, carbon fiber or equal)
L5950	Addition, endoskeletal system, above knee (AK), ultra-light material (titanium, carbon fiber or equal)
L5960	Addition, endoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5961	Addition, endoskeletal system, polycentric hip joint, pneumatic or hydraulic control, rotation control, with or without flexion and/or extension control
L5962	Addition, endoskeletal system, below knee (BK), flexible protective outer surface covering system
L5964	Addition, endoskeletal system, above knee (AK), flexible protective outer surface covering system
L5966	Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system
L5968	Addition to lower limb prosthesis, multiaxial ankle with swing phase active dorsiflexion feature
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5970	All lower extremity prostheses, foot, external keel, SACH foot
L5971	All lower extremity prostheses, solid ankle cushion heel (SACH) foot, replacement only
L5972	All lower extremity prostheses, foot, flexible keel
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source
L5974	All lower extremity prostheses, foot, single axis ankle/foot
L5975	All lower extremity prostheses, combination single axis ankle and flexible keel foot
L5976	All lower extremity prostheses, energy storing foot (Seattle Carbon Copy II or equal)
L5978	All lower extremity prostheses, foot, multiaxial ankle/foot
L5979	All lower extremity prostheses, multiaxial ankle, dynamic response foot, one-piece system
L5980	All lower extremity prostheses, flex-foot system
L5981	All lower extremity prostheses, flex-walk system or equal
L5982	All exoskeletal lower extremity prostheses, axial rotation unit
L5984	All endoskeletal lower extremity prostheses, axial rotation unit, with or without adjustability
L5985	All endoskeletal lower extremity prostheses, dynamic prosthetic pylon
L5986	All endoskeletal lower extremity prostheses, dynamic prosthetic pylon
L5987	All lower extremity prostheses, shank foot system with vertical loading pylon
L5988	Addition to lower limb prosthesis, vertical shock reducing pylon feature
L5990	Addition to lower extremity prosthesis, user adjustable heel height
L5999	Lower extremity prosthesis, not otherwise specified

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Date Created	Date Reviewed	Date Last Revised
2004	10/05/2010 MDCRPC, 12/07/2010 MDCRPC, 10/04/2011MDCRPC, 08/07/2012 MDCRPC, 02/05/2013 MDCRPC ,12/03/2013 MPC, 10/07/2014MPC, 01/06/2015MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/04/2021	Updated applicable coding.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Low Vision Aides and Devices

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Refractive Lenses (L33793)
Local Coverage Article	Refractive Lenses – Policy Article (A52499) **Low vision aids (V2600, V2610, V2615) will be denied as noncovered because coverage under the Medicare prosthetic benefit is limited to persons with congenital absence or surgical removal of the lens of the eye.*

For Non-Medicare Members

A. To qualify for low vision aides or devices a member must have best corrected vision of 20/70 or worse in the better eye with glasses or contacts on.
   1. The following codes are identified and coverable per contract for low vison aides and devices:
      - **V2600** – Handheld low vision aids and other non-specific mounted aids.
      - **V2610** – Single Lens Spectacles mounted low vision aids
      - **V2615** – Telescope and other compound lens system, including distance vision telescopic, near vision telescopic and compound microscopic lens system.
      - **92354** – Fitting of spectacle mounted low vision aid: single element system
      - **92355** – Fitting of spectacle mounted low vision aid: Telescopic or compound lens system

If requesting one or more of these items, please send the following documentation to support medical necessity:

- Clinical notes from requesting provider &/or specialist indicating corrected visual acuity

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A wide variety of rehabilitation options are available to help people with low vision live and/or work more effectively, efficiently, and safely. Most people can be helped with one or more low vision treatment options. The more commonly prescribed devices are: Handheld low vision aids and other non-spectacle mounted aids, Single lens spectacle mounted low vision aids, Telescopic and other compound lens system, including distance vision telescopic, near vision telescopes and compound microscopic lens system.

Applicable Codes

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Medicare – Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
V2600	Handheld low vision aids and other nonspectacle mounted aids
V2610	Single lens spectacle mounted low vision aids
V2615	Telescopic and other compound lens system, including distance vision telescopic, near vision telescopes and compound microscopic lens system

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
92354	Fitting of spectacle mounted low vision aid; single element system
92355	Fitting of spectacle mounted low vision aid; telescopic or other compound lens system

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/03/2013	12/03/2013[MPC], 09/16/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	09/10/2018

[MPC] Medical Policy Committee

Revision History	Description
08/04/2015	Editorial changes were made to criteria
09/10/2018	Added coverage article A52499

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Clinical Review Criteria
Laparoscopic Uterine Nerve Ablation (LUNA) for Dysmenorrhea

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Laparoscopic Uterine Nerve Ablation (LUNA) for Dysmenorrhea,” for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Laparoscopic Uterosacral Nerve Ablation (LUNA) (A-0284) MCG* for medical necessity determinations. This procedure is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Dysmenorrhea refers to painful cramping in the lower abdomen that occurs during or just before the menses. The cramping sensation is often accompanied by other symptoms, including sweating, headaches, nausea and vomiting. Dysmenorrhea is sometimes divided into two sub-categories. Primary dysmenorrhea is menstrual pain without any identifiable organic pathology and generally first occurs in women younger than 20. Secondary dysmenorrhea is menstrual pain associated with an identifiable pathological condition, such as endometriosis, cervical stenosis or pelvic adhesions, and is most often seen in women over 20 (Stenchever, 2001).

Non-steroidal anti-inflammatory drugs (NSAIDS) are the standard therapy for primary dysmenorrhea. These act by suppressing prostaglandin levels. Although the pathogenesis of primary dysmenorrhea is still not known, there

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is a close association between dysmenorrhea symptoms and an elevated level of prostaglandin F2a. Oral contraceptive pills (OCPs) are also a commonly prescribed medication treatment for primary dysmenorrhea. OCPs may relieve dysmenorrhea because of a modulating effect on the hypothalamus or a direct reduction in the amount of endometrium present (Stenchever, 2001). Treatment of secondary dysmenorrhea generally involves treating the underlying condition.

Pelvic nerve surgery can be used to treat primary dysmenorrhea that fails to respond to medical therapy and can be used in conjunction with other surgical procedures for secondary dysmenorrhea, such as operative laparoscopy for endometriosis. Laparoscopic uterine nerve ablation (LUNA) involves the use of laser or cauterization to destroy nerves in the uterosacral ligaments, at the point where they insert into the cervix. Doyle first reported that vaginal transection of the uterosacral nerves could be effective for dysmenorrhea in 1955. LUNA is generally associated with few side effects. Potential rare complications include uterine prolapse and bladder dysfunction. There is also a second type of pelvic nerve surgery, laparoscopic presacral neurectomy (LPN). This involves the total removal of the presacral nerves that lie within the boundary of the interiliac triangle and is generally believed to have more side effects than LUNA. More radical surgery, such as hysterectomy, is the treatment of last resort for patients with persistent dysmenorrhea (Proctor et al., 2006; Johnson et al., 2004).

LUNA for dysmenorrhea has not been previously reviewed for MTAC.

Medical Technology Assessment Committee (MTAC)

Laparoscopic Uterine Nerve Ablation

04/03/2006: MTAC REVIEW

Evidence Conclusion: Evidence from the two largest and highest quality RCTs (Johnson et al., 2004; Vercellini et al., 2003) suggests that laparoscopic uterine nerve ablation (LUNA) is not an effective treatment for secondary dysmenorrhea (dysmenorrhea among women with symptoms of endometriosis). The Vercellini study was limited by lack of an intention to treat analysis on pain outcomes. There is insufficient evidence to draw conclusions about laparoscopic uterine nerve ablation (LUNA) as a treatment for primary dysmenorrhea. There is evidence from only one well-done RCT comparing LUNA to a control group (Johnson et al., 2004). However, this study was designed to evaluate LUNA for pelvic pain, not specifically dysmenorrhea. The study included some women who did not present with dysmenorrhea and results were not stratified according to baseline dysmenorrhea status. There were four main pain outcomes. In addition to dysmenorrhea, these were non-menstrual pelvic pain, deep dyspareunia and dyschezia. In the intention to treat analysis, the Johnson study found one statistically significant outcome at $p<0.05$. This was reduction in dysmenorrhea, favoring the LUNA group ($p=0.045$). If the investigators had adjusted for multiple comparisons (i.e. the four primary pain outcomes), the difference in treatment success between the LUNA and control groups would not have been statistically significant.

Articles: There was a Cochrane Collaboration systematic review on surgical interruption of pelvic nerve pathways for dysmenorrhea. The Cochrane literature search identified two high-quality RCTs on LUNA for dysmenorrhea. These two RCTs, which were also identified in the Medline search, were critically appraised. The remainder of the RCTs identified by Cochrane were small and had methodological flaws. The Cochrane Collaboration investigators searched the literature through June 2004. No RCTs on LUNA for dysmenorrhea were identified that were published after the Cochrane search data. *The RCTs reviewed were* Johnson NP, Farquhar CM, Crossley S et al. A double-blind randomized controlled trial of laparoscopic uterine nerve ablation for women with chronic pelvic pain. BJOG 2004; 111: 950-959. See Evidence Table.

The use of laparoscopic uterine nerve ablation in the evaluation of dysmenorrheal does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPCS Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
04/27/2006	04/03/2006[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 02/07/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	05/03/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/03/2016	Adopted MCG guideline

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PATIENT REFERRAL GUIDELINES
Lung Transplant [i], [ii], [iii]

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Criteria

For Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for lung & heart/lung transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral, rather should be applied together with careful clinical judgment.

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for lung & heart/lung transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral, rather should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, early referral should be made.

b. Patients with a history of malignancy with moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

c. Uncontrollable active infection is a contraindication to transplant.

d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low. [4, 5, 6] Exceptions may be made on a case-by-case basis.

e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.

f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

   i. Patients must have a care giver or care givers who are physically and cognitively able to assist the patient with self- care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

   ii. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre- transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.

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g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
h. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
   i. Evidence of such non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
i. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR LUNG TRANSPLANT

a. Must meet all prerequisites listed in the General Principles section
b. Any disease state in which transplantation has become an accepted mode of treatment worldwide including
   i. Chronic obstructive pulmonary disease (COPD), which may include asthma, chronic bronchitis, emphysema and/or Alpha 1 antitrypsin deficiency
   ii. Idiopathic pulmonary fibrosis
   iii. Sarcoidosis
   iv. Connective tissue disease-related pulmonary fibrosis
   v. Eosinophilic granulomatosis
   vi. Bronchiectasis
   vii. Cystic fibrosis (CF)
   viii. Pulmonary hypertension (both primary and secondary)
   ix. Lymphangiomyomatosis (LAM)
   x. Interstitial lung disease not otherwise defined.
c. Patients should be referred for transplant evaluation by a pulmonologist or a cardiologist who has accumulated data defining both the disease as potentially treatable by transplantation and progression is occurring despite maximal medical therapy.
d. Early referral is strongly encouraged for progressive lung disease with a poor prognosis[7]
e. Ideally, the patient should be ambulatory with rehabilitation potential.

3. CONTRAINDICATIONS FOR LUNG TRANSPLANT

a. Must meet all prerequisites listed in the General Principles section
b. Invasive mechanical ventilator support[8].
c. Unresolved infection (except in cystic fibrosis and bronchiectasis).
d. Uncontrolled chronic infection (i.e., HIV with detectable viral load)
e. Other systemic diseases including but not limited to:
   i. Diabetes with end organ effects; i.e., renal, cardiac or uncorrectable peripheral vascular disease. Insulin use itself is not a contraindication.
   ii. Uncontrolled hypertension.
   iii. Significant neurologic disease impairing cognitive function.
   iv. Malnutrition [9]
   v. Obesity >140% ideal body weight or BMI >32 kg/m2 [10, 11](with an understanding that a BMI <30 may be necessary for transplantation).
      1. May wish to consider initiating transplant workup if patient has pulmonary fibrosis and BMI >32 (but <34) if showing willingness to lose weight.
   vi. Advanced hepatic dysfunction.
   vii. Advanced renal dysfunction (creatinine clearance < 50 ml/min. after maximum therapy). However, patients with underlying cardiopulmonary causes of low creatinine clearance can be considered for transplant on a case-by-case basis.
   viii. Evidence of clinically significant obstructive coronary artery disease and/or LVEF <40%. [12]
   ix. Active or unresolved peptic ulcer disease.
   x. Chronic opiate use: Patients should be seen by a pain management specialist for alternative forms of therapy.
   xi. Uncorrectable bleeding diathesis or clotting disorder

RELATIVE CONTRAINDICATIONS

a. Patients with previous thoracotomy and/or sclerosing procedures should be considered on a case by case basis.

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b. Systemic corticosteroid therapy >10 mgs prednisone daily.
c. Esophageal dysmotility and reflux. Surgical repair may be necessary.[13]
d. Age >70 for lung transplant referral.
e. Symptomatic osteoporosis.
f. Major mechanical chest deformity (such as kyphoscoliosis).
g. Short stature patients (in USA 4'11" for females and 5'4" for males) are significantly disadvantaged and early consideration of multiple listing is encouraged.

PATIENT PROFILE FOR COMMON DIAGNOSES LUNG TRANSPLANT REFERRAL GUIDELINES

Any or all of the listed guidelines for each disease entity should raise consideration for lung transplantation evaluation. Clinical correlation is always of primary importance.

1. GROUP A – Obstructive Lung Disease [14, 15] (See Table 1 Below)
    1. FEV1 < 25 %
    2. DLCO < 40%
    3. Hypoxemia; PO2 < 55
    4. Hypercapnia; PCO2> 51[16]
    5. Bode Index > 5
2. GROUP B – Pulmonary Arterial Hypertension (See Table 1 Below)[17, 18, 19]
    a. Patients with clinically significant PAH should be evaluated by physicians experienced in treating pulmonary hypertension and have received maximum available pharmacological treatment.
    b. Possible indications for referral include:
        i. Pericardial Effusion[20]
        ii. World Health Organization (WHO) (New York Heart Association) class 3 or 4
        iii. Lack of improvement in WHO Class 3 or 4 and/or lack of improvement in 6-minute walk test of < 350 meters, despite maximum pharmacological therapy.
    c. Definite indications, after maximum pharmacologic treatment for referral include: [21]
        i. Mean RA > 15 mmHg
        ii. Cardiac Index < 2L per minute. Untreated, the mean survival for patients with these criteria is 10-11 months.

GROUP C – Cystic Fibrosis [22](See table 1 Below)

a. FEV1 < 40%
b. PO2 < 55
c. Clinical deterioration, especially in young female patients, as characterized by increasing number of hospitalizations, including recurrent pneumothoraxes, rapid fall of FEV1, recurrent major hemoptysis uncontrolled by embolization and/or increasing cachexia should prompt consideration for transplant referral.
d. PCO2 > 51
e. Patients with Burkholderia cepacia have a relative contraindication.

GROUP D – Restrictive Lung Disease) 22, [23](See Table 1 Below)

a. Force Vital Capacity < 80%[22]
b. Decline in Forced Vital Capacity of ≥10% and/or decline in DLCO ≥ 15% during 6 months of follow-up[22]
c. Diffusing Capacity (corrected for alveolar volume) < 60%
d. Evidence of interstitial lung disease on HRCT in conjunction with one or more of the above.

Referral to lung transplant program should be considered when a definitive diagnosis of usual interstitial pneumonitis (UIP) or idiopathic pulmonary fibrosis (IPF) is made and may be considered for the diagnosis of fibrotic nonspecific interstitial pneumonitis (NSIP).

OTHER CONDITIONS

Other conditions for which transplant may be appropriate include the Lung diseases described ~~in~~ Table 1 below.[24]

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Table 1: Lung allocation score (LAS) primary diagnostic groupings for lung transplant candidates

LAS lung disease diagnosis grouping	
Group A (obstructive lung disease)	• Chronic obstructive pulmonary disease (COPD), with or without alpha-1-anti deficiency, due to chronic bronchitis and or emphysema • Lymphangioleiomyomatosis (LAM) • Bronchiectasis, including primary ciliary dyskinesia • Sarcoidosis with a mean pulmonary artery (PA) pressure ≤30 mmHg
Group B (pulmonary vascular disease)	• Idiopathic pulmonary arterial hypertension (iPAH, formerly known as primary hypertension [PPH]) • Eisenmenger's syndrome • Other pulmonary vascular diseases
Group C (cystic fibrosis or immunodeficiency disorders)	• Cystic fibrosis (CF) • Immunodeficiency disorders such as hypogammaglobulinemia
Group D (restrictive lung disease)	• Idiopathic pulmonary fibrosis (IPF) • Pulmonary fibrosis due to other causes • Sarcoidosis with mean PA pressure >30 mmHg • Obliterative bronchiolitis (nonretransplant)

Source: Revision to policy 3.7.6.1.

ADDENDUM

GUIDANCE FOR LUNG TRANSPLANT FOR IRREVERSIBLE PULMONARY FAILURE FROM COVID-19

Background: Transplant has been successful for other conditions, including infections, that lead to irreversible pulmonary failure, so this disease has some familiar aspects within the lung transplant community. Because of the specific conditions surrounding the effects of SARS-C0V-2, and because much of the mechanism underlying the development of lung injury and recovery are still unclear, the following elements are recommended for any consideration for referral of and authorizations for potential candidates for lung transplant. The below represent elements, *IN ADDITION TO THE USUAL CRITERIA PROVIDED IN THE CMS LUNG PATIENT REFERRAL GUIDELINES:*

1. Age under 65 if ECMO has been used as bridge to transplant
2. Disease has progressed in spite of maximal non-invasive ventilatory support
3. No other significant organ dysfunction exists
4. Sufficient time for recovery must be allowed: once on invasive mechanical support or ECMO, referral should not be considered fewer than 4-6 weeks after ventilator-dependent or ECMO-supported pulmonary failure
5. Patients on prolonged 0_2 therapy other than mechanical support or ECMO should be given sufficient time to determine irreversibility of the condition (usually three months) and should be ambulatory with good opportunity for rehabilitation.
6. Evidence of irreversible lung disease (bullae, fibrosis) must be present
7. The ability to gain patient, not surrogate, approval for transplant is an essential ethical concept in light of the relatively poor long-term outcomes from lung transplant
8. Ability to do adequate pulmonary rehabilitation while on support for respiratory failure
9. Have 2 negative SARS-COV-2 PCR tests at least 24 hours apart with one of the samples being a deep respiratory specimen.
10. Transplants should be performed only at lung transplant programs experienced in the highest risk lung transplants including familiarity with transplanting patients with ECMO bridging to transplant. Furthermore, they should have:
    a. Broad donor pool (represented by low time to transplant measures), and
    b. Low wait-list mortality

Reference: Cypel M, Keshavjee S. Comment When to consider lung transplantation for COVID-19. Lancet Respir Med. 2020;8:944–6. https://doi.org/10.1016/S2213-2600(20)30393-3 .

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ISHLT guidance https://ishlt.org/ishlt/media/documents/SARS-CoV-2_Guidance-for-Cardiothoracic-Transplant-and-VAD-center.pdf

Footnotes

1. See Addendum 1, New system for lung allocation (enclosed)
2. Orens, JB, et al, 'International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation', *Journal of Heart and Lung Transplantation*, 25(7), July 2006, 745-755.
3. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2015; 34:1–15
4. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
5. *Liver Transplant Surg,*. 1997, Vol 3, 304 – 310.The natural history of alcoholism and its relationship to liver transplantation.
6. 6. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
7. J Thorac Dis. 2019 Sep; 11(Suppl 14): S1708–S1720.
8. Under acceptable case-by-case circumstances, a patient who has been listed for a lung transplant and previously ambulatory, and now requires mechanical ventilation, may still be a potential candidate for lung transplantation. Patients who have been listed for lung transplant, and require invasive mechanical ventilation, can remain on the transplant list provided that there remains rehabilitation potential. On a carefully selected case-by-case basis, patients who are on invasive mechanical support, and are ambulatory with a potential for rehabilitation, can be listed for lung transplant. *Chest 2001; 119* (1) 224-227.
9. Any disorder of nutrition causing a lack of necessary or proper food substances in the body or improper absorption and distribution of them (Taber's Cyclopedic Medical Dictionary).
10. *Journal of Heart and Lung Transplantation Vol. 18 (8), August 1999, pg 750-761*
11. *The Journal of Heart and Lung Transplantation 2010*; 29 (9), 1026 – 1033. Impact of Recipient Body Mass Index on Survival after Lung Transplantation.
12. Potential candidate for Heart/Lung transplantation will be evaluated independently.
13. Annals of Surgery, 2006. Vol.244 (4) 491-497.
14. Lung Transplantation in Advanced COPD: Is it Worth it? Semin Respir Crit Care Med. 2010 June; 31(3): 365-372; Selecting lung transplant candidates: where do current guidelines fall short? Expert Rev Respir Med. 2012 February; 6(1): 51-61.
15. Amer *Rev Respir Dis* 140: S92 and S95 1989; Ann Int Med 99: 612: 1983; *New England Journal of Medicine*,1999 340(14), 1081-91
16. Celli BR, Cote CG, Marin JM et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. N Engl J Med 2004;350:1005-12.
17. Applicable to idiopathic pulmonary arterial hypertension, familial pulmonary arterial hypertension, collagen vascular disease limited to the lungs, pulmonary veno-occlusive disease, pulmonary capillary hemangiomatosis, and drug induced pulmonary hypertension. *CHEST, 2004*, Volume 126 (Supplement 1).
18. AJRCCM 201. 184: 159-171 - Thorough review of lung transplantation; J Heart Lung Transplant. 2006. 25(7): 745-55. - Consensus report from ISHLT Pulm Circ. 2011. April-June. 1(2): 182-191 - PH and lung transplant.
19. *Transplantation*. 2010 Aug 15. 90(3): 298-305. - Suggests that 6MWD </= 300 m and RAP >/= 14 mm Hg is better predictor of wait list mortality than LAS scoring system.
20. McGoon MD and Miller DP. Eur Respir Rev. 2012; 21(123):8-18.
21. *Ann Int Med* 115: 343 1991
22. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2015; 34:1–15
23. Nathan, SD., Lung Transplantation- Disease-Specific Considerations for Referral', CHEST 2005; 127: 1006-1016.
24. OPTN Policy 10: Allocation of Lungs, 10.1.F.i Lung Disease Diagnosis Groups, Effective Date 9/1/2016

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Lung transplant is a last resort treatment for end stage lung disease. The first human transplant was conducted in 1965. The first successful single lung transplant was done in 1983.

The diseases treated by lung transplants include:

- chronic obstructive pulmonary disease (COPD), including emphysema;
- idiopathic pulmonary fibrosis;
- cystic fibrosis;
- idiopathic (formerly known as "primary") pulmonary hypertension;

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- alpha 1-antitrypsin deficiency;
- replacing previously transplanted lungs that have since failed;
- other causes, including bronchiectasis and sarcoidosis.

Prior to 2005, donor lungs were allocated by the United Network for Organ Sharing on a first-come, first-serve basis to patients on the transplant list. This was replaced by the current system, in which prospective lung recipients of age of 12 and older are assigned a lung allocation score or LAS, which takes into account various measures of the patient's health. The new system allocates donated lungs according to the immediacy of need rather than how long a patient has been on the transplant list. Patients who are under the age of 12 are still given priority based on how long they have been on the transplant waitlist. The length of time spent on the list is also the deciding factor when multiple patients have the same lung allocation score.

Patients who are accepted as good potential transplant candidates must carry a pager with them at all times in case a donor organ becomes available. These patients must also be prepared to move to their chosen transplant center at a moment's notice and relocate to within close proximity of the center. Such patients may be encouraged to limit their travel within a certain geographical region in order to facilitate rapid transport to a transplant center.

Evidence and Source Documents

The scientific literature is periodically reviewed, and patient selection criteria are updated when new efficacy data becomes available.

Kaiser Permanente Committee on Medically Emerging Technology:
Transplant, Lung, Double-7/12/91-Double lung transplantation is efficacious for appropriately selected patients.
Transplant, Lung, Single-7/12/91 Single lung transplantation is efficacious for appropriately selected patients.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass

Medicare – **Considered not medically necessary**
Non-Medicare – Considered medically necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed
0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field
0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour (List separately in addition to code for primary procedure)

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S2060	Lobar lung transplantation *S codes not covered by Medicare

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Date Created	Date Reviewed	Date Last Revised
05/1996	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 05/01/2012[MDCRPC], 03/05/2013[MDCRPC], 01/07/2014[MDCRPC], 11/04/2014 [MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC] , 03/01/2022[MPC], 03/07/2023[MPC]	01/10/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt KP National Criteria for Lung Transplant
09/03/2019	MPC approved to change General Principles 1.3 to *Uncontrollable infection is a contraindication to transplant* as recommended by KP National Transplant Services.
03/03/2020	MPC approved proposed changes from KP National Transplant Services
04/06/2021	MPC approved proposed changes from KP National Transplant Services. Requires 60-day notice, effective date September 1, 2021.
01/10/2022	MPC approved proposed changes from KP National Transplant Services. 60-day notice is not required.

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Clinical Review Criteria
Lutetium Lu 177 Dotatate (Lutathera)

- Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Lutetium Lu 177 Dotatate (Lutathera),*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Candidates must meet ALL of the following:

1) Presence of metastasized or locally advanced, unresectable (with curative intent) gastroenteropancreatic neuroendocrine tumors (GEP-NET) **and**
2) Ki-67 protein ≤ 20% (patients with higher-grade disease need to be evaluated on case-by-case basis) **and**
3) Progressive disease under somatostatin analog therapy (SSA) **and**
4) At least 18 years of age **and**
5) Target lesions overexpressing somatostatin receptors as demonstrated on ^{68}Ga-DOTATATE PET/CT scan within last 3 months **and**
6) Monitoring labs must be conducted within the first 4 weeks of injection (baseline); 4-6 weeks after each Lutathera injection and 2 days prior to subsequent Lutathera injections

Contraindications:

1) Women who are or may be pregnant, as this agent can cause fetal harm when administered to a pregnant woman (pregnancy category X) **or**
2) Women who are breast feeding **or**
3) Pediatric patients (<18 years of age)

Lutathera Therapy is not covered when:

1) Recent surgery, radioembolization, chemoembolization, radiofrequency ablation or chemotherapy within 4 weeks prior to initiation of Lutathera treatment.
2) Known brain metastases unless these metastases have been treated and stabilized.
3) Uncontrolled congestive heart failure (NYHA II, III, IV)
4) Treatment with *short-acting* somatostatin analog therapy (SSA) that cannot be interrupted for 24 hours before Lutathera administration, or treatment with *long-acting* (LAR) somatostatin analog therapy SSA that cannot be interrupted for at least 4 weeks before initiation of Lutathera

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a) Patient may go on short acting somatostatin analog therapy (SSA) as a bridge between LAR injection and Lutathera treatment, but this must be stopped 24 hrs. before Lutathera treatment.
5) Prior external beam radiation therapy to >25% of the bone marrow.
6) Current spontaneous urinary incontinence making it unsafe to administer Lutathera

Please click here to view clinical criteria for PET Scan: Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)

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Background

Gastroenteropancreatic neuroendocrine tumors are rare. It is estimated that approximately one out of 27,000 people are diagnosed with gastroenteropancreatic neuroendocrine tumors (GEP-NETs) per year (Voelker, 2018). However, their incidence has increased in the last thirty years (Cives & Strosberg, 2018). Neuroendocrine tumors of the midgut represent the most common malignant gastrointestinal neuroendocrine tumors. Overall survival rate is less than 50% especially in patients with metastatic disease (Modlin, Lye, & Kidd, 2003; Yao et al., 2008). Initial therapy includes somatostatin analogue (Caplin, Pavel, & Ruszniewski, 2014). However, there exists a lack of second-line treatment for neuroendocrine tumors (except for everolimus for nonfunctional neuroendocrine tumors (Yao et al., 2016)) if first-line treatment fails. Radiolabeled somatostatin analogue, Lutetium-177, has been the center of attention and it may be promising for the management of advanced neuroendocrine tumors (NETs).

Lutathera or Lutetium Lu 177 dotatate is a radioactive targeted therapy. The medication binds to somatostatin receptors which are present on certain tumors. Once Lutathera binds to the receptor, it enters the cell and uses radiation to cause damage. However, it does not impact normal cells. Lutathera delivers beta- and gamma radionuclides to cancerous cells with a maximum particle range of 2 mm and a half-life of 160 hours (van der Zwan et al., 2015). It is administered as four infusions separated by eight weeks interval.

On January 29, 2018, the Food and Drug Administration approved lutetium Lu 177 dotatate (LUTATHERA, Advanced Accelerator Applications USA, Inc.) a radiolabeled somatostatin analog, for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Medical Technology Assessment Committee (MTAC)

Lutetium Lu 177 Dotatate (Lutathera) for Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

01/14/2019: MTAC Review

Evidence Conclusion:

- There is limited evidence comparing Lu-Dotatate and octreotide
  - Based on one RCT with moderate risk of bias, Lu-Dotatate may be more effective than octreotide LAR in adult population with predominantly low grade, higher level of expression of somatostatin receptors gastroenteropancreatic NETs who failed initial therapy.
  - However, Octreotide results in lower adverse events than Lu-Dotatate.
- In non-comparative studies, low evidence suggests that Lu-Dotatate may be effective and safe in patients with advanced gastroenteropancreatic neuroendocrine tumors.

Articles: PubMed was searched through October 19, 2018. Search terms include ((Lutathera OR lutetium Lu 177 dotatate OR lutetium 177 dotatate OR Lu-177 OR 177Lu-DOTATATE)) AND (Neuroendocrine tumors OR pancreatic neuroendocrine tumors OR gastrointestinal neuroendocrine tumors). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Several articles were identified but only one RCT (NETTER-1 trial) met the inclusion criteria. Clinicaltrial.gov was also searched on October 11, 2018 and identified several ongoing studies with no available results. See Evidence Table**.**

The use of Lutetium Lu 177 Dotatate (Lutathera) for Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A9513	Lutetium Lu 177, dotatate, therapeutic, 1 mCi

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
02/05/2019	02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC]	03/05/2019

[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt coverage criteria for Lutathera; added 01/2019 MTAC review
03/05/2019	MPC approved to adopt criteria for Lutathera as presented.

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Clinical Review Criteria

Lymphedema Therapy/ Lymphedema Therapy Training

- Complete Decongestive Therapy
- Lymphatic Venous Anastomosis (LVA) for the Treatment of Lymphedema

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Criteria

Complete Decongestive Therapy (CDT) is comprised of four components: Manual lymph drainage (MLD), compression bandaging, exercises and skin care. The goals of CDT are to reduce lymphedema, increase mobility and range of motion (ROM), decrease the risk of cellulitis, and ultimately providing for a better quality of life. The goal of CDT training is to educate the patient and/or the caregiver to be successful in performing decongestive techniques. In the process of learning lymphedema therapy techniques, the patient's lymphedema may improve and stabilize. However, the goal of therapy and training is to transfer the knowledge and skills to the patient, or their caregiver so ongoing decongestive techniques can be performed by the patient or their caregiver, not to necessarily completely decongest the affected limb. Ongoing responsibility for completion and maintenance of decongestion is with the patient and/or the caregiver.

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Lymphedema Decongestive Treatment (A52959)

For Non-Medicare Members

Complete Decongestive therapy is considered medically necessary if **ALL of the following** are met:

1. The treating or consulting practitioner (within the scope of their practice) documents a diagnosis of primary or secondary lymphedema and specifically orders CDT training ***and***

2. CDT training is not routinely covered prophylactically, but patients at risk (such as having recent surgical removal of lymph nodes) who are "Stage 0" can be approved for up to 2 visits for patient education on future management ***and***

3. The patient or patient's caregiver has the ability to understand and provide home-based exercise and management, as the patient and/or caregiver will need to be able to manage the condition on their own after discharge ***and***

4. CDT training services must be performed by a licensed PT or OT that has received specific training for this service ***and***

5. The frequency and duration of services must be necessary and reasonable. CDT services are comprised of up to 15 sessions over a 2-12-week period ***and***

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6. A CDT course of training is generally expected to occur no more than once per lifetime. However, if medically necessary, refresher training will be approved for 1-2 sessions to review CDT techniques and measure for compression garments

Continued therapy may be indicated if ONE of the following are met:

1. 15 visits can extend beyond 12 weeks, if treatment is interrupted by chemotherapy or radiation therapy ***or***
2. Severe lymphedema that is showing progress with decreasing limb girth, more appointments may be approved if **ALL of the following** are met:
   a. Documentation of the patient's condition before, during and after therapy supports that progress was measurably sustainable ***and***
   b. Documentation indicates clear objective evidence of improvement, generally within the first week or 10 days of therapy (changes in weight, extremity circumference, etc.) ***and***
   c. Member or their caregiver has not yet mastered and demonstrated understanding of complex decongestive therapy techniques. For continued training to be approved, there must be documentation of the amount of further training required and an assessment if the patient or caregiver will be able to learn these techniques in a reasonable period of time.
   d. The goal of lymphedema therapy is not to fully decongest the affected limb, rather it is to transfer the skills and knowledge of lymphedema therapy techniques to the member or their caregiver.

Complete Decongestive Therapy is NOT covered when:

1. Therapy is limited to exercise or elevation of the affected area and is not CDT
2. Therapy does not include ongoing patient education
3. Therapy treatment is designed principally for temporary benefit
4. The patient or patient caregiver do not have the capacity to learn and perform CDT techniques within a reasonable amount of time

Covered Diagnosis

1. Primary lymphedema
2. Secondary lymphedema caused by:
   a. destruction of lymph nodes by radiation therapy or surgery for treatment of cancer.
   b. destruction of lymph system by:
      - trauma or
      - recurrent episodes of cellulitis in the affected limb (two episodes of cellulitis requiring antibiotic or
      - the result of severe chronic venous insufficiency

Lymphatic Venous Anastomosis (LVA) for the Treatment of Lymphedema:

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

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Background

Primary lymphedema refers to lymphedema that is caused by the imperfect or abnormal development/lymphatic dysplasia of the lymph vascular system. Primary lymphedema may be due to such causes as Milroy's Disease, Meige's Disease, Turner Syndrome Noonan Syndrome, Klippe-Trenaunay Syndrome, Parks Weber Syndrome, Prader-Willi Syndrome, Emberger Syndrome and other genetic and non- genetic syndromes (also known as hereditary and sporadic lymphedema). Secondary lymphedema is caused by known factors that damage the lymphatic system. Causes of secondary lymphedema include Filariasis, surgery and/or radiation for cancer, cancer, trauma, infection, and chronic venous insufficiency. Obesity is an independent risk factor for

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lymphedema. The most common cause of secondary lymphedema in developed countries is treatment for cancer, especially breast cancer, due primarily to the removal and/or damage of lymph nodes, and damage to lymph vessels. Complete decongestive therapy can be effective for both primary and secondary lymphedema.

Differential diagnosis must include medical conditions which cause swelling which are *not* considered lymphedema and should be treated medically. These conditions include hepatic/renal disorders, congestive heart failure, venous obstruction (DVT) and in some cases, immobility of the limb where the muscle pump is not active, hypoproteinemia, malnutrition, malabsorption syndromes, sepsis, allergic reactions, lipedema, myxedema (disorder of the thyroid), fluid retention syndrome, neurological conditions which can cause weakness or paralysis resulting in immobility of the limbs and even as a side-effect of certain medications and self-inflicted swelling.

Lymphedema can co-occur with other conditions and may be amenable to CDT treatment, especially if the condition is chronic and medical treatment has not completely resolved the edema. **Chronic venous insufficiency** can lead to lymphedema because as the increased amount of fluid in the interstitium which is filtered from the capillaries begins to overwhelm the lymphatic system and can cause damage to the lymphatics, this usually occurs in Stage 2 of CVI. If the conditions are chronic and swelling continues, they may be amenable to a course of CDT.

Evidence and Source Documents

Medicare B Issues Notice 177, Page 14, 15, 16

Lymphatic Venous Anastomosis (LVA) for the Treatment of Lymphedema

BACKGROUND

Lymphedema is the accumulation of fluid in the lymphatic system. Lymphedema is an imbalance between interstitial fluid production and the transport capacity of the lymphatic system ("The diagnosis and treatment of peripheral lymphedema: 2013 Consensus Document of the International Society of Lymphology," 2013). It is caused by congenital anomalies of the lymphatic vessels or any factors that damage the lymphatic system. Lymphedema is classified as primary or secondary depending on etiology. Primary lymphedema is due to a congenital malformation of the lymphatic vessels. It manifests, more commonly, by edema of the lower limbs at birth which can be present up to two years after birth. Secondary lymphedema is due to infection, injury/trauma, inflammation, obesity, cancer and cancer treatment, and chronic venous insufficiency.

Patients may experience swelling, pain, discomfort, heaviness, limited range of motion, and skin lesions. The diagnosis is made by history, physical exam, and measurements (Mehrara, B. et al., 2019).

The treatment of lymphedema can be difficult. However, the foundation of treatment is conservative and multimodal. Multimodal treatment consists of general measures along with compression therapy and physiotherapy. General measures include self-monitoring, limb elevation, maintenance of adequate body weight through diet and exercise, avoidance of skin infection or injury, avoidance of limb constriction. Compression therapy includes bandaging, compression garments, and intermittent pneumatic compression. Physiotherapy is comprised of manual lymphatic drainage and complete decongestive therapy (Mehrara, B. et al., 2019).

Complete decongestive therapy, also called complex decongestive therapy, complex decongestive physiotherapy, or decongestive lymphatic therapy is comprised of two phases: the first phase which is the treatment phase involves manual lymphatic drainage, limb compression, skin care, and exercise. This occurs every day five days per week and lasts two to four weeks. The second phase also called the maintenance phase entails compression garments, self-compression bandaging at night, skin care, exercise, and, if necessary, self-manual lymphatic drainage (Mehrara, B. et al., 2019). The treatment is provided by a health care professional. However, patients or caregivers can treat themselves especially in the second phase of the treatment after being trained.

Medical Technology Assessment Committee (MTAC)

Lymphatic Venous Anastomosis

06/20/2011: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of lymphatic venous anastomosis in the treatment breast cancer-related lymphedema.

Articles: The literature on the on lymphatic venous anastomosis (LVA) for the treatment of breast cancer-related lymphedema (BCRL) is very limited; the search did not reveal any meta-analyses or randomized controlled trials that evaluated efficacy or safety of the procedure. The empirical study published on the LVA for the treatment (BCRL) was a small case series with ten patients.

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The use of lymphatic venous anastomosis (LVA) for the treatment of post-breast cancer lymphedema does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Complete decongestive therapy for the treatment of lymphedema
04/08/2019: MTAC REVIEW
Evidence Conclusion:

- Low evidence indicates no difference between complete decongestive therapy and compression bandaging or garments in terms of reduction in limb volume, edema volume, limb-related volume change, QOL, and arm function in patients with secondary lymphedema due to breast cancer treatment on the short and mid-terms (≤1 year).
- There is insufficient evidence for or against the effectiveness of complete decongestive therapy training in term of lymphedema reduction.
- Moderate quality study suggests that decongestive lymphedema therapy may be safe.

Articles: PubMed was searched from 2012 to March 20, 2019 with the search terms Complete decongestive therapy OR complex decongestive therapy OR complex decongestive physiotherapy OR decongestive lymphatic therapy. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. RCTs and observational studies were included as filters. See Evidence Table.

The use of Complete decongestive therapy for the treatment of lymphedema does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Microsurgical Treatment of Lymphedema Following Breast Cancer Surgery. Lansdale, PA: Hayes, Inc.; 7/2013

Interregional New Technologies Committee (INTC) Review

02/02/2021: SCPMG Evidenced-Based Medicine
Overall Conclusion:

- The body of literature on LYMPHA for prevention of secondary extremity lymphedema consists of six comparative studies (including 2 RCTs) and eight non-comparative studies and involved a total of 1,067 participants (range: N=10 to N=380). Follow-up periods ranged from 3 months to 4 years. Most studies involved breast cancer patients, but several studies included patients with other types of cancer.
- The included studies were at high risk of bias and most had small sample sizes. There was also heterogeneity in terms of cancer type, lymphedema classification, treatment courses, and follow-up times. However, the studies consistently demonstrated substantial reductions in risk of lymphedema occurrence with the LYMPHA, compared with standard care.
- Incidence of lymphedema in the included studies ranged from 0% to 12.5%, with lymphedema occurring transiently in some patients and persisting in others. The highest rate of persistent lymphedema was 9% (in a retrospective case series, N=27). The overall quality of the evidence on the efficacy of LYMPHA was found to be low.
- Four studies (1 small RCT; 1 small prospective case series; 2 retrospective) reporting safety outcomes did not indicate any serious concerns regarding safety or complications associated with LYMPHA for prevention of secondary lymphedema. The overall quality of the evidence on the safety of LYMPHA is very low.
- We applied the ROBIS (i.e., risk of bias in systematic reviews) tool to the Hayes, Inc. assessment and found risk of bias in their review to be low.
- Given the overall low quality of the body evidence on LYMPHA, there remains a need for large, high-quality comparative studies or RCTs to draw a conclusion regarding the efficacy and safety of LYMPHA for prevention of secondary lymphedema, compared with standard care.

Applicable Codes

Complete Decongestive Therapy (CDT) - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description

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97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
S8950	Complex lymphedema therapy, each 15 minutes

Lymphatic Venous Anastomosis (LVA) - Considered not medically necessary:

CPT® or HCPC Codes	Description
No specific codes – often submitted as *38999 Unlisted procedure, hemic or lymphatic system*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
01/1996	06/01/2010 MDCRPC, 04/05/2011 MDCRPC, 02/07/2012 MDCRPC ,12/04/2012 MDCRPC , 10/01/2013 MPC,08/05/2014 MPC,05/05/2015 MPC, 03/01/2016MPC, 05/03/2016MPC, 03/7/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC , 12/01/2020MPC,12/07/2021MPC ,12/06/2022MPC	09/12/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/05/2015	The criteria were completely revised to mirror Medicare guidelines to support payment for comprehensive decongestive therapy only.
05/03/2016	Merged CDT & LVA criteria into one document under Lymphedema Therapy
04/13/2017	Added Hayes Technology Brief Review
03/05/2019	MPC approved to expand criteria to treat members with lymphedema caused by other diagnosis other than cancer
04/08/2019	MTAC review for Complete Decongestive Therapy for the treatment of lymphedema was added
09/12/2022	INTC Review for Lymphovenous Anastomosis (LVA) (LYMPHA) for Prevention of Lymphedema from 02/01/2021 was added

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KAISER PERMANENTE®

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Clinical Review Criteria

Magnetic Resonance Guided Focused Ultrasound for Treatment of Uterine Fibroids (MRgFUS)

- ExAblate 2000 Technology for Ablation of Uterine Fibroids

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Magnetic Resonance Guided Focused Ultrasound for Treatment of Uterine Fibroids (MRgFUS)"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Uterine fibroids (or leiomyoma) are benign tumors of the uterus with a rich blood supply that may cause excessive bleeding and pelvic pain. The prevalence of uterine fibroids is estimated to be 20-40% in women older than 35. Hysterectomy is the standard permanent treatment for women who do not have a strong desire to retain their uterus. Other treatments include watchful waiting, medical management with hormonal therapy, myomectomy (local surgical removal) and uterine artery embolization (UAE). UAE is covered for GHC members when recommended by a GHC physician.

The ExAblate 2000 system (Insightec Ltd., Israel) is a minimally invasive, uterine-sparing treatment for uterine fibroids. The system is used in conjunction with a commercially available MRI scanner, the GE Signa 1.5T MR imaging system. A special coil is required to use the GE device with the ExAblate system. The MRI is used for planning, and also for monitoring during the procedure. The treatment is also known as MR guided focused ultrasound (MRI-FUS or MRgFUS).

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During the procedure, focused ultrasound waves heat the targeted fibroid tissue to approximately 65-85o C. causing cell necrosis. Over time, the necrotic tissue is absorbed by the body. The treatment can take several hours, and it requires collaboration between a gynecologist and a radiologist.

The ExAblate system was approved by the FDA in October 2004 for ablation of uterine fibroid tissue in pre- or peri- menopausal women with symptomatic uterine fibroids who want a uterine sparing procedure. Patients must have a uterine size of <24 weeks' gestation and have completed child-bearing. Prior to commercial availability in the U.S., the ExAblate system was used in Europe (since 2002) and, to a limited extent, in Japan.

The ExAblate 2000 technology for ablation of uterine fibroids has not been reviewed previously by MTAC.

Medical Technology Assessment Committee (MTAC)

Magnetic Resonance Guided Focused Ultrasound in the Treatment of Uterine Fibroids

06/04/2008: MTAC REVIEW

Evidence Conclusion: In the FDA pivotal study in which 109 women were treated using the ExAblate 2000 technology (Stewart et al., 2006), there was a statistically significant improvement in self-reported symptoms pre- and post-treatment. The Funaki et al. (2007) case series did not report pre- and post-comparisons. 25 out of 69 women (53%) reported improving a great deal or being symptom-free 3 months after being treated. An additional 17 women (28%) said their symptoms were somewhat improved. In both studies, the main outcomes were self-report measures. A sham or comparison group is needed in this type of study to evaluate the extent to which treatment with ExAblate had a placebo effect on women's perception of their symptoms. None of the published studies focused on objective health outcomes such as bleeding or anemia. There is insufficient evidence to draw conclusions about the safety and effectiveness of the ExAblate 2000 technology for ablation of uterine fibroids. The empirical literature consists of case series. There are no studies comparing this technology to sham treatment or other accepted treatments such as UAE and myomectomy.

Articles: The Medline search yielded 35 articles. There was also an unpublished FDA document from October 2004, entitled, "Summary of safety and effectiveness data". The pivotal study submitted by InSightec to the FDA was a cohort study with n=109 receiving MRI-FUS with ExAblate and n=83 receiving hysterectomy. The FDA document describes pre- and post-treatment findings in each group but does not present statistical comparisons comparing results in the two groups. Several subsequent published articles described subjective treatment effects in the 109 patients who received ExAblate in the FDA pivotal study. These include Hindley et al., 2004 (short-term outcomes) and Stewart et al., 2006 (6- and 12- month outcomes). No published articles were identified that compared the ExAblate and hysterectomy groups in the FDA pivotal study. No published randomized or non-randomized controlled studies were identified that compared ExAblate to sham or to a less invasive alternative treatment such as uterine artery embolization or myomectomy. Two studies were identified that compared different protocols of MRI-FUS. One was a small study in which one of the two groups received a GnRh agonist pre-treatment and the other evaluated compared a standard and slightly modified treatment guideline with the ExAblate system. Stewart et al. also published an article in 2007 that combined and re-evaluated data from the FDA study and other case series sponsored by Insightec. This article included selected data and post-hoc analyses which can be misleading and thus was not evaluated further. The Stewart et al., 2006 study reporting the clinical outcomes from the FDA pivotal trial was critically appraised. In addition, a case series from Japan with a reasonably large sample size was critically appraised. References are: Stewart EA et al. Clinical outcomes of focused ultrasound surgery for treatment of uterine fibroids. Fertil and Steril 2006; 85: 22-29. See Evidence Table.

The use of Magnetic resonance guided focused ultrasound in the treatment of uterine fibroids does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Magnetic Resonance-Guided Focused Ultrasound (MRgFUS)

07/25/2016: Medical Technology Assessment Team (MTAT) Review

Evidence Conclusion:

The studies identified in this assessment have limitations that make it difficult to have confidence in the estimates regarding efficacy and safety of MRgFUS or MR-HIFU for treatment of uterine fibroids. Given the small sample sizes of most of the studies, the lack of evidence on long-term health and pregnancy outcomes, and a substantial concern about the existence of confounding in study design:

1. There is low quality evidence that MRgFUS or MR-HIFU is as efficacious as hysterectomy and UAE for treating symptomatic uterine fibroids. The available evidence suggests MRgFUS or MR-HIFU is *less efficacious* than hysterectomy and UAE for treating symptomatic uterine fibroids.
2. There is very low-quality evidence that MRgFUS or MR-HIFU is as safe as hysterectomy and UAE for treating symptomatic uterine fibroids**.**

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The potential benefits of MRgFUS or MR-HIFU for treating uterine fibroids should be weighed against the potential harms (e.g., need for re-intervention following treatment). Additional large, high quality longitudinal studies are needed to assess the long-term efficacy and safety of MRgFUS or MR-HIFU for treating uterine fibroids.

Articles: Two systematic reviews (Clark, 2014; Canadian Agency for Drugs and Technologies in Health (CADTH), 2016 (Chen, Pitre, Kaunelis, & Singh, 2016)) and one technology assessment (Hayes, Inc., 2014) addressing efficacy and/or safety of MRgFUS or MR-HIFU were identified. The most comprehensive systematic review of comparative studies involving any type of MRgFUS versus hysterectomy, myomectomy, or UAE is from CADTH. We therefore used the CADTH report as our primary evidence source. Our update search identified one pilot randomized controlled trial (PROMISe Trial; Jacoby, et al., 2016) that assessed the efficacy and safety of MRgFUS compared to a sham procedure. Therefore, a total of three comparative studies (two from the CADTH report and one from our update search) were selected for inclusion in the SCPMG EBM assessment. CADTH (2016) found that MRgFUS (or MR-HIFU) was associated with more re-interventions but also fewer complications compared with hysterectomy and UAE. The review included RCTs, non-randomized studies, and economic evaluations assessing the clinical effectiveness and safety of uterine-preserving interventions in women with symptomatic uterine fibroids. Interventions of interest included myomectomy, myolysis, UAE, uterine artery occlusion (UAO), or endometrial ablation. They were compared with each other or with hysterectomy. The search for health technology assessments, systematic reviews, meta-analyses, and guidelines was limited to documents published since January 1, 2005, while the search for randomized controlled trials (RCTs), controlled clinical trials, cohort studies, and economic studies was not limited by publication year. A total of two non-randomized observational studies comparing MRgFUS versus hysterectomy and UAE (Taran et al., 2009 and Ikink et al., 2014, respectively) were reviewed and appraised (last CADTH search date: November 24, 2015).

The use of Magnetic resonance guided focused ultrasound in the treatment of uterine fibroids does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary:

CPT® or HCPC Codes	Description
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/17/2008	06/04/2008[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	06/04/2008

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
02/13/2017	Added KP MTAT Review

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Massage Therapy

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None

Medicare covers massage when delivered by a physical therapist as part of the rehabilitation plan of care. It is not covered when delivered by a massage therapist who is not licensed as a physical therapist.

For Non-Medicare Members

A. Massage therapy is indicated when **ALL of the following** are met:
   1. An assessment and diagnosis documents objective physical and functional limitations.
   2. It will have physical therapeutic benefits.
   3. It has been ordered by the treating physician.
   4. The condition or the level of function can be expected to improve significantly within a reasonable and generally predictable period of time with massage treatment.

OR

B. The patient is terminally ill, and the therapy is needed for comfort.

Massage therapy is not covered when:

1. It is provided for prevention, recreation (spa therapy) or stress reduction.
2. It is directed at the maintenance of current level of functioning.
3. The patient has achieved therapeutic goals or is not showing meaningful progress.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

This service is covered when it is described as a benefit in the consumer's coverage contract and the consumer receives a health plan referral. Special work groups that have included licensed massage therapists identified the clinical conditions and screening criteria in order to determine clinical appropriateness for the service.

Low back pain (LBP) is a major health problem in the modern society. More than two thirds of the population will experience low back pain at some time in their lives. LBP is usually benign and self-limiting; almost 90% of all patients with acute low back pain will get better quickly regardless of therapy. The remaining 10% may develop chronic back pain and disability.

LBP is associated with a complex dysfunction and impaired endurance of the paraspinal muscles. Different therapies including exercise and spinal manipulation are often recommended, yet their clinical effectiveness has not been documented. Research on the effectiveness of these therapies has yielded inconsistent results.

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The use of massage therapy for back pain has a long history. Massage therapy may have the potential to increase the blood flow in the muscles, enhance muscle tone, reduce muscle fatigability, and improve muscle endurance. It may relax the mind and increase the pain threshold. Massage is considered a safe treatment with no risk or adverse effects. It is, however, contraindicated when several other conditions are present, including acute inflammations, skin infections, unhealed fractures, and burns.

Massage is rubbing or kneading part of the body usually with the hands to stimulate circulation and make the muscles or joints suppler. It is also defined as soft tissue manipulation using the hands or a mechanical device. Massage can be applied to the lumbar region only or to the whole body. It is usually used as an adjunct therapy for other physical treatments; however, many massage therapists use it as the only intervention. Examples of soft tissue massage are Shiatsu, Rolfing, Swedish massage, reflexology, myofascial release, craniosacral therapy, and Bindege webs massage. Massage therapy is applied through various techniques including friction, kneading, hacking, petrissage, neuromuscular, trigger, and pressure points.

Massage therapists are licensed by the state of Washington. Licensure requires a minimum of 500 hours of training at an accredited school of massage therapy.

Medical Technology Assessment Committee (MTAC)

Massage Therapy in the Treatment of Chronic Neck and Back Pain

11/2001: MTAC REVIEW

Evidence Conclusion: Two of the studies reviewed show that massage is an effective therapy for non-specific subacute and chronic low back pain (Cherkin, Preyde). Cherkin's study did not compare massage to a placebo or no treatment. Preyde's study, which compared massage to sham treatment, had a short follow-up duration. On the other hand, Pope et al found no significant difference between massage, spinal manipulation, corset, and transcutaneous muscle stimulation (TMS). Various confounding factors may affect the outcome of massage therapy including the type of massage given, number and duration of treatment sessions, experience of the therapists, size of massage area, amount of pressure, as well as the type of injury or problem, chronicity, level of stress, and other aggravating factors. Many of the studies reviewed did not address or adjust for these variables. Further research is needed to study the patients' variables and to help ascertain which type of low back pain will respond best to massage therapy. Studies with a longer-term follow-up are also needed to determine the elements and techniques of massage therapy that will give the most benefit. Use of a control group with a placebo or no treatment would also strengthen the validity of the results.

Articles: The search yielded 32 articles. There were two systematic reviews, with no statistical pooling or meta-analysis due to the heterogeneity of the studies. There were eight randomized, controlled trials. Massage was the main therapy under investigation in only two of the RCTs revealed by the search. *The studies selected for critical appraisal were:* Cherkin, D., Eisenberg, D., et al. Randomized trial comparing traditional Chinese medical acupuncture, therapeutic massage, and self-care education for chronic low back pain. Arch Intern Med 2001; 161: 1081-1088 See Evidence Table. Preyde, M., Effectiveness of massage therapy for subacute low-back pain: a randomized controlled trial. CMAJ 2000; 162: 1815-20 See Evidence Table. Pope, M.H., et al. A prospective randomized three-week trial of spinal manipulation, transcutaneous muscle stimulation, massage, and corset in the treatment of subacute low back pain. Spine 1994; 22: 2571-2577 See Evidence Table.

The use of massage therapy in the treatment of chronic neck and back pain meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
with type of service massage	

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Date Created	Date Reviewed	Date Last Revised
11/20/2002	10/5/2010 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC,12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	06/21/2007

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Medicare Only – Miscellaneous Criteria

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medical service.

**Note: This list is not all-inclusive – refer to the Medicare Coverage Database for additional coverage documentation.*

Category	Location of Policy	Name of Policy and Link
Durable Medical Equipment	NCD	• Ambulatory Blood Pressure Monitoring 20.19 • Ambulatory EEG Monitoring 160.22-Retired • Hospital Beds 280.7
	LCD	• Hospital Beds and Accessories L33820
	Decision Memo	• Ambulatory blood Pressure Monitoring (ABPM)
Radiology	NCD	• Bone (Mineral) Density Studies 150.3
	LCD	• Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L37738)
Laboratory	NCD	• Alpha-fetoprotein 190.25 • Chimeric Antigen Receptor (CAR) T-cell Therapy 110.24 • Human Tumor Stem Cell Drug Sensitivity Assays 190.7
	LCD	• B-type Natriuretic Peptide (BNP) Testing (L34038) • Vitamin D Assay Testing L34051
	Decision Memo	• Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451)
Other Diagnostic Tests	NCD	• Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) 20.16 • Challenge Ingestion Food Testing 110.12 • Collagen Crosslinks, any Method 190.19 • Displacement Cardiography 20.24 • HIS Bundle Study 20.13
	LCD	• Polysomnography and Other Sleep Studies L34040
Surgical Procedures	NCD	• Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee 150.9 • Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors 110.20 • Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers 20.8.3 • Carotid Body Resection/Carotid Body Denervation 20.18 • Ultrasonic Surgery 50.8 • Vertebral Artery Surgery 20.1
	LCD	• Injection - Tendon, Ligament, Ganglion Cyst, Tunnel Syndromes and Morton's Neuroma L34076
	LCA	• Arthroscopic Lavage and Arthroscopic Debridement for Osteoarthritic Knees A54063
Medical Procedures	NCD	• Apheresis (Therapeutic Pheresis) 100.14

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Category	Location of Policy	Name of Policy and Link
		• Abortion 140.1 • Verteporfin (Photosensitive Drugs) 80.3
Rehabilitation Services	NCD	• Inpatient Hospital Pain Rehabilitation Programs 10.3 • Intensive Behavioral Therapy for Cardiovascular Disease 210.11 • Intensive Behavioral Therapy for Obesity 210.12 • Outpatient Hospital Pain Rehabilitation Programs 10.4
Others	Manuals	• Hospice Chapter 9

Date Created	Date Reviewed	Date Last Revised
04/13/2009	04/13/2009[MDCRPC], 05/03/2011[MDCRPC], 08/02/2011[MDCRPC], 06/05/2012[MDCRPC], 04/02/2013[MDCRPC], 02/04/2014[MPC], 04/01/2014[MPC], 05/06/2014[MPC], 07/01/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/18/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description of Change
04/30/2015	Added Transcatheter Mitral Valve Repair
05/26/2015	Added Oral Appliances for Obstructive Sleep Apnea
09/08/2015	Revised LCD B-type Natriuretic Peptide (BNP) Testing L34057 and L34038, Medicare Non-Covered Services 34886, Vitamin D Assay Testing LCD L34094 and L34051, Polysomnography and Other Sleep Studies LCD L34040, Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy LCD L34995, Injection - Tendon, Ligament, Ganglion Cyst, Tunnel Syndromes and Morton's Neuroma L34076, Oral Appliances for Obstructive Sleep Apnea L33611
01/27/2016	Added LCD L35457 and L34980
04/11/2017	Added Decision Memo for Leadless Pacemakers
08/03/2017	Added NCD for Leadless Pacemakers
06/12/2019	Added LCD L37738
04/07/2020	Removed Leadless Pacemakers, Implantable Automatic Defibrillators and Hyperthermia for Treatment of Cancer categories since they have their own individual KPWA criteria.
12/02/2022	Added LCD L39242 replacing retired LCD L34980
03/01/2023	Added NCD 160.22 Ambulatory EEG Monitoring - Retired
03/23/2023	Review for Endothelial Cell Photography is no longer required.
04/18/2023	Removed Magnetic Resonance Imaging NCD 220.2 due to having independent criteria pages for MRI. Removed Epidural Steroid injections for Pain management L39242 due to having independent criteria page for ESI.

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Medicare Medical Policy Development

Kaiser Permanente Medicare Advantage Medical Policies identify the clinical criteria for determining when medical services are considered 'reasonable and necessary' (medically necessary). Medicare Advantage plans are required by CMS to provide the same medical benefits to Medicare Advantage members as Original Medicare. As such, whenever possible, Medicare Advantage Medical Policies are based on Medicare coverage manuals, National Coverage Determinations (NCDs), and Local Coverage Determinations (LCDs) when available. If there is no applicable NCD or LCD for the service under review, then per CMS other evidence-based criteria may be applied. In addition, each member's unique, clinical situation is considered in conjunction with current CMS guidelines

Kaiser Permanente Medicare Medical Policy Hierarchy

The following hierarchy is used to determine Kaiser Permanente Medicare Advantage (MA) Medical Policy:

- *CMS Coverage Manuals or other CMS-based Resource*
  Coverage provisions in interpretive manuals are instructions that are used to further define when and under what circumstances items or services may be covered (or not covered). Other CMS-based resources include, but are not limited to, documentation such as Medicare Learning Network (MLN) and Federal Register (FR) publications.

- *National Coverage Determinations (NCD)*
  For some services, procedures, and technologies, CMS has developed an NCD, which is to be applied on a national basis for all Medicare beneficiaries. Once published in a CMS program instruction, the NCD is binding on all Medicare Advantage plans. (1)

- *Local Coverage Determinations (LCD), Articles (LCA), and other contractor-based bulletins*
  When there is no NCD or other coverage provision outlining medical necessity criteria within a Medicare manual, or when there is a need to further define an NCD, then the Medicare Administrative Contractor (MAC) for a service area may develop an LCD. (2) Noridian Healthcare Solutions (Noridian) is the designated MAC for the state of Washington.

- *Retired LCD/LCD*
  LCDs are retired due to lack of evidence of current problems with utilization, or in some cases because the material is addressed by a National Coverage Determination (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. The guidance in the retired LCD may still be helpful in assessing medical necessity. (3)

- *Commercial Medical Policies*
  In coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, a Medicare Advantage Organization (MAO) may adopt the coverage policies of other MAOs in its service area. (4)
  However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO:
  - Must make its own coverage determination;
  - Must provide CMS an objective evidence-based rationale relying on authoritative evidence such as:
    - Studies from government agencies (e.g., the FDA);
    - Evaluations performed by independent technology assessment groups (e.g. BCBSA); and
    - Well-designed controlled clinical studies that have appeared in peer review journals; and
  - In providing its justification, the MAO may not use conclusory statements with no accompanying rationale (e.g., "It is our policy to deny coverage for this service.")

- *MCG™ Care Guidelines*
  If no policy criteria are available within an NCD, LCD, coverage manual, or existing medical policy for the services in question, MCG™ guidelines may be applied at the discretion of the physician reviewer.

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Kaiser Permanente may consider some services to have insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies. When a procedure or device is deemed to have "insufficient evidence" by Kaiser Permanente, the term "insufficient evidence" does not mean the procedure or device has not been approved by the Food and Drug Administration (FDA). Rather, it means the procedure or device does not meet Kaiser Permanente's objective, evidence-based technology assessment based on authoritative evidence. See the Kaiser Permanente Medical Technology Assessment Committee for further details regarding their evidence-based evaluation process.

Noridian may also provide coverage or non-coverage guidance in a Part B News Article published on the noridianmedicare.com website. Thus, these articles may be used in Medicare Advantage coverage decisions even though they are not in the form of an LCD or an LCA.

In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare beneficiaries around the country. This generally occurs when there is only one provider of a particular item or service (for example, certain pathology and lab tests furnished by independent laboratories). In this situation, MA plans must follow the coverage policy reflected in an LCD issued by the A/B MAC that enrolled the provider and processes all of the Medicare claims for that item or service. (5)

For genetic and molecular diagnostic testing, Noridian has implemented the guidelines published by Palmetto GBA under the Molecular Diagnostic (MolDX) Program for their Jurisdiction F (J-F) service area. (6). MolDX guidelines, when available, should be applied to requests for genetic and molecular diagnostic testing. In the absence of a guideline for a genetic test the above hierarchy will apply.

References:
1. Medicare Managed Care Manual, Pub. #100-16, Chapter 4 – Benefits and Beneficiary Protections, §90.2 - Definitions Related to National Coverage Determinations (NCDs)
2. Medicare Managed Care Manual, Pub. #100-16, Chapter 4 – Benefits and Beneficiary Protections, §90.4 - Local Coverage Determinations (LCDs)
3. Medicare Managed Care Manual, Pub. #100-16, Chapter 4 - Benefits and Beneficiary Protections, §90.4.1 – MAC with Exclusive Jurisdiction over a Medicare Item or Service
4. Noridian MolDX Website https://med.noridianmedicare.com/web/jfb/policies/moldx
5. Medicare Managed Care Manual, Pub. #100-16, Chapter 4 - Benefits and Beneficiary Protections, §90.5 - Creating New Guidance
6. LCD Retirement Clarification https://med.noridianmedicare.com/web/jfb/article-detail/-/view/10546/lcd-retirement-clarification

[5] - 90.5 – Creating New Guidance

(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

In coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, a Medicare Advantage Organization (MAO) may adopt the coverage policies of other MAOs in its service area. However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO:

- Must make its own coverage determination;
- Must provide CMS an objective evidence-based rationale relying on authoritative evidence such as:
  - Studies from government agencies (e.g., the FDA);
  - Evaluations performed by independent technology assessment groups (e.g. BCBSA); and
  - Well-designed controlled clinical studies that have appeared in peer review journals; and
  - In providing its justification, the MAO may not use conclusory statements with no accompanying rationale (e.g., "It is our policy to deny coverage for this service.")

The requirement that an MA plan provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. MA plans may encourage enrollees to see more cost-effective provider types than would be the typical pattern in original Medicare, as long as those providers are licensed and working within the scope of their licenses and the plan complies with the provider anti-discrimination rules set forth in 42 CFR §422.205.

An MA plan's flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program. If original Medicare covers a service only when certain conditions are met, then such conditions must be met in order for the service to be considered part of the

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original Medicare benefits component of an MA plan. An MA plan may cover the same service when the conditions are not met, but these benefits would then be defined as supplemental.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Date Created	Date Reviewed	Date Last Revised
01/18/2017	09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/03/2019

[MPC] Medical Policy Committee

Revision History	Description
09/03/2019	Updated policy to reflect changes in Medicare Managed Care Manuals

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Clinical Review Criteria
Micronutrient Panel Testing
Intracellular micronutrient analysis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Micronutrient Panel Testing"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that micronutrient testing provides better long-term outcomes than current standard services/therapies.

Micronutrient testing, also known as functional intracellular analysis, essential metabolic analysis, intracellular micronutrient analysis, or leukocyte nutrient analysis, is a blood test consisting of multiple micronutrient levels intended to assess nutritional deficiencies and offer supplementation suggestions. Micronutrient tests are considered **not medically necessary**.

Some examples of commercially available micronutrient tests include but are not limited to the following:

- Genova Diagnostics ION Profile®
- IntraCellular Diagnostics EXA Test®
- SpectraCell Laboratories Micronutrient Test
- VibrantAmerica Micronutrients

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Micronutrient testing assesses the level of multiple nutrients in the body. These panels may include measurement of numerous vitamins, minerals, amino acids, fatty acids, oxidation products, organic acids, toxins and antioxidants. The test results are proposed to help determine the cause of various symptoms, such as hair loss and fatigue, and various disease processes. Antioxidant function testing (e.g., Spectrox™) has been proposed as a method to evaluate the ability of cells to resist damage caused by free radicals and other forms of oxidative stress. SpectraCell Laboratories, Inc., (Houston, TX) offers a micronutrient testing panel proposed to measure how micronutrients function within the white blood cell. The Individual Optimal Nutrition (ION) (Genova Diagnostics, Asheville, NC) is a blood test that measures levels of vitamins, minerals, antioxidants, and organic, fatty, and amino acids. ExaTest®, offered by IntraCellular Diagnostics, Inc® (Medford. OR) is an intracellular tissue analysis of mineral electrolytes. The test is proposed to provide information on mineral electrolyte deficiencies or imbalances not available by blood testing. The analysis is made from an epithelial cell scraping from the sublingual area. The sample is analyzed using high energy photos (x-rays).

Currently, there is insufficient evidence in the published, peer-reviewed, scientific literature to establish the clinical utility of nutrient panel testing or antioxidant function testing or to demonstrate that the use of such testing results in improved health outcomes.

Applicable Codes

Micronutrient Test (identified by the volume of lab tests for vitamins, minerals, amino acids, antioxidants, and metabolites for diagnoses such as fatigue)

The following is a list of codes that will not be covered when billed for a Micronutrient Test. This is not an all-inclusive list.

CPT® Codes	Description
82136	Amino acids, 2 to 5 amino acids, quantitative, each specimen
82180	Ascorbic acid (Vitamin C), blood
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82310	Calcium; total
82379	Carnitine (total and free), quantitative, each specimen
82495	Chromium
82525	Copper
82607	Cyanocobalamin (Vitamin B-12)
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed
82725	Fatty acids, nonesterified
82746	Folic acid; serum
82978	Glutathione
83735	Magnesium
83785	Manganese
84207	Pyridoxal phosphate (Vitamin B-6)
84252	Riboflavin (Vitamin B-2)
84255	Selenium
84425	Thiamine (Vitamin B-1)
84446	Tocopherol alpha (Vitamin E)
84590	Vitamin A
84591	Vitamin, not otherwise specified
84597	Vitamin K
84630	Zinc
86353	Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis

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Date Created	Date Reviewed	Date Last Revised
05/05/2020	05/05/2020 MPC, 05/04/2021 MPC, 05/03/2022MPC, 05/02/2023MPC	05/05/2020

MPC Medical Policy Committee

Revision History	Description
05/05/2020	MPC approved to adopt new non-coverage policy. Requires 60-day notice, effective date 9/1/2020.

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KAISER PERMANENTE®

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Clinical Review Criteria
Microvolt T-Wave Alternans

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Microvolt T-Wave Alternans 20.30
Local Coverage Determinations (LCD)	None
Local Coverage Article	Decision Memo for Microvolt T-wave Alternans

For Non-Medicare Members

Kaiser Permanente has elected to use the Microvolt T-Wave Alternans (MTWA) (A-0399) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. This procedure is not covered per MCG guideline. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

The term alternans applies to conditions characterized by the sudden appearance of a periodic beat-to-beat change in some aspect of cardiac electrical or mechanical behavior. Many different examples of electrical alternans have been described clinically; a number of others have been reported in the laboratory.

T-wave alternans has long been recognized as a marker of electrical instability in acute ischemia, where it may precede ventricular tachyarrhythmia. Studies have shown that T wave (or ST-T) alternans can also precede non-ischemic ventricular tachyarrhythmias. Considerable interest has recently been shown in the detection of microvolt T wave alternans as a noninvasive marker of the risk of ventricular tachyarrhythmia in patients with chronic heart disease.

Assessment of left ventricular ejection fraction (LVEF), Holter monitoring, and signal-averaged late potentials are the principal non-invasive means of determining the risk of ventricular arrhythmias after myocardial infarction (MI).

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However, these measures of vulnerability to arrhythmias have been found to be less predictive of arrhythmic events than invasive electrophysiologic testing.

Microvolt T-wave alternans testing is performed by placing high-resolution electrodes, designed to reduce electrical interference, on a patient's chest prior to a period of controlled exercise (CMS, 2005). These electrodes detect tiny beat-to-beat changes, on the order of one-millionth of volt, in the EKG T-wave. Spectral analysis is used to calculate these minutes voltage changes. Spectral analysis is a sensitive mathematical method of measuring and comparing time and the electrocardiogram signals. Software then analyzes these microvolt changes and produces a report to be interpreted by a physician.

Applicable Codes

Medicare

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Non-Medicare

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
93025	Microvolt T-wave alternans for assessment of ventricular arrhythmias

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/01/2014	07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	07/01/2014

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Minimally Invasive Lumbar Decompression

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (150.13)
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Decision Memo for PERCUTANEOUS IMAGE-GUIDED LUMBAR DECOMPRESSION for Lumbar Spinal Stenosis (CAG-00433R)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Lumbar spinal stenosis (LSS) is one of the most common degenerative diseases of the lumbar spine, and the most common indication for spinal surgery in elderly patients. LSS is a condition where the dural sac and nerve roots are compressed by a combination of degenerative features including bulging of the intervertebral discs, hypertrophy of the facet joints, and thickening of the ligamentum flavum. In LSS the space within the spinal canal narrows leading to asymptomatic compression of the nerves and ultimately symptomatic neurogenic claudication, which is described as pain, paresthesia, weakness or heaviness radiating to lower extremities that occurs with walking or prolonged standing. The severity of these symptoms varies widely among patients, and may be disabling in some (Deer 2011, Brown 2012, Popov 2012, Wong 2012).

Conservative therapies for LSS include rest, pain medication, and physical therapy with or without epidural steroid injections. If these therapies fail, the patient may be advanced to more invasive surgical procedures. The goal of any surgical treatment of LSS is the relief of symptoms by adequate neural decompression while preserving as much of the anatomy, stability, and biomechanics of the lumbar spine as possible. Until the last decade, open spinal surgery was the standard treatment of LSS. The traditional surgical approach involves performing a wide, bilateral decompression laminectomy and resection of the medial portion of the facet joints to decompress the affected neural elements. This can successfully alleviate nerve compression symptoms but has the drawback of

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the open approach including the amount of soft tissue dissection, blood loss, postoperative pain, muscular atrophy, and potential for iatrogenic instability of the spinal segment (Popov 2012).

A number of less-invasive surgical techniques have been developed in recent years as an alternative to the traditional spine surgeries to limit the injury to the patient's native anatomy and reduce complication rates. These procedures are particularly attractive to spine surgeons for their small-skin incision, minimization of soft tissue injury, reduction of blood loss, infection rates, hospitalization time, narcotic usage, and minimization of physiological stress on the patient. Minimally invasive lumbar decompression techniques include the unilateral lumbar laminotomy for bilateral decompression, micro-endoscopic decompressive laminectomy, and lumbar micro-decompression (Deer 2010, Payer 2011, Smith 2012).

The *mild* ® (Minimally Invasive Lumbar Decompression) procedure (Vertos Medical Inc., Aliso Viejo, California) is a minimally invasive alternative to open or endoscopic lumbar decompression in the treatment of lumbar spinal stenosis. *Mild* ® treats LSS by removing small but adequate portions of the interlaminar bone (laminotomy) and partial excision (debulking) of the ligamentum flavum (LF) to restore space in the spinal canal while minimizing trauma to the surrounding tissue and bony structure. The procedure is typically performed under intravenous sedation monitored anesthesia and fluoroscopic guidance. The *mild* ® device kit is comprised of a single-use 6 gauge (5.1 mm diameter) *mild*® portal cannula with trocar to access into the soft tissue of the posterior lumbar spine, followed by a Bone Sculptor Ronguer which is used to precisely sculpt small pieces of lamina prior to tissue resection of the hypertrophic ligamentum flavum, then the *mild*® Tissue Sculpture is used to remove ligamentous and fibrous tissues from the hypertrophic ligamentum flavum (Deer 2010, 2011, Wong 2012).

The Vertos Medical *mild* ® Device Kit was FDA approved through the 510k process as a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions (FDA website accessed June 26, 2012).

Medical Technology Assessment Committee (MTAC)

Minimally Invasive Lumbar Decompression

08/20/2012: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine that *mild* ® Vertos procedure leads to similar or better outcomes than traditional surgery among in patients with symptomatic spinal stenosis who failed conservative therapy. There is limited published literature on the procedure. No published randomized controlled trials compared the procedure to the traditional surgical approach, or to other less invasive surgical techniques. The only published RCT to date was a small study that compared the outcomes of *mild* ® procedure to epidural steroid injection (ESI) in patients with symptomatic spinal stenosis and painful lower limb neurogenic claudication. The authors indicated that patients had to fail conservative therapy to be included in the trial, yet the procedure was compared to epidural steroid injection (ESI), which is considered a conservative management. In addition, the epidural steroid was delivered through interlaminar injections and not the preferable transforaminal route to maintain blinding (according to the author). The other published studies were prospective or retrospective case series with potential biases and were all funded by Vertos Medical the manufacturer of *mild*® *device*.
Articles: The literature search revealed one small RCT that compared the *mild*® procedure with epidural steroid injection, two multicenter observational studies with no control group, and few small prospective and retrospective case series. The RCT and the prospective multicenter observational study with one-year follow-up were selected for critical appraisal: Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the *mild* ® procedure in patients with symptomatic lumbar spinal stenosis. *Pain Practice*. 2012; 12:333-341. See Evidence Table. Mekhail N, Vallejo R, Coleman MH, et al. Long-term results of percutaneous lumbar decompression *mild* ® for spinal stenosis. *Pain Practice*.2012;12:184-193. See Evidence Table.

The use of minimally invasive lumbar decompression for treatment of spinal stenosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
62380	**Review no longer required after November 1, 2022** Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

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Creation Date	Review Dates	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	06/15/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/01/2020	Removed CPT code 0274T
06/15/2022	Added 62287 CPT code (per neurosurgery consultation this is more accurate than 62380); 62380 will no longer require review after 11/1/2022

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Clinical Review Criteria
Transcatheter Mitral Valve Repair (TMVR)

- MitraClip

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Decision Memo	Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R)

For Non-Medicare Members

Transcatheter mitral valve repair using a device approved by the U.S. Food and Drug Administration for use in mitral valve repair may be considered medically necessary for patients with symptomatic, primary mitral regurgitation who are considered at prohibitive risk for open surgery.

Prohibitive risk for open mitral valve repair surgery may be determined based on the following:

- The documented presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater

AND/OR

- The documented presence of a logistic EuroSCORE of 20% or greater

Transcatheter mitral valve repair with a device approved by the U.S. Food and Drug Administration may be considered medically necessary for patients with heart failure and moderate-to-severe or severe* symptomatic secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy**.

* Moderate to severe or severe MR may be determined by:

- Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography
- New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies.

**Optimal guideline directed medical therapy (GDMT) - see reference below:
https://www.jacc.org/doi/10.1016/j.jacc.2020.11.022

Transcatheter mitral valve repair is considered investigational in all other situations.

Reference

Maddox, T. M., Januzzi, J. L., Allen, L. A., Breathett, K., Butler, J., Davis, L. L., Fonarow, G. C., Ibrahim, N. E., Lindenfeld, J. A., Masoudi, F. A., Motiwala, S. R., Oliveros, E., Patterson, J. H., Walsh, M. N., Wasserman, A., Yancy, C. W., Youmans, Q. R., J.L., J., Al., E., … F.J., de A. (2021, February 1). *2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: Answers to 10 pivotal issues about heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee*. Journal of

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the American College of Cardiology. Retrieved February 11, 2022, from https://www.jacc.org/doi/10.1016/j.jacc.2020.11.022

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Name of the Food and Drug Administration (FDA) approved device to be used

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Background

Transcatheter mitral valve repair (TMVR) is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation (MR); currently MitraClip® is the only one with Food and Drug Administration (FDA) approval.

U.S. FDA–MitraClip Clip Delivery System (MitraClip CDS) (Abbott Vascular, Menlo Park, CA): The MitraClip CDS received FDA approval through the PMA process on October 24, 2013. It is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. The device is contraindicated in patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen, and those with active endocarditis of the mitral valve, rheumatic mitral valve disease, or evidence of intracardiac, inferior vena cava or femoral venous thrombus.

The MitraClip system consists of implant catheters and the MitraClip device, a permanent implant that attaches to the mitral valve leaflets. The procedure results in a double opening of the mitral valve that allows greater closure and reduces mitral regurgitation.

Medical Technology Assessment Committee (MTAC)

MitraClip System

BACKGROUND

Mitral regurgitation (MR) is the second most common valvular heart disease after aortic stenosis. The natural history of severe MR without surgical intervention is poor, leading to worsening LV failure, pulmonary hypertension, atrial fibrillation and death. It is reported that without surgical treatment, patients with severe symptomatic MR have an annual mortality rate of 5% per year, and as high as 60% at 5 years if associated with significant heart failure (Mauri 2010).

MR is broadly categorized as primary or secondary. Primary MR, also known as degenerative MR (DMR), describes an abnormality of the leaflets varying from a prolapse of an isolated segment in a normally shaped valve, to multiple segment prolapse involving one or both leaflets in a valve with significant excessive tissue and large annular size. Secondary MR, also known as functional MR (FMR), is secondary to left ventricular (LV) remodeling with structurally preserved mitral leaflets. Surgical mitral valve repair/replacement remains the gold standard for the treatment of symptomatic MR, though it has some controversy in FMR due to the lack of clear survival benefit and high recurrence rates of MR at 1 year after surgery. Current guidelines recommend MV surgery in patients with moderate to severe (grade 3+) or severe (4+) MR associated with symptoms or evidence of LV dysfunction. Surgical repair of the valve before the onset of limiting symptoms or LV dysfunction can restore normal life expectancy and quality of life. The conventional surgery for MV repair/replacement is an open-heart surgery performed under cardiopulmonary bypass. It is reported that as many as 49% of patients in need of MR repair or replacement are considered at high surgical risk and are denied surgical treatment due to their age, advanced LV systolic dysfunction, previous bypass surgeries, or significant comorbidities. Patients who do not qualify for surgical correction of the MV are treated with medical therapy alone, which may reduce their symptoms, but does not stop the disease progression (Estevez-Loureiro 2013 Mauri 2013, Vakil 2013, Wan 2013, Munkholm-Larsen 2014). In the past 15 years, percutaneous valve therapy has been advancing rapidly especially for the aortic and pulmonic valve replacement. This development of percutaneous mitral valve (MV) therapies has been slower due to the anatomy of the MV and its relationship with the left ventricle. A number of devices for MV repair have been introduced as potential alternatives to open surgical procedures; many have failed, and more

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are at different stages of investigation. Percutaneous or minimally invasive repair systems target the MV leaflets, annulus or the left ventricle, e.g. the Neochord DS1000, the Carillon Mitral Contour System, and the MitraClip system. The latter is the only one in clinical use across the United States and Europe (Munkholm-Larsen 2014, Rana 2015).
The concept of the MitraClip system (Abbott Vascular, Menlo Park, California) is based on the edge-to-edge repair technique developed by Alfieri and colleagues in the early 2000s. This technique involves suturing of the middle scallops of the anterior and posterior MV leaflets resulting in a double orifice valve. The MitraClip is a single-sized system that consists of a 4mm wide cobalt chromium clip with two foldable arms designed to grasp the moving leaflets; a 10Fr delivery catheter, with a radiopaque distal tip, and a 24-Fr steerable sleeve. The procedure is performed in the cardiac catheterization laboratory under general anesthesia, anticoagulation, and fluoroscopic and transesophageal echocardiographic guidance. The MV is accessed via the femoral vein and right atrium then to the left atrium via a transseptal puncture. The system is advanced into the left ventricle and the clip is deployed for permanent approximation of the anterior and posterior MV leaflets creating a double orifice MV during diastole. Reduction in MR is assessed by echocardiography during the procedure, and more than one clip may be used at the operator's discretion. At the end, the catheters are withdrawn, and the patient treated with aspirin for 6 months and clopidogrel for 30 days (Wan 2013, Vakil 2013, Munkholm-Larsen 2014, Rana 2015).
Several anatomic parameters must be satisfied to determine the appropriate patients for the procedure. These differ for patients with DMR and FMR. Anatomical criteria for DMV include flail width and gap size, prolapse location, length of posterior MV leaflet (PMVL) and MV orifice size. The criteria for MV anatomy include coaptation depth and length, the MV orifice size, and the MV transvalvular gradient. Lesions ideal for MitraClip lie within the central portion at the coaptation line, have a flail width <15 mm with a flail gap <10mm, and as the MitraClip reduces the MV orifice, the preimplantation area should be >40 mm^2. A hypoplastic posterior leaflet is a contraindication, and heavy calcification, fibrosis, or deep clefts within the clip grasping area have potential for clip implantation failure. The percutaneous MV repair with the MitraClip system depends heavily on echo-imaging during the implantation and early on for assessing the suitability for clip placement, which is the cornerstone for the success of the technique. It has been reported that some technical aspects of the MitraClip implantation remain operator dependent and have not been fully standardized, and that the correct strategy for patients with complex valve anatomy remains controversial (Paranskaya 2013, Rana 2015).
The MitraClip treatment of MR is less invasive than surgery but may be associated with potentially life-threatening complications. The incidence of the reported procedure-related complications is generally low and varies considerably between studies. These included bleeding that require >2 units of blood transfusion (the most common), vascular access site complications, transseptal puncture
(which may also cause to aortic root needle puncture), partial clip detachment, clip attachment to a single leaflet, leaflet injury or laceration, mitral valve stenosis, mitral valve injury, acute heart failure, and stroke (Bakker 2013).
According to the device manufacturer and the FDA (approval in October, 2013), MitraClip implantation is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral valve (degenerative MR), who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. It is contraindicated in patients who cannot tolerate anticoagulation required during the procedure or antiplatelet therapy required after the procedure; in patients with active MV endocarditis; rheumatic MV disease; and in patients with evidence of femoral venous, inferior vena cava, or intracardiac thrombus. (http://mitraclip.com, and FDA webpage accessed July 17, 2015)

08/17/2015: MTAC REVIEW
MitraClip System
Evidence Conclusion:
There is evidence from EVEREST II RCT with 4 years of follow-up, that the implantation of MitraClip is less effective than surgery in improving the mitral regurgitation in patients with moderate or severe symptomatic mitral valve regurgitation who are suitable candidates for conventional surgery. The is low quality, but consistent evidence from observational studies and registries that implantation of MitraClip in patients with symptomatic moderate or severe symptomatic mitral valve regurgitation who are at high surgical risk, is feasible and is associated with clinical improvement and relatively low risk of major adverse events. However, there is no evidence to date to determine the durability of clinical improvements and optimal criteria for patient selection. There is insufficient evidence to determine the outcomes of MitraClip device by etiology of mitral regurgitation (FMR or DMR). Two ongoing RCTs (COPAT in the US and RESHAPE-HF trial in Europe) are comparing MitraClip implantation versus medical therapy in high surgical risk patients, and their results may provide more evidence on the relative safety and efficacy of implanting the device in these patients.
Articles: The literature search revealed EVEREST I feasibility trial; EVEREST II randomized controlled with four publications (the last of which reported on 4-years follow-up outcomes); 4 other nonrandomized
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comparative studies with retrospective controls including EVEREST II High Risk Study (HRS); a number of uncontrolled studies; a meta-analysis that pooled the results of the RCT and comparative studies; 3 systematic reviews (2 on the safety and efficacy of MitraClip in patients at high surgical risk, and one for patients with severe MR); and a number of industry-supported or industry-independent registries (REALISM, ACCESS Europe, Everest High-risk register) TRAMI German registry, and GRASP registry),The EVEREST II RCT, the EVEREST II HRS, and the meta-analysis that examined the safety and efficacy of MitraClip for patients at high surgical risk were selected for critical appraisal. Feldman T, Foster E, Glower DD, et al for the EVEREST II Investigators. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med*. 2011 Apr 14; 364(15):1395-406. See Evidence Table 1. Mauri L, Garg P, Massaro JM, Foster E, et al. The EVEREST II Trial: design and rationale for a randomized study of the evalve mitraclip system compared with mitral valve surgery for mitral regurgitation. *Am Heart J*. 2010 Jul; 160 (1):23-29. See Evidence Table 1. Philip F, Athappan G, Tuzcu EM, et al. MitraClip for severe symptomatic mitral regurgitation in patients at high surgical risk: a comprehensive systematic review. *Catheter Cardiovasc Interv*. 2014 Oct; 84(4):581-590. See Evidence Table 3. Mauri L, Foster E, Glower DD, et al. for the EVEREST II Investigators. 4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation. *J Am Coll Cardiol*. 2013 Jul 23; 62(4):317-328. See Evidence Table 1. Wan B, Rahnavardi M, Tian DH, et al. A meta-analysis of MitraClip system versus surgery for treatment of severe mitral regurgitation. *Ann Cardiothorac Surg.* 2013. Nov; 2(6):683-692. Whitlow PI, Feldman T, Pederson WS et al on behalf of the EVEREST II Investigators. Acute and 12-Month Results with Catheter-Based Mitral Valve Leaflet Repair: The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. *J Am Coll Cardiol*. 2012. January; 59:130–139. See Evidence Table 2.

The use of the MitraClip System does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
05/13/2015	09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC] 02/01/2022[MPC], 02/07/2023[MPC]	01/05/2021

[MPC] Medical Policy Committee

Revision History	Description
01/05/2021	MPC approved to adopt changes to criteria to include symptomatic secondary mitral regurgitation and high-risk score for traditional surgery. Requires 60-day notice, effective date 06/01/2021.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Monitored Anesthesia Care (MAC) for Gastrointestinal Endoscopic Procedures

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	4/09/2018 Noridian Retired LCD for Monitored Anesthesia Care (MAC) (L34100). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search. Medical necessity review is no longer required for Medicare members. However, providers are expected to validate medical necessity per Medicare’s guidance in retired LCD L34100 (see above).
Local Coverage Article	None

For Non-Medicare Members

Effective until March 1, 2023

Monitored anesthesia care (MAC) is considered medically necessary during gastrointestinal endoscopic procedures when there is documentation by the operating physician and the anesthesiologist that demonstrates any of the following higher risk situations exist:

- Prolonged or therapeutic endoscopic procedure requiring deep sedation**; Such as endoscopic ultrasound (EUS), double balloon enteroscopy (push endoscopy), transanal endoscopic microsurgery (TEM), endoscopic retrograde cholangio-pancreatography (ECRP) or
- A history of or anticipated intolerance to standard sedatives (e.g., patient on chronic high dose narcotics or high dose benzodiazepines, or has an unstable neuropsychiatric disorder which would prevent cooperation); or
- Increased risk for complication due to severe comorbidity. American Society of Anesthesiologists **ASA class IV physical status or greater** (as documented by Anesthesia)
- Pediatric age group (16 years and younger); or
- Pregnancy; or

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- History of active drug or alcohol abuse; (marijuana use, either daily or intermittent, does not by itself require MAC anesthesia) or
- Morbid obesity (BMI>40); or
- Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); or
- Spasticity or movement disorder complicating procedure; or
- Increased risk for airway obstruction due to anatomic variant including any of the following:
  - Documented history of previous problems with anesthesia or sedation; or
  - History of stridor or severe sleep apnea requiring oxygen **and** bipap; or
  - Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy-21; or
  - Presence of significant oropharyngeal abnormalities, such as tonsillar hypertrophy or oropharyngeal mass, as documented by Anesthesia; or
  - Neck abnormalities including but not limited to short neck, obesity involving the neck and facial structures, limited neck extension, decreased hyoid-mental distance (less than 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis as documented by Anesthesia; or
  - Jaw abnormalities including but not limited to micrognathia, retrognathia, trismus, or significant malocclusion as documented by Anesthesia

Effective March 1, 2023

Monitored anesthesia care (MAC) is considered an acceptable clinical option during gastrointestinal endoscopic procedures when there is documentation by the operating physician and the anesthesiologist that demonstrates any of the following higher risk situations exist:

- Prolonged or therapeutic endoscopic procedure requiring deep sedation**; Such as endoscopic ultrasound (EUS), double balloon enteroscopy (push endoscopy), transanal endoscopic microsurgery (TEM), endoscopic retrograde cholangio-pancreatography (ERCP) or
- A history of or anticipated intolerance to standard sedatives (e.g., patient on chronic high dose narcotics or high dose benzodiazepines, or has an unstable neuropsychiatric disorder which would prevent cooperation);
- Member is currently using Suboxone or
- Increased risk for complication due to severe comorbidity. American Society of Anesthesiologists **ASA class III* or greater physical status** (as documented by Anesthesia)
- Pediatric age group (16 years and younger); or
- Pregnancy; or
- History of active drug or alcohol abuse; (marijuana use, either daily or intermittent, does not by itself require MAC anesthesia) or
- Morbid obesity (BMI>40); or
- Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); or
- Spasticity or movement disorder complicating procedure; or
- Increased risk for airway obstruction due to anatomic variant including any of the following:
  - Documented history of previous problems with anesthesia or sedation; or
  - History of stridor or severe sleep apnea requiring oxygen **and** bipap; or
  - Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy-21; or
  - Presence of significant oropharyngeal abnormalities, such as tonsillar hypertrophy or oropharyngeal mass, as documented by Anesthesia; or
  - Neck abnormalities including but not limited to short neck, obesity involving the neck and facial structures, limited neck extension, decreased hyoid-mental distance (less than 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis as documented by Anesthesia; or
  - Jaw abnormalities including but not limited to micrognathia, retrognathia, trismus, or significant malocclusion as documented by Anesthesia

*ASA Physical Status Classification System – please click here to see ASA PS Classification table

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ASA PS Classification	Definition	Adult Examples, Including, but not Limited to:	Pediatric Examples, Including but not Limited to:	Obstetric Examples, Including but not Limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use	Healthy (no acute or chronic disease), normal BMI percentile for age	
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease	Asymptomatic congenital cardiac disease, well controlled dysrhythmias, asthma without exacerbation, well controlled epilepsy, non-insulin dependent diabetes mellitus, abnormal BMI percentile for age, mild/moderate OSA, oncologic state in remission, autism with mild limitations	Normal pregnancy*, well controlled gestational HTN, controlled preeclampsia without severe features, diet-controlled gestational DM.
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.	Uncorrected stable congenital cardiac abnormality, asthma with exacerbation, poorly controlled epilepsy, insulin dependent diabetes mellitus, morbid obesity, malnutrition, severe OSA, oncologic state, renal failure, muscular dystrophy, cystic fibrosis, history of organ transplantation, brain/spinal cord malformation, symptomatic hydrocephalus, premature infant PCA <60 weeks, autism with severe limitations, metabolic disease, difficult airway, long term parenteral nutrition. Full term infants <6 weeks of age.	Preeclampsia with severe features, gestational DM with complications or high insulin requirements, a thrombophilic disease requiring anticoagulation.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis	Symptomatic congenital cardiac abnormality, congestive heart failure, active sequelae of prematurity, acute hypoxic-ischemic encephalopathy, shock, sepsis, disseminated intravascular coagulation, automatic implantable cardioverter-defibrillator, ventilator dependence, endocrinopathy, severe trauma, severe respiratory distress, advanced oncologic state.	Preeclampsia with severe features complicated by HELLP or other adverse event, peripartum cardiomyopathy with EF <40, uncorrected/decompensated heart disease, acquired or congenital.
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction	Massive trauma, intracranial hemorrhage with mass effect, patient requiring ECMO, respiratory failure or arrest, malignant hypertension, decompensated congestive heart failure, hepatic encephalopathy, ischemic bowel or multiple organ/system dysfunction.	Uterine rupture.
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes			

(ASA, 2002, 2018; American Society for Gastrointestinal Endoscopy [ASGE], 2002, 2003, 2012, 2018)

Not Medically Necessary:

The routine assistance of an anesthesiologist or Certified Registered Nurse Anesthetist (CRNA) for patients not meeting the above criteria who are undergoing standard upper or lower gastrointestinal endoscopic procedures is considered not medically necessary. (American College of Gastroenterology [ACG], American Gastroenterological Association [AGA] & ASGE, 2004; ASGE, 2002, 2003, 2012).

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Each year in the United States, 145,000 people will be diagnosed with colon cancer; 54,000 will die. Getting recommended colorectal cancer screening could potentially save the lives of up to 60% of these patients. Increasing patient participation in routine screening is a matter of serious concern.

With the increased emphasis on prevention and the importance of the role of colonoscopy as a tool there is a need to evaluate the use of monitored anesthesia care in conjunction with endoscopic evaluation. Kaiser Permanente has developed this policy in response to our findings.

Medical Technology Assessment Committee (MTAC)

Monitored Anesthesia Care (MAC) for Gastrointestinal Endoscopic Procedures

2/22/2010: MTAC REVIEW

Evidence Conclusion: The following are conclusions based on a review of several systematic reviews, meta-analyses, randomized controlled trials, and published internal data on sedation involving propofol compared to standard sedation: There is good evidence of improved patient satisfaction and reductions in discharge and

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recovery times with propofol used alone or in combination with other agents compared to standard sedation for colonoscopy exams. There is fair evidence from a KP SCAL-based comparative study of improved cecal intubation rates with propofol used as a single agent for sedation during colonoscopy. The evidence is of insufficient quantity or quality to draw definitive conclusions on differences in polyp detection. There is less comparative data on EGD procedures, but some evidence of improved recovery and patient satisfaction with propofol sedation. The evidence is of insufficient quantity and/or quality to draw definitive conclusions on comparative risk of serious adverse events, including death, neurologic injury, endotracheal intubations, bleeding, and colonic perforations during these procedures. There does not appear to be a significant difference in the risk of cardiopulmonary and respiratory events with propofol compared to standard sedation and no evidence of greater risk for serious adverse events for either colonoscopy or EGD procedures in lower risk patients (ASA I or II). Following the review of one systematic review and two comparative observational studies, the evidence is of insufficient quantity and quality to draw definitive conclusions on the safety of anesthesiologist- versus non anesthesiologist-directed or administered propofol sedation in GI endoscopy. Controlled prospective studies with standardized protocols, patient selection, and reporting are needed. Serious Adverse Events. The best available comparative evidence from the United States is a large observational registry study that suggests comparable rates of serious adverse events for anesthesiologist-directed propofol under monitored anesthesia care and gastroenterologist-administered propofol during colonoscopy procedures (0.16% and 0.14%) but a significantly increase risk of serious adverse events with gastroenterologist-administered propofol for upper endoscopy procedures, including EGDs (0.16% vs 0.5%). However, it is likely that these events differentially occurred in higher risk patients (ASAI III) who were also included in the study. Overall Cardiopulmonary Adverse Events. There is evidence from the same study of a significant increased risk of overall cardiopulmonary events with endoscopic-administered propofol in ASA I or II patients undergoing colonoscopy and upper endoscopy. The majority of the cardiopulmonary events are most likely to be of minor clinical consequence, but the challenge remains to identify which cardiopulmonary events are more likely to result in serious adverse events and what risk factors are specific to upper versus lower endoscopy procedures. The evidence is of insufficient quantity and quality to draw conclusions on the safety of RN-administered propofol as compared to standard sedation for colonoscopy and EGD in ASA I and II patients. Based on a review of several systematic reviews and randomized controlled trials, there is no evidence of a significant increase in risk of adverse events with propofol compared to standard sedation and the risks appear to be comparable. However, these studies were not adequately sampled to detect or compare rates of serious adverse events. Comparative data from large and well-designed observational studies is needed. The existing series of RN-administered propofol are large and report low rates of adverse events.

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MDCRPC voted to adopt the Kaiser evidence review conclusions.

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MONITORED ANESTHESIA CARE (MAC) FOR CHRONIC MARIJUANA USERS UNDERGOING GASTROINTESTINAL ENDOSCOPIC PROCEDURES

BACKGROUND

Marijuana use

Marijuana is the most commonly used federally illegal drug in the United States. Its use has significantly increased across the country in recent years, especially among young people and in the states that have legalized the recreational cannabis use. It is estimated that approximately 3 in 10 people who use marijuana have marijuana use disorder, the risk of which is higher among those who begin using it before the age of 18, The National Survey on Drug Use and Health National Institute on Drug Abuse estimated that 5.1% (or about 14.2 million people) aged 12 or older in 2020 had a cannabis use disorder in the past 12 months (2020 National Survey on Drug Use and Health National Institute on Drug Abuse and CDC website).

Th term “Marijuana” is commonly used interchangeably with “Cannabis”; however, they don’t mean exactly the same thing. Cannabis refers to all products derived from the plant Cannabis sativa that includes more than 500 compounds among which are cannabinoids, terpenoids, and flavonoids. Marijuana on the other hand refers to the dried flowers, leaves, stems, and seeds of the cannabis plant that contain substantial amounts of tetrahydrocannabinol (THC) that is primarily responsible for the effects of marijuana on a person’s mental state. The main cannabinoids in the cannabis are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), each with its own effects and uses. THC is the main psychoactive compound in cannabis and is responsible for the “high” that most people associate with cannabis. CBD is also a psychoactive cannabinoid, but is non-intoxicating and non-euphoric, i.e., does not cause a “high”. It is often used to help reduce inflammation and pain, and also to ease nausea, migraine, seizures, and anxiety. (Andre et al, 2016, Boninin et al, 2018, Bakshi, et al 2019, Balant, et al 2021, Irvine , et al 2022, and the CDC website

Marijuana use has negative clinical effects on different body organs and systems including the respiratory, cardiovascular, and central nervous system, gastrointestinal tract, and others. These vary by the quantity and chronicity of the marijuana used. However, it can be difficult to the quantity the active compound of the marijuana consumed as the formulations of the products and their CBD-to-THC-content ratios are very heterogeneous. Research suggests that cannabis users require significantly higher doses of sedation for upper endoscopic procedures compared with nonusers. Propofol, a primary anesthetic agent, is metabolized through similar enzymatic pathways as the THC and cannabis users may present a higher-than-normal risk for subanesthetic dosing, leading to greater incidence of awareness or recall. They are also at a higher risk of adverse events such as bronchospasm, laryngospasm, tachycardia, and others (Twardowski, et al 2019, Imasogie et al 2021, Ladha et al, 2021).

With the increasing prevalence of cannabis use among adults, and with the known effects of marijuana on the different systems it is important that anesthesia professionals consider the potential effects of cannabis use when providing perioperative care to chronic marijuana users.

Monitored anesthesia care (MAC)

Monitored anesthesia care is defined by the American Society of Anesthesiologists (ASA) as a planned procedure during which the patient undergoes local anesthesia together with sedation, and analgesia provided by an anesthesiologist. I.e., it is an anesthesia technique combining local anesthesia with parenteral drugs for sedation and analgesia. The purpose of the conscious sedation during MAC is providing the patient with safe sedation, comfort, and control of pain and anxiety. The patients under conscious sedation maintain ventilatory and cardiovascular function and are able to respond to verbal and tactile stimulation. The discretion and judgment of an experienced anesthesiologist are required for the safety and efficacy as the airway of the patient is not secured. The attending anesthesiologist should be aware of the possibility of airway obstruction, desaturation, or even aspiration due to the possibility of deep sedation after infusion of a combination of two or more drugs (GHISI, et al 2005, Sohn and Ryu 2016. In contrast, moderate sedation /analgesia (conscious sedation) is a drug induced depression of consciousness during which patients respond purposefully to verbal commands alone or with
light tactile stimulation. No interventions are required to maintain a patent airway, spontaneous ventilation is adequate and cardiovascular function is usually maintained.

MAC allows for the safe administration of a maximal depth of sedation more than that provided during moderate sedation. The qualified anesthesiologist /provider is able to adjust the sedation level from full

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consciousness to general anesthesia during the procedure according to the patient needs and procedural requirements. An essential component of MAC is the periprocedural anesthesia assessment and understanding of the comorbidities and management of the patient's actual or anticipated physiological instabilities during a diagnostic or therapeutic procedure. MAC may include the administration of sedatives and/or analgesics often used for moderate sedation, however the qualified MAC provider is focused exclusively and continuously on the patient for any attendant airway, hemodynamic and physiologic instabilities, and must be prepared and qualified to convert to general anesthesia. The provider's ability to intervene to rescue a patient's airway from any sedation-induced compromise is required. On the other hand, moderate sedation is not expected to induce the level of sedation that would impair the patient's respiratory function or ability to maintain the integrity of his or her airway, and the moderate sedation provider or anesthesiologist focus is on the procedure itself. (ASA 2018)

The use of MAC is increasing for a variety of diagnostic and therapeutic procedures in and outside of the operating room due to the rapid postoperative recovery with the use of relatively small amounts of sedatives and analgesics compared to general anesthesia. Procedures performed with MAC include eye surgery, otolaryngologic surgery, cardiovascular procedures, pain procedures, and endoscopy. Sedation and analgesia during MAC are provided by an anesthesia care team following the same preoperative evaluation, perioperative management, monitoring, and postoperative recovery care used for general or regional anesthesia (Sohn and Ryu 2016).

Some researchers found that the overall rate of complications during and after MAC may be similar to that for general anesthesia. These potential complications associate with MAC include

- Respiratory complications, including airway obstruction, respiratory depression with hypoxemia and hypercarbia, and aspiration due to depression of airway reflexes.
- Cardiovascular compromise, including hypotension, cardiac ischemia, cardiac arrest, and arrhythmias.
- Complications related to patient movement
- Burn injuries, particularly involving the head and neck
- Local anesthetic systemic toxicity (LAST

10/10/2022: MTAC REVIEW

Evidence Conclusion: To date, there are no published literature on the comparative efficacy and safety of monitored anesthesia care and moderate sedation for patients on chronic marijuana use undergoing gastrointestinal endoscopic procedures.

Additional research is needed to determine the efficacy and safety of MAC in these patients.

Articles: The literature search did not reveal any published RCTs or observational studies that compared the outcomes of MAC versus moderate conscious sedation for GI endoscopic procedures in adults on chronic marijuana use. The published literature mainly discussed the effects of cannabis use on the anesthesia risk, the dose of propofol required, the need for using adjuncts such as fentanyl and ketamine, and or the risk of adverse cardiac or respiratory events during or immediately after anesthesia.

The use of Monitored Anesthesia Care (MAC) For Chronic Marijuana Users Undergoing Gastrointestinal Endoscopic Procedures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
00731	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified
00811	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified
00812	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy
00813	Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum

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Date Created	Date Reviewed	Date Last Revised
09/10/2012	10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	12/07/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2015	Slight changes were made to the existing policy, which included the following: • Removal of the 70-age limit • Definition of pediatric age group as 16 years and younger • Clarification of “high dose” & “unstable” • “as documented by anesthesia” language was added
09/08/2015	Revised LCD L34100
10/3/2016	Added prolonged procedure clarification
09/06/2017	Changed BMI to 40
10/19/2017	Added examples of prolonged procedures
04/09/2018	MA retired LCD 34100
05/23/2018	Removed the language regarding the Mallampati score
09/04/2018	Added specific language regarding marijuana use
05/05/2020	MPC approved to adopt updates to align with ASA class ASGE recommendations. Requires 60-day notice, effective date 9/1/2020. Removed deleted CPT codes 00740 and 00810 and added CPT code 00732.
06/16/2020	Removed 00732 (ERCP)
11/02/2021	MPC approved to remove the prior-authorization requirement for Medicare members, effective January 1, 2022.
09/06/2022	MPC approved the MAC criteria update for ASA class from IV to III and the inclusion of coverage for members with current suboxone use. 60-day notice required; effective 2/1/2023.
12/06/2022	Updated MAC effective date to 3/1/2023 per Provider Relations.
12/07/2022	Added MTAC Review for Monitored Anesthesia Care (MAC) For Chronic Marijuana Users Undergoing Gastrointestinal Endoscopic Procedures to criteria.

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Clinical Review Criteria

Magnetic Resonance Enterography (MR per OS) for the Diagnosis and Monitoring of Crohn's and Celiac Diseases

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (MRI) (220.2)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Kaiser Permanente considers magnetic resonance enterography medically necessary to evaluate and monitor Crohn's disease and other small bowel disorders and does not require medical necessity review.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract. In 80% of cases it involves the small bowel, more specifically the ileum, and is characterized by luminal, transmural and mesenteric abnormalities. Crohn's usually manifests in early adulthood and typically runs a relapsing and remitting course. Initial diagnosis aims at establishing and characterizing the disease including the location, extent of inflammation, and the presence of stenosis, fistulae or abscesses. Several modalities such as radiology, endoscopy, and serologic markers are being used to diagnose and assess the disease activity. None is recognized as a gold standard, but radiological procedures including small bowel series and fluoroscopic enteroclysis continue to lead the diagnostic tools that examine the small bowel in its entirety. Because there is no known cure, and the condition is typically relapsing, patients with Crohn's disease normally undergo several radiological investigations during the course of the disease to monitor the treatment response, recurrence, and /or development of complications (Negaard 2007, 2008, Masselli 2006, Lin 2008).

Celiac disease is a gluten-sensitive enteropathy of the gastrointestinal tract that affects the small intestine in genetically susceptible individuals at any age. The disease is relatively common in European countries and occurs less frequently in the US. Celiac disease has a wide range of nonspecific clinical manifestations which make it challenging to diagnose. Its may be silent and go clinically undetected or present with symptoms that range from fatigue and abdominal pain to weight loss, diarrhea, and malabsorption with steatorrhea. In children it may be associated with apathy, anorexia, and muscle wasting. It is reported that a small-intestine biopsy is mandatory to confirm the diagnosis of celiac disease. Imaging plays a role in suggesting celiac disease in adults with intestinal disorders, and in ruling out complicating lesions in patients with known disease (Paolantonio 2007).

The traditional imaging techniques used to evaluate the small bowel are the conventional barium studies e.g. small bowel follow-through or conventional enteroclysis (CE) Historically CE has been the radiological method of

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choice. It was found to be highly accurate for diagnosing Crohn's disease and detecting partially or non-obstructive lesions that may not be demonstrated by cross-sectional imaging techniques. The procedure involves distension of the entire small bowel with barium suspension which when adequate, would allow the radiological demonstration of mucosal abnormalities and provide functional information on the ability of the small bowel to distend. CE, however, exposes the patient to ionizing radiation, may be hindered by the overlapping bowel loops, and does not provide information on the transmural and extramural extension, or other complications of the disease such as fistulae and abscesses (Schreyer 2004, Bernstein 2005, Masselli 2008).

Computed tomographic (CT) enterography, magnetic resonance (MR) enterography, and MR enteroclysis are emerging techniques for small bowel imaging. They have a benefit over traditional barium fluoroscopic techniques in their ability to visualize superimposed bowel loops and extraluminal extensions, and complications. CT provides excellent temporal and spatial high-resolution images of the small bowel, and is less susceptible to motion artifacts than MRI, but at the cost of radiation exposure. MRI on the other hand, has several advantages over CT, such as its superior tissue contrast, ability to provide direct cross-sectional imaging in multiple planes, functional or real-time examination of the bowel, and lack of ionizing radiation exposure which is particularly important in Crohn's patients who need repeated evaluation. The real-time imaging can be helpful in evaluating the progress of bowel filling with contrast agents during enteroclysis, determining the ability of the narrowed areas to distend, and improving differentiation of contractions from strictures. In addition, the gadolinium contrast agents used in MRI are known to have an excellent safety profile and can be used in patients with iodine contrast allergies, renal insufficiency, or during pregnancy. MRI, however, has inferior spatial and temporal resolution compared to CT, and its image quality may be degraded by artifacts from bowel peristalsis. Other reported constraints for MRI use include the limited number and access to MR scanners as well as its high cost (Rieber 2000, Bruining 2006, Fidler 2007).

MRI for small bowel disease may be performed by MR enteroclysis (luminal contrast) or MR enterography (MRI per OS, oral contrast). MR enteroclysis requires the fluoroscopic passage of a nasojejunal catheter and controlled administration of significant volumes (up to 3 liters) of enteric contrast agents. The small bowel can be filled with manual injection or hand-held infusion pumps while the patient is in the scanner. The procedure is associated with significant patient discomfort particularly due to the catheter introduction and manipulation, as well as the profuse diarrhea which results from the infused contrast medium. Moreover, the continuous infusion of the contrast agent may result in gastro-esophageal reflux especially in the obstructed patient, leading to potential vomiting and aspiration (Negaard 2007, Lohan 2007).

To achieve a compromise between patient tolerability and reproducible diagnostic image acquisition, MRI techniques with oral contrast (MR enterography) have been introduced. For this procedure, the patient is required to ingest a large amount of fluid (1.5-2 liters) to distend the stomach and small bowel in continuity. Various substances and volumes have been added to the oral solutions to increase the bowel distension. It is reported that there is no agreement on the optimal oral contrast, but investigators found that high osmolarity of the contrast e.g. mannitol, improves the bowel distension. MR enterography may be associated with adverse effects such as diarrhea, nausea, abdominal pain, ileus due to the increased fluid content, and other side effects (Masselli 2006, Lohan 2007).

Medical Technology Assessment Committee (MTAC)

Magnetic Resonance Enterography (MR per OS)

02/02/2009: MTAC REVIEW

Evidence Conclusion: Most of the published studies on MR imaging of the small bowel used the enteroclysis technique that requires intubation of the proximal small bowel followed by the administration of contrast agent. Few studies performed MR enterography where the contrast material is ingested orally. Different modalities for the diagnosis of Crohn's disease were used as reference standards, as there is no non-surgical gold standard to date.

In the studies reviewed, MR imaging was used for patients with suspected or confirmed Crohn's disease to characterize the disease, assess the extent and severity of bowel inflammation, and detect any stenosis, fistula, or other associated lesions. In both MR techniques, good distension of the small bowel loops during examination is essential to accurately evaluate the bowel wall pathology because collapsed loops may hide the disease or falsely identify a collapsed segment as a thickened wall. Negaard et al's study (2007) included 40 participants with known or suspected Crohn's. All participants were examined with both MR techniques, and the diagnosis of the disease was based on clinical evaluation, ileoscopy with histopathology, capsule endoscopy, or surgery. The study had several limitations, no comparison was made to with conventional enteroclysis, and lesions in jejunum and proximal ileum were not evaluated. Moreover, the reference standards were performed 2-3 months after the

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MR imaging, which may affect the presence or absence of some disease-related findings. The overall results of the study show that bowel distension was statistically significantly inferior in MR enterography compared to MR enteroclysis at both the jejunal and ileal levels. The difference was, however, insignificant for the terminal ileum. The accuracy of the two MR imaging techniques had similar sensitivity in assessing the intestinal wall thickness, enhancement and ulcer detection, when compared to reference standards used in the study. MR enteroclysis was more sensitive and specific than MR enterography in detecting intestinal stenosis, but less specific for the three other measures. MR enterography was associated with bowel obstruction in two patients one of which required abdominal surgery to treat the condition. Masselli and colleagues' study (2008) compared the diagnostic accuracy of MR enterography, with MR enteroclysis, and conventional enteroclysis as a reference standard in 40 patients with histologically proven Crohn's disease. All participants underwent conventional enteroclysis and either the MR enteroclysis or enterography on an alternating basis. The study was small and had several limitations. Its overall results show that conventional enteroclysis detected significantly more mucosal and mural abnormalities, but less mesenteric findings vs. MR enteroclysis and MR enterography. There was no significant difference between the two MR imaging techniques in the image quality, or assessment of mural stenosis and fistulae. However, MR enterography was statistically significantly inferior in bowel distension vs. MR or conventional enteroclysis. It was also inferior to MR enteroclysis in detecting the involved affected segments, superficial erosions, and deep ulcers. Conclusions: The published studies indicate that MR enterography may be inferior to conventional and MR enteroclysis in bowel distension, and detection of some associated lesions. There is insufficient evidence to determine the role of MR enterography in the diagnosis or assessment of celiac disease. There is insufficient evidence to determine the role of MR enterography in monitoring patients with Crohn's or celiac disease. There is insufficient evidence to determine the safety of the MR enterography in patients with Crohn's or celiac disease.
Articles: The literature search revealed over three hundred publications. The majority was reviews, articles that dealt with the technical aspects of the tests, or that were unrelated to the current review. The studies on the use of MR imaging for the evaluation of small bowel diseases mainly included patients with Crohn's disease; only one small retrospective case series evaluated the test for patients with celiac disease. The literature on MR enterography was very limited compared to MR enteroclysis. One study compared both MR techniques (enteroclysis and enterography) to conventional enteroclysis, and one to a combination of reference standards. The technology was also compared to capsule endoscopy or CT enterography in two small studies. The test was mainly used for the initial assessment of known or suspected Crohn's. Only one small study that included patients with recurrent disease was identified, but there were no published studies on the use of MR enterography for monitoring treatment response. The studies that compared MR enterography of the small bowel to conventional enteroclysis and/or MR enteroclysis, and that had more valid methodology and data analysis, were selected for critical appraisal. Negaard A, Paulson V, Sandvick L, et al. A prospective randomized comparison between two MRI studies of the small bowel in Crohn's disease, the oral contrast methods and MR enteroclysis. Eur Radiol 2007;17:2294-2301. See Evidence Table. Masselli G, Casciani E, Polettini E, et al. Comparison of MR enteroclysis with MR enterography and conventional enteroclysis in patients with Crohn's disease. Eur Radiol. 2008;18:438-47. See Evidence Table.

The use of Magnetic Resonance Enterography (MR per OS) for the diagnosis and monitoring of Crohn's and celiac diseases does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medical Necessity Review not required:

CPT® or HCPC Codes	Description
No Specific Codes	

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Date Created	Date Reviewed	Date Last Revised

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03/12/2009	05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
06/06/2017	MPC approved criteria for medical necessity
05/04/2021	MPC approved to remove the medical necessity review requirement for Magnetic Resonance Enterography. Requires 60-day notice, effective date 10/1/2021.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Brain MRI

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Criteria

For Medicare Members

This policy does not apply to Medicare members.

For Non-Medicare Members

***Site of Care review also applies -** See the High-end imaging Site of Care Medical Policy

Magnetic resonance imaging (MRI) studies of the brain may be medically necessary when the following criteria are met:

I. **Evaluation of headache:**
   Brain MRI is not indicated for any of the following headache diagnoses in the absence of focal neurological deficits: migraine, cluster headache, tension-type headache, or chronic stable headache**.**
   MRI can be considered for 1 or more of the following –
   a. Chronic headache with a change in character/pattern (e.g., more frequent, increased severity, or duration) not explained after evaluation of common causes (e.g., medication overuse syndrome or cervicogenic headache) and failure to respond to standard medical management
   b. Suspected aneurysm rupture/leak or AVM. Typically described as a new onset (< 48 hours) of “worst headache in my life” or “thunderclap” headache. A thunderclap type headache is a sudden onset new headache reaching maximum intensity within 2-3 minutes, lasting more than 5 minutes.
   c. Prior history of stroke or intracranial bleed with sudden onset of severe headache
   d. New onset of headache and any of the following:
      i. Onset of headache before age 6 years
      ii. Onset of headache after age 50 years not explained after evaluation of common causes (e.g., medication overuse syndrome or cervicogenic headache)
      iii. A combination of acute, new, or fluctuating neurologic deficits such as unilateral sensory deficits, unilateral limb weakness, speech difficulties, visual loss, lack of coordination, gait disturbance, seizures, otherwise unexplained vomiting, otherwise unexplained acute hypertension, cranial nerve abnormality, mental status changes, or with papilledema or other signs of increased intracranial pressure
      iv. Clinical signs and symptoms strongly suggesting metastatic cancer as the cause of the headache
      v. Significantly immunocompromised patient (i.e., patient with HIV or immunosuppression)
      vi. Patients with risk factors for cerebral venous thrombosis:
         1. Pregnancy or post-partum
         2. Known history of active coagulation disorder (e.g., sickle cell crisis, or clinical signs of active coagulation disorder)
      vii. Fever or meningismus with suspected CNS cause
      viii. Reproducible headache immediately preceded by physical exertion, sexual activity, Valsalva maneuver, or positional change, e.g., leaning forward
   e. MRI can be considered in a **pediatric age (0-16 years old)** patient with worsening headache and **1 or more** of the following:
      i. Occipital location

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ii. Age < 6 years
iii. Repeatedly awakens child from sleep or is present upon awakening

II. **Acute, new, or fluctuating neurologic symptoms or deficits** such as **1 or more** of the following:
a. Ataxia or gait disturbance without other cause
b. Change in speech or language (e.g., dysarthria, aphasia)
c. Cranial nerve palsy (not otherwise explained (e.g., Bell's Palsy or diabetic CN III palsy)
d. Focal sensory /motor deficit suggesting brain or spinal cord cause (e.g., unilateral numbness or paresthesia's of face, arm and leg *OR* arm and leg)
e. Horner syndrome (unilateral miosis, ptosis, facial anhidrosis)
f. Papilledema
g. New visual disturbance (e.g., diplopia, visual field defect, nystagmus, visual loss)

III. **Evaluation of known or suspected seizure disorder and 1 or more** of the following:
a. New onset of a seizure (first focal seizure or first unprovoked generalized seizures)
b. Newly identified change in seizure activity/pattern not otherwise explained.
c. Medically refractory epilepsy
d. Preoperative evaluation when surgery being considered
e. Seizure in child younger than 2 years, excluding those with febrile seizures

IV. **Evaluation of movement disorders** – **Not indicated for **typical** Parkinson's Disease, essential tremor, primary dystonia, restless leg syndrome, or tics/spasms which can be duplicated at will*
a. Evaluation of suspected Parkinson's with atypical feature(s) or unresponsive to levodopa
b. Evaluation of new non-Parkinson symptoms in known Parkinson's disease complicating the evaluation of the current condition
c. Evaluation of other movement disorder to exclude a structural lesion (e.g., suspected Huntington disease, chorea, atypical parkinsonian syndromes, hemiballismus, secondary dystonia)
d. Prior to surgery or deep brain stimulation in patient with known Parkinson disease

V. **Evaluation of new or acutely worsened cognitive impairment with unclear cause (to rule out large frontal tumor or frontal stroke). Not indicated if the patient has a classic Alzheimer 's history of several years of progressive decline. CT may be sufficient if MRI cannot be done. Must meet ALL of the following:**
a. Change in mental status with a mental status score of either Mini-Mental State Exam (MMSE) or Montreal Cognitive Assessment (MoCA) of less than 26 or other similar mental status instruments showing at least mild cognitive impairment **AND**
b. A completed medication review and exclusion of medical causes (e.g., thyroid function testing, liver function testing, complete blood count, electrolytes, and B12) without cause found

VI. **Evaluation of known or suspected inflammatory disease or infection** (e.g., meningitis or abscess) for **1 of the following:**
a. Intracranial abscess or brain infection with acute altered mental status OR positive lab findings (such as elevated WBC's) OR follow up assessment during or after treatment completed
b. Meningitis with positive signs and symptoms (such as fever, headache, mental status changes, stiff neck) OR positive lab findings (such as abnormal lumbar puncture fluid exam)
c. Suspected encephalitis with a headache, altered mental status OR positive lab finding, (such as elevated WBC's)
d. Endocarditis with suspected septic emboli
e. Central nervous system (CNS) involvement in members with known or suspected vasculitis or autoimmune disease with positive lab findings

VII. **Evaluation of vertigo/dizziness** *All patients should have full neurologic examination, medication review, orthostatic vitals, and Dix-Hallpike test for peripheral vertigo prior to consideration of MRI.
MRI can be considered appropriate if **1 or more** of the following signs or symptoms suggestive of a CNS lesion:
a. Brainstem findings (e.g., dysarthria, Horner syndrome, double vision, vertical nystagmus) **OR**
b. Cerebellar findings (e.g., ataxia/incoordination of voluntary movements, intention tremor, disorder of equilibrium or gait, diminished muscle tone) **OR**
c. Focal neurologic findings (e.g., weakness, numbness, paresthesia's on one side of body) **OR**

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d. Acute or rapidly progressing unilateral hearing loss

VIII. **Evaluation of syncope, with 1 or more of the following:**
a. Concurrent bowel or bladder incontinence
b. Witnessed tonic-clonic seizure
c. Strong clinical suspicion of symptomatic third ventricular cyst

IX. **Precocious puberty** (central), as indicated by **ALL of the following**:
a. Clinical findings suggestive of central precocious puberty
b. Patient has been evaluated by pediatric endocrinologist

X. Global developmental delay or developmental delay with abnormal neurological examination (initial evaluation)

XI. Other indications for a brain MRI
a. Multiple sclerosis – known or strong clinical suspicion after discussion with neurology
   i. Frequency after diagnosis: annually to monitor for new lesions or following clinical flare up
b. Trauma to the head with acute, new, or fluctuating neurologic findings
c. Brain tumor, mass, or metastasis – known or strong clinical suspicion based on history and physical exam
d. Routine surveillance of previously diagnosed brain tumor based on treatment plan from neuroscience specialty or oncology
e. Initial evaluation of stroke/TIA
f. Evaluation of known or suspected congenital abnormality with any acute, new, or fluctuating neurologic, motor, or mental status changes (hydrocephalus, craniosynostosis)
g. Evaluation of suspected acute subarachnoid hemorrhage (SAH) if CT scan is non-diagnostic
h. Evaluation of known or suspected cerebrospinal fluid (CSF) leakage
i. Follow-up of a recent brain hemorrhage to check for underlying tumor or AVM
j. Immunocompromised member (e.g., transplant recipients, HIV with CD4 < 200, primary immunodeficiency syndromes, hematologic malignancies) with focal neurologic symptoms, headaches, behavioral, cognitive, or personality changes
k. Pre-operative evaluation for brain/skull surgery, stereotactic radiosurgery
l. Post-operative/procedural evaluation - A follow-up study may be needed to help evaluate a member's progress after treatment, procedure, intervention or surgery. Documentation requires a medical reason that clearly indicates why additional imaging is needed for the type and area(s) requested
m. Suspected acoustic neuroma include IAC protocol (to ensure that imaging looks in detail at that part of the anatomy)
n. Anatomy or structural defect evaluation – e.g., when Chiari malformation is clinically suspected
o. Suspected intracranial vasculitis
p. Evaluation of neurological signs or symptoms in sickle cell disease
q. Unexplained acute unilateral hearing loss after other reasonable causes ruled out
r. Optic neuritis – consider orbit MRI in addition to brain MRI
s. Abnormal eye findings on physical or neurologic examination (e.g., papilledema, pathologic nystagmus, ocular nerve palsies, new onset anisocoria, visual field deficit)
t. Horner's syndrome with symptoms localizing the lesion to the central nervous system
u. Trigeminal neuralgia if medication is not effective or if atypical features/exam (e.g., bilateral, hearing loss, dizziness/vertigo, visual changes, sensory loss, numbness, pain >2 min, pain outside trigeminal nerve distribution, progression)
v. Bell's palsy - only if atypical signs, or no improvement at four months, or facial twitching/spasms prior to onset
w. Psychological changes with neurological deficits on exam or after completion of a full neurological assessment by a neurologist that suggests a possible neurologic cause
x. Multiple cranial neuropathies.

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

MRI can detect a variety of conditions of the brain such as cysts, tumors, bleeding, swelling, developmental and structural abnormalities, infections, inflammatory conditions, or problems with the blood vessels. It can determine if a shunt is working and detect damage to the brain caused by an injury or a stroke.

MRI of the brain can be useful in evaluating problems such as persistent headaches, dizziness, weakness, and blurry vision or seizures, and it can help to detect certain chronic diseases of the nervous system, such as multiple sclerosis.

In some cases, MRI can provide clear images of parts of the brain that can't be seen as well with an X-ray, CAT scan, or ultrasound, making it particularly valuable for diagnosing problems with the pituitary gland and brain stem.

Applicable Codes

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Medicare – Medical Necessity Review not required

CPT® or HCPCS Codes	Description
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions, and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
02/01/2022	02/01/2022[MPC],02/07/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
02/01/2022	MPC approved to adopt criteria for Brain MRI for non-Medicare members. Requires 60-day notice, effective date 07/01/2022.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Breast MRI with and without Computer-Aided Detection (CAD)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (MRI) (220.2)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance specific to breast MRI, KPWA has chosen to use their own Clinical Review Criteria for ***indications for breast MRI***, for medical necessity determinations. Use the Non-Medicare criteria below.

Effective until November 1, 2023

For Non-Medicare Members

I. Breast MRI may be indicated for **One or more of the following**:
   A. Breast abnormality evaluation needed, as indicated by **One or more of the following**:
      Note: If an area of distortion is found on mammography, a breast ultrasound should be the next step to confirm. If breast ultrasound shows a correlate, that area can then be biopsied under ultrasound guidance. If a breast ultrasound biopsy cannot be done of the area for some reason or is unsuccessful, and tomosynthesis guided or stereotactic guided breast biopsy is also not an option, consultation with a breast surgeon is recommended. MRI is not indicated in this situation.
      1. A single 6-month MRI for f/u if requested by the radiologist who attempted or performed the original MRI guided biopsy
      2. Breast MRI is covered for members with suspected silicone (not saline) implant leaks or rupture when **ALL** of the following have been met:
         a. Implants were placed as a result of **ONE of the following**:
            - Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity;
            - Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer
         b. Records must document need for this test for evaluation and management
         c. A recent mammogram and/or ultrasound (depending on local breast center protocol) does not confirm leakage
         d. The leakage is not the result of a cosmetically placed implant as this would be a complication of a non-covered service
         e. It is not being requested for routine surveillance of a silicone implant

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B. Breast cancer diagnosis (new within the last 3 months) and **ONE or more** of the following:

1. After positive nipple-areolar biopsy for Paget disease, to define extent of disease and identify additional disease
2. Assessment of tumor response to neoadjuvant (preoperative) chemotherapy to determine appropriateness of breast-conserving surgery to assist with surgical planning
3. Evaluation of a newly diagnosed invasive breast cancer (e.g., lobular, ductal) (see below**).
4. Evaluation of a newly diagnosed DCIS and there is documentation that the patient is requesting breast conserving surgery (see below**).
5. Post lumpectomy, (within 6 weeks) for assessment of residual disease with the finding of close or positive margins on pathology.

C. Occult breast cancer, suspected (e.g., unknown primary), as indicated by **ALL of the following**:
1. Diagnosis of adenocarcinoma or carcinoma not otherwise specified in **ONE or more of the following**:
   a. Axillary lymph nodes
   b. Supraclavicular lymph nodes
2. Mammogram and breast ultrasound show no evidence of cancer.
3. No palpable breast mass suitable for biopsy

D. Annual MRI for breast cancer screening for **One or more of the following**:

Not indicated for patients who have undergone bilateral mastectomy for risk reduction or for treatment.

1. A lifetime risk of 20% or greater, as defined by validated models such as the following models: Tyrer-Cuzick, Gail Model, BRCAPro, Claus.
   a. The specific risk model must be documented in the clinical notes
   b. If member has had breast or ovarian cancer diagnosed after age 50, calculate the risk *prior* to the diagnosis
2. BRCA1 or BRCA2 mutation carrier
3. Personal history of radiation to chest between ages 10 and 30 years
4. Annual MRI is indicated for individual with a personal history of breast cancer (including DCIS), diagnosed at or before age 50 and treated with breast conservation therapy of the affected breast (lumpectomy). Patients treated with mastectomy (unilateral or bilateral) would not routinely qualify.
5. Other high-risk family history of breast cancer, as indicated by **ONE or more of the following**:
   - Male relative with breast cancer
   - Untested first-degree relative [A*] of BRCA1 or BRCA2 mutation carrier
   - Woman not of Ashkenazi Jewish ancestry, with **ONE or more of the following**:
     i. First-degree [A*] or second-degree [B*] relative with breast cancer and **ONE or more of the following**:
        - Diagnosed at age 45 years or younger
        - Diagnosed at age 50 years or younger, with limited family history [C*]
        - Diagnosed at age 50 years or younger, who in turn has one or more close blood relatives [D*] with breast cancer, with at least one diagnosed at age 50 years or younger (29)
        - Diagnosed at age 50 years or younger, who in turn has one or more close blood relatives [D*] with epithelial ovarian [E*] cancer diagnosed at any age
        - Diagnosed at age 60 years or younger, with triple-negative breast cancer [F*]
        - Epithelial ovarian [E*] cancer
   - First-degree [A*] or second-degree [B*] relative with 2 breast primaries, with the first primary diagnosed at age 50 years or younger
   - First-degree [A*] or second-degree [B*] relative with breast cancer diagnosed at any age, who in turn has **One** or more of the following:
     i. Two or more close blood relatives [D*] with breast or epithelial ovarian [E*] cancer diagnosed at any age
     ii. One or more close male blood relatives [D*] with breast cancer

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- First-degree [A] or second-degree relative [B*] with breast cancer who is of ethnicity associated with deleterious mutations, including Icelandic, Hungarian, Swedish, and Dutch
- First-degree [A*] or second-degree relative [B*] with breast or ovarian cancer diagnosed at any age, who in turn has 2 or more close blood relatives [D*] with pancreatic cancer diagnosed at any age

a. First-degree [A*] or second-degree relative [B*] with pancreatic cancer diagnosed at any age, who in turn has 2 or more close blood relatives [D*] with ONE or more of the following:
   - Breast cancer diagnosed at any age
   - Ovarian cancer diagnosed at any age
   - Pancreatic cancer diagnosed at any age

b. Third-degree relative [H*] with breast or epithelial ovarian [E*] cancer, who in turn has **ONE or more of the following**:
   - One close blood relative [D*] with epithelial ovarian [E*] cancer and another close blood relative [D*] with breast cancer diagnosed at age 50 years or younger
   - Two or more close blood relatives [D*] with breast cancer, with at least one diagnosed at age 50 years or younger
   - Two or more close blood relatives [D*] with epithelial ovarian [E*] cancer

c. Woman of Ashkenazi Jewish ancestry, with **One or more of the following**:
   - One or more first-degree relatives [A*] with breast cancer or epithelial ovarian cancer
   - Two or more second-degree relatives, [B*] on same side of family, [I*] with breast cancer
   - Two or more second-degree relatives, [B*] on same side of family, [I*] with epithelial ovarian cancer

d. Patient has diagnosis of, or has first-degree relative [A] with, **One or more of the following**:
   - Bannayan-Riley-Ruvalcaba syndrome
   - Cowden syndrome
   - Li-Fraumeni syndrome

Effective November 1, 2023

I. Breast MRI may be indicated for **ONE or more of the following**:

A. Breast abnormality evaluation needed, as indicated by **ONE or more of the following**:
Note: If an area of distortion is found on mammography, a breast ultrasound should be the next step to confirm. If breast ultrasound shows a correlate, that area can then be biopsied under ultrasound guidance. If a breast ultrasound biopsy cannot be done of the area for some reason or is unsuccessful, and tomosynthesis guided or stereotactic guided breast biopsy is also not an option, consultation with a breast surgeon is recommended. MRI is not indicated in this situation.

1. A single 6-month MRI for f/u if requested by the radiologist who attempted or performed the original MRI guided biopsy
2. Breast MRI is covered for members with suspected silicone (not saline) implant leaks or rupture when **ALL** of the following have been met:
   a. Implants were placed as a result of **ONE of the following**:
      - Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity;
      - Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer
   b. Records must document need for this test for evaluation and management
   c. A recent mammogram and/or ultrasound (depending on local breast center protocol) does not confirm leakage
   d. The leakage is not the result of a cosmetically placed implant as this would be a complication of a non-covered service
   e. It is not being requested for routine surveillance of a silicone implant
3. Nipple Discharge, a breast MRI is indicated when **ALL of the following** conditions are met:
   a. Discharge is clear or bloody
   b. Discharge is unilateral and coming from a single duct
   c. Discharge is spontaneous (i.e., does not happen only with expression) and persistent (i.e., not a single episode)

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d. Discharge is reproducible on exam
e. Mammography and ultrasound have been completed and did not detect a pathologic etiology. *If mammography, ultrasound or ductography were done, and was abnormal, MRI would not be indicated

B. Breast cancer diagnosis (new within the last 3 months) and **ONE or more** of the following:

1. After positive nipple-areolar biopsy for Paget disease, to define extent of disease and identify additional disease
2. Assessment of tumor response to neoadjuvant (preoperative) chemotherapy to determine appropriateness of breast-conserving surgery to assist with surgical planning
3. Evaluation of a newly diagnosed invasive breast cancer (e.g., lobular, ductal) (see below**).
4. Evaluation of a newly diagnosed DCIS and there is documentation that the patient is requesting breast conserving surgery (see below**).
5. Post lumpectomy, (within 6 weeks) for assessment of residual disease with the finding of close or positive margins on pathology.

C. Occult breast cancer, suspected (e.g., unknown primary), as indicated by **ALL of the following**:
1. Diagnosis of adenocarcinoma or carcinoma not otherwise specified in **ONE or more of the following**:
   a. Axillary lymph nodes
   b. Supraclavicular lymph nodes
2. Mammogram and breast ultrasound show no evidence of cancer.
3. No palpable breast mass suitable for biopsy

D. Annual MRI for breast cancer screening for **One or more of the following**:

Not indicated for patients who have undergone bilateral mastectomy for risk reduction or for treatment.

1. A lifetime risk of 20% or greater, as defined by validated models such as the following models: Tyrer-Cuzick, Gail Model, BRCAPro, Claus.
   a. The specific risk model must be documented in the clinical notes
   b. If member has had breast or ovarian cancer diagnosed after age 50, calculate the risk *prior* to the diagnosis
2. Carrier of high-risk[A] breast cancer gene mutation (including but not limited to: BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53)
3. Personal history of radiation to chest between ages 10 and 30 years
4. Annual MRI is indicated for individual with a personal history of breast cancer (including DCIS), diagnosed at or before age 50 and treated with breast conservation therapy of the affected breast (lumpectomy). Patients treated with mastectomy (unilateral or bilateral) would not routinely qualify.
5. Other high-risk family history of breast cancer, as indicated by **ONE or more of the following**:
   - Male relative with breast cancer
   - Untested first-degree relative [A*] of BRCA1 or BRCA2 mutation carrier
   - Woman not of Ashkenazi Jewish ancestry, with **ONE or more of the following**:
     ii. First-degree [A*] or second-degree [B*] relative with breast cancer and **ONE or more of the following**:
     - Diagnosed at age 45 years or younger
     - Diagnosed at age 50 years or younger, with limited family history [C*]
     - Diagnosed at age 50 years or younger, who in turn has one or more close blood relatives [D*] with breast cancer, with at least one diagnosed at age 50 years or younger (29)
     - Diagnosed at age 50 years or younger, who in turn has one or more close blood relatives [D*] with epithelial ovarian [E*] cancer diagnosed at any age
     - Diagnosed at age 60 years or younger, with triple-negative breast cancer [F*]
     - Epithelial ovarian [E*] cancer

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- First-degree [A*] or second-degree [B*] relative with 2 breast primaries, with the first primary diagnosed at age 50 years or younger
- First-degree [A*] or second-degree [B*] relative with breast cancer diagnosed at any age, who in turn has **One** or more of the following:
  i. Two or more close blood relatives [D*] with breast or epithelial ovarian [E*] cancer diagnosed at any age
  ii. One or more close male blood relatives [D*] with breast cancer
- First-degree [A] or second-degree relative [B*] with breast cancer who is of ethnicity associated with deleterious mutations, including Icelandic, Hungarian, Swedish, and Dutch
- First-degree [A*] or second-degree relative [B*] with breast or ovarian cancer diagnosed at any age, who in turn has 2 or more close blood relatives [D*] with pancreatic cancer diagnosed at any age

a. First-degree [A*] or second-degree relative [B*] with pancreatic cancer diagnosed at any age, who in turn has 2 or more close blood relatives [D*] with ONE or more of the following:
   - Breast cancer diagnosed at any age
   - Ovarian cancer diagnosed at any age
   - Pancreatic cancer diagnosed at any age
b. Third-degree relative [H*] with breast or epithelial ovarian [E*] cancer, who in turn has **ONE or more of the following**:
   - One close blood relative [D*] with epithelial ovarian [E*] cancer and another close blood relative [D*] with breast cancer diagnosed at age 50 years or younger
   - Two or more close blood relatives [D*] with breast cancer, with at least one diagnosed at age 50 years or younger
   - Two or more close blood relatives [D*] with epithelial ovarian [E*] cancer
c. Woman of Ashkenazi Jewish ancestry, with **One or more of the following**:
   - One or more first-degree relatives [A*] with breast cancer or epithelial ovarian cancer
   - Two or more second-degree relatives, [B*] on same side of family, [I*] with breast cancer
   - Two or more second-degree relatives, [B*] on same side of family, [I*] with epithelial ovarian cancer
d. Patient has diagnosis of, or has first-degree relative [A] with, **One or more of the following**:
   - Bannayan-Riley-Ruvalcaba syndrome
   - Cowden syndrome
   - Li-Fraumeni syndrome

* See below for the definition:
A - First-degree relatives consist of male or female parents, siblings, or children
B - Second-degree relatives consist of male or female grandparents, grandchildren, aunts, uncles, nieces, nephews, or half- siblings
C - Examples of a limited family history include fewer than 2 first-degree or second-degree female relatives or fewer than 2 female relatives in either maternal or paternal ancestry surviving beyond 45 years of age. (
D - Close blood relatives include first-degree, second-degree, or third-degree relatives on the same side of the family
E - A triple-negative breast cancer is one that is estrogen receptor-negative, progesterone receptor-negative, and human epidermal growth factor receptor 2-negative
F - Two primaries may be either bilateral disease or 2 or more clearly separate ipsilateral tumors, either synchronous or asynchronous
H - Third-degree relatives consist of first cousins, great-aunts, great-uncles, great-grandchildren, or great-grandparents
I - Each side of the family, maternal or paternal, should be considered independently

**Ideally, this should be ordered after discussion with the patient about risks and benefits or per recommendation of a multidisciplinary care conference, if available.

"Don't routinely order breast MRI in new breast cancer patients." per The American Society of Breast Surgeons Choosing Wisely initiative:

After a new diagnosis of breast cancer, breast MRI can be useful in selected patients to aid treatment decisions. However, there is a lack of evidence that routine use of MRI lessens cancer recurrence, death from cancer or the need for re-operation after lumpectomy surgery. The routine use of MRI is associated with an increased need for subsequent breast biopsy

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procedures, delays in time to treatment and higher cost of care. Increased mastectomy rates can occur if the MRI finds additional cancers or indeterminate findings cause patient anxiety, leading to patient requests for mastectomy.

(https://www.choosingwisely.org/clinician-lists/breast-surgeons-mris-in-new-breast-cancer-patients/)

Routine Surveillance of Silicone Breast Implants
Breast MRI is not covered for routine surveillance of silicone breast implants. The FDA made a recommendation (not a requirement) when they re-approved silicone implant use that members receive periodic breast MRIs. The FDA did not fund this screening. The choice of silicone vs saline is a patient preference and the use of MRI in this case cannot be described as medically necessary.

Computer-aided detection applied to breast MRI
No longer requires review

If requesting this service, please send the following documentation to support medical necessity:

- Documentation to support medical necessity (i.e., family history, prior treatment, genetic testing results, other imaging studies and diagnostic results, etc.)
- Applicable CPT code(s)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Breast Cancer Screening and Lesions:
Mammography has been the standard tool used for breast cancer imaging. Community breast cancer screening programs have found an overall sensitivity of 75% and a specificity of 92%. The sensitivity of mammography in randomized trials is in the range of 68-88% (Elmore et al., 2005).

Due to limitations in the sensitivity of mammography, there has been research into alternative imaging modalities, particularly for women at high-risk of breast cancer. Interest in more accurate screening tests has grown since the identification of the BRCA1 and BRCA2 genes in the mid-1990s. Population-based studies have found that women with BRCA1 mutations have a approximately a 65% risk of developing breast cancer by age 70, and women with BRCA2 mutations have a 45% risk (Saslow et al., 2006). Mammography may not be adequate for detecting breast cancer in women with the BRCA1/2 mutation. In a study of BRCA1/2 mutation carriers who underwent annual mammography, screening detected only 5 out of 9 cases of breast cancer; the remaining were interval cancers (Brekelmans et al., 2001).

Contrast-enhanced magnetic resonance imaging (MRI) is proposed as an adjunct to mammography for women at high-risk of breast cancer. Breast MRI involves the injection of a contrast agent, usually gadolinium. Breast carcinomas tend to enhance, or get brighter, following injection of the contrast agent. MRI may be able to detect small breast lesions missed by mammography. However, contrast-enhanced MRI may not be able to distinguish between breast carcinoma and benign disease which also enhance, thus reducing the specificity of MRI.

The American Cancer Society (ACS) issued guidelines in May 2007 on breast screening with MRI as an adjunct to mammography (Saslow et al., 2007). The recommendations include:

- Annual screening for women with a lifetime risk of ≥20-25%, BRCA mutation or untested first-degree relative of BRCA carrier.
- No recommendation for or against screening women with a lifetime risk of 15-20%.
- Recommendation against screening women with <15% lifetime risk due to insufficient evidence.

The ACS recommends the BRCAPRO or other model largely dependent on family history be used to determine lifetime risk. BRCAPRO is a computer program on a statistical model for estimating an individual's probability of carrying a BRACA1/2 mutation on the basis of their own cancer status, and the history of breast and ovarian cancer among her first- and second-degree relatives (Berry et al., 2002). Other risk models, such as the Gail model risk calculator, which is also based on family history, may be easier to use in the primary care setting. An individual's risk level may vary with the different models (Saslow et al., 2007).

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The Kaiser Permanente breast clinic already generally recommends MRI screening for women with known BRCA mutations, who are a first-degree relative of a BRCA carrier but are untested or have a 30-49% lifetime risk.

Silicone Implant Leakage:
Silicone-gel breast implants were first available for commercial use in the early 1960s. It is estimated that 1.5 to 2 million women in the United States have received an artificial breast implant, and the number is growing. Almost four-fifths of these women received the implant for cosmetic purposes to enhance or remodel breast shape, or to correct traumatic or congenital deformities. In only 20% of the cases they received it for breast reconstruction after mastectomy. At least three major generations and over 200 models of silicone gel-filled breast implants have been manufactured. The differences between the generations are primarily in the types of silicone gel and thickness of elastometric shell. The first generation of silicone gel-filled implants (early 1960s to the mid 1970s) had a thick elastometric shell with firm silicone gel. The second generation (mid 1970s to late 1980s) had a thin elastometric shell, and a less viscous gel. The third generation (mid 1980s to date) has a multilayer shell with a barrier layer and thick cohesive viscous silicone gel. In 1993 a newer generation of highly cohesive silicone implants (Style 410) was developed, however it is widely used in Europe and other countries, but not in the US (Brown 2002, Belli 2002, Scaranelo 2004, Gamper 2007, Gorczyca 2007).

Silicone implants may have psychological benefits but could be associated with local complications and systemic effects. Local implant-related complications include wound infection, hematomas, sensory nerve injury, capsular contracture, and implant rupture. The latter is a well-known complication and could range from focal rupture involving pinhole sized holes, through large visible tears, to complete disintegration of the implant shell. Implant rupture can be divided into two major categories: intracapsular (80-90% of all ruptures) and extracapsular. Unlike rupture, gel bleed is microscopic escape of silicone particles through the intact silicone envelope, in the absence of gross holes or tears. This is usually confined to the fibrous capsule that forms around the implant. Implant age, and design were found to be the most important factors associated with rupture. Other potential causes of rupture include trauma, mammography, and history of closed capsulotomy. The age of implant at rupture varied between reports between 4 and 22 years, with means also varying between studies from 11 to 16 years (Cher 2001, Samuels 1994, Gorczyca 2007).

Silicone gel-implant rupture may be clinically silent and pass unnoticed by the patient and the physician. It could remain undetected for years especially when it is contained within the fibrous capsule. A symptomatic rupture may present with local symptoms as breast pain, nodules, capsular contracture, and change in symmetry, size, or shape of the breast. Silicone gel granulomas and chronic disseminated granulomatous inflammation have been associated with implant rupture and gel migration. The potential health implications of silicone implant rupture are greatly debated. Some researchers reported that seepage of silicone and distant migration of the free silicone may lead to serious symptoms and foreign body reactions. Others indicated that it is harmless and does not lead to significant clinical symptoms or activate the humoral immune system (Ahn 2003, Holmich 2004, Gampper 2007).

The clinical diagnosis of asymptomatic implant rupture can be challenging. It was reported that less than one third of ruptures in asymptomatic patients can accurately be detected by experienced plastic surgeons. The gold standard for diagnosing an implant rupture is removal and examination of the implant. Mammography, ultrasonography, computed tomography, and magnetic resonance imaging have all been used in the diagnosis of silicone breast implant rupture. Each was reported to have its specific indications, advantages, and limitations. The type of silicone implant may also be a factor in choosing the modality for evaluating its integrity.

Mammography is a rapid inexpensive test, used routinely for screening, and can easily detect free silicone within the breast parenchyma due to extracapsular rupture. It, however, has a small radiation risk, and limited ability to detect intracapsular rupture which accounts for 80-90% of implant failures. The dense silicone is not easily penetrated by the X-ray energies used for typical screening mammography (Samuels 1994, Gampper 2007, Gorczyca 2007).

Ultrasonography is inexpensive, does not use ionizing radiation, can detect intracapsular rupture, and may also detect small amounts of free silicone mixed within the surrounding breast tissues. However, its usefulness for detecting implant rupture depends on the experience of the operator, type of equipment used, as well as other technical factors. It was also reported that ultrasonography may have its limitations in the evaluation of the posterior aspect of the implant, pectoralis muscle and chest wall (Belli 2002, Gorczyca 2007).

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MRI does not use ionizing radiation, has the ability to detect implant rupture, and to localize extensive free silicone. It can also be used with severe capsular contracture. Specialized breast coils increase the image quality and reduce scan time. However, it was reported that MRI cannot detect microscopic silicone leakage (gel bleeds). It is expensive, less available, less comfortable for the patient, and cannot be used among those with pacemakers, or other internal metallic devices that are not compatible with the MRI. Some patients may be claustrophobic and are unable to complete the examination (Beekman 1999, Gorczyca 2007, Gampper 2007)

FDA recommends MRI, with a dedicated breast coil and a magnet of at least 1.5 Tesla, as the current method of choice for detecting silent rupture of silicone gel implant. This is recommended to be performed three years after the implant, then every 2 years thereafter. The FDA also recommends the removal of ruptured breast implants.

With Computer-Aided Detection (CAD):
(Background information quoted from Blue Cross Blue Shield Association Technology Evaluation Center, BCBSA TEC report, June 2006)

Over the past decade, MRI of the breast has been studied in a variety of clinical settings, including both benign and malignant conditions of the breast…While MRI has a very high sensitivity for detecting lesions, its specificity is variable and often quite low because of the difficulty in distinguishing between benign and malignant lesions. The sensitivity for detection of invasive carcinoma overall is above 90%, while specificities between 37% and 90% have been reported (Deurloo et al. 2005a). The low specificity is particularly challenging in younger women, who are more likely to have enhancing benign lesions (Gilhuijs et al., 2002) …

Some investigators have incorporated additional criteria into the determination of MRI results in an attempt to increase the specificity without compromising sensitivity (Liberman 2004; Nunes et al. 2001). Descriptive features of lesion morphology such as those used in X-ray mammography may be helpful in this regard. For example, lesions with irregular or spiculated margins are characteristically malignant, while lesions with smooth, regular margins are usually benign (Nunes et al. 1997a) …CAD systems for MRI… provide easier ways of interpreting the patterns of contrast enhancement and washout across a series of images, which in turn may help identify lesions and their likelihood of being malignant. In contrast to CAD systems used with mammography, CAD for MRI is not aimed primarily at identifying lesions for consideration by a radiologist. Unlike the subtle appearance of lesions on mammography, most cancers enhance on MRI. The challenge is determining which lesions are benign and which are malignant. A large number of images are produced during MRI of the breast: images are taken at varying 'depths' throughout each breast multiplied by the number of times the breast is imaged to capture different time points in the enhancement process… Radiologists view the images to detect suspicious areas, and then they can pick a region of interest and look at the enhancement pattern. However, there may be variations across radiologists in the regions of interest selected and in the precise definition of the region of interest. CAD systems, in contrast, use color-coding and differences in hue to indicate the patterns of enhancement for each pixel in the breast image. It thereby may allow the radiologist to analyze the enhancement patterns systematically, although there is some question about how effective it is in reducing interobserver variability (Gabriel et al. 2005). Some CAD programs apparently incorporate morphological characteristics as well to estimate a probability of malignancy…"

There are several FDA-approved CAD systems for use with MRI of the breast. These include:
- CADstream (Confirma, Inc. Kirkland, WA). Originally cleared in 2003. CADstream version 4.0 was cleared in 2008.
- MRI Soft Tissue Motion Correction Software (Siemens Medical Solutions. Malvern, PA). Cleared September 2005.
- Z3D (Clario Medical Imaging): Cleared September 2008.

Medical Technology Assessment Committee (MTAC)

MRI in the Diagnosis of Breast Cancer and Breast Lesion

02/13/2002: MTAC REVIEW

Evidence Conclusion: All studies reviewed were retrospective, had several limitations, and data were obtained from records. Tan's study showed that MRI had an impact on the clinical management in almost one fifth of the patients. MRI findings were false positive among 61.5 % of the patients who underwent an additional surgery, which was a mastectomy in one case. Olson's study showed that MRI had a sensitivity of 95%, and specificity of 80%. These were based on data obtained from patients who underwent additional breast surgery, not all the sample. The clinical usefulness of a diagnostic test depends not only on its accuracy but also its reliability i.e. the consistency of interpretation on different occasions and by different observers. Mussurakis' study shows that all

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readers achieved a high sensitivity in cancer detection, their specificity however was much lower. The study also revealed a significant inter-observer variability in the interpretation of breast MRI. The high false positive rates, i.e. low specificity, and high inter-observer variability indicate that MRI, with its current limitations, is not an accurate or a reliable technology, compared to the gold standard of biopsy. Randomized trials, with a large study population will be required to confirm the findings and define the patients most likely to benefit from MRI. Moreover, further efforts are needed to improve, and standardize the indications, techniques, and image interpretation.
Articles: The search yielded 63 articles. Selection was based on study type. The majority were reviews, editorials, letters, and commentaries. The literature did not reveal any randomized controlled trials or longitudinal studies.
The following articles were selected for critical appraisal: Tan J E, Schnall M D, et al. Role of magnetic resonance imaging and magnetic resonance imaging-guided surgery in the evaluation of patients with early-stage breast cancer for breast conservation treatment. *Am J Clin Oncol* 1999; 22(4): 414-18 See Evidence Table. Olson JA, Morris EA, et al. Magnetic resonance imaging facilitates breast conservation for occult breast cancer. *Annals of Surgical Oncology* 2000; 7(6): 411-15 See Evidence Table. Mussurakis S et al. Observer variability in the interpretation of contrast enhanced MRI of the breast. *The British Journal of Radiology*1996; 69: 1009-16. See Evidence Table.

The use of MRI in the diagnosis of breast cancer and breast lesions does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/04/2007: MTAC REVIEW
MRI in the Diagnosis of Breast Cancer and Breast Lesion
Evidence Conclusion: The major prospective studies comparing screening asymptomatic women at moderate-to-high risk of breast cancer with MRI and mammography are summarized in Table 1. All of these studies were judged to be of reasonable validity. All studies were prospective and eligibility criteria included an assessment of risk based on genetic and family history factors. In addition, all of the studies included an independent evaluation of MRI and mammograms. The gold standard was biopsy/histology for positive tests in all studies. Gold standards for negative tests varied. Most studies used 1-year follow-up of negative tests to identify false negatives; Kuhl et al., 2005 used 6 months' follow-up. The Lehman et al., 2005 study was the weakest for several reasons. This is the only study in which the authors did not attempt to verify the accuracy of negative tests. In addition, only 4 cases of cancer were identified, a number too small for statistical analysis. The absolute difference in the breast cancer detection rate between combined testing with MRI and mammography and mammography alone ranged from 1% (Kriege et al., 2004) to 5% (Warner et al., 2004; Kuhl et al. 2005). The Kriege study included moderate-to-high risk women (≥15% lifetime risk) whereas the other two studies included only high-risk women. None of the studies reported whether the difference in the breast cancer detection rate with MRI plus mammography versus mammography alone was statistically significant. The recall rate (proportion of women called back for follow-up testing) ranged from 4% to 8% higher with MRI screening than with mammography-alone screening. None of the studies reported the recall rate with combined screening, but this would likely reflect the higher MRI rates. The sensitivity and specificity of combined screening with MRI and mammography versus mammography alone was reported in two studies. Leach et al., 2005 found a higher sensitivity with combined screening (94% versus 40%) and a lower specificity (77% versus 93%). Kuhl et al. (2005) also found a higher sensitivity with combined testing than mammography alone (93% versus 33%) and similar levels of specificity with the two methods (96% and 97%). Neither study reported p-values for the difference in sensitivity and specificity. The Kuhl et al., 2005 study did a sub-analysis by level of risk (see Table 2). The risk categories were moderate-risk (20% lifetime risk) and high-risk (21-40% lifetime risk). The sensitivity of combined screening was 100% in both the moderate and high-risk groups. This was substantially higher than the sensitivity with mammography alone, 50% for the moderate risk group and 25% for the high-risk group. Specificities of combined screening and mammography alone were similar for both risk levels. This analysis is limited in that it is based on a small number of cancer cases, only 6 for the moderate-risk group. This results in imprecise and unreliable statistics and should be viewed as preliminary data. For example, mammography correctly detected 3/6 cancers (50%); if only one additional cancer had been identified, the sensitivity would be dramatically altered to 4/6 (67%). Conclusion There is no high-grade evidence on whether combined screening with MRI and mammography improves health outcomes such as breast cancer mortality or overall mortality. The available evidence from 6 prospective studies suggests that combined screening of asymptomatic women at moderate-to-high risk of breast cancer with MRI plus mammography results in a 1-5% absolute increase in the cancer detection rate over mammography alone. The recall rate is substantially higher with MRI alone (4-8%) and would thus be higher with combined screening. Findings of 2 prospective studies are that combined screening substantially improves sensitivity compared to mammography alone and may decrease specificity. Data on women at moderate risk of breast cancer (≤20% lifetime risk) are insufficient to draw conclusions about detection rate or diagnostic accuracy.
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Articles: There were no randomized or non-randomized controlled trials that compared health outcomes in high-risk women who received screening with mammography alone versus screening with mammography plus MRI. As reported in the American Cancer Society review (Saslow et al., 2007), there were 6 published prospective studies examining diagnostic yield and/or sensitivity/specificity of mammography compared to MRI for asymptomatic women at moderate-to-high risk of breast cancer. These 6 studies were critically appraised and presented in a joint evidence table. The Kaiser Permanente national breast cancer screening guideline included the topic of breast MRI screening for high-risk women. They identified additional observational studies comparing mammography to MRI. These studies were not included in the MTAC review due to methodological limitations such as a retrospective design, small sample size or only a minority of the study population underwent MRI screening. *The studies reviewed include:* Kriege M et al. for the MRI Screening Study Group. Efficacy of MRI and mammography for breast-cancer screening in women with a familial or genetic predisposition. NEJM 2004; 351: 427-437**.** See Evidence Table. Kuhl CK et al. Mammography, breast ultrasound, and magnetic resonance imaging for surveillance of women at high familial risk of breast cancer. J Clin Oncol 2005; 23: 8469-8476. See Evidence Table. Leach MO et al. for the MARIBS Study Group. Screening with magnetic resonance imaging and mammography of a UK population at high familial risk of breast cancer: a prospective multicentre cohort study (MARIBS). Lancet 2005; 365: 1769-1778. See Evidence Table. Lehman CD et al. for the International Breast MRI Consortium Working Group. Screening women at high risk of breast cancer with mammography and magnetic resonance imaging. Cancer 2005; 103: 1898-1895. See Evidence Table. Sardanelli F et al. for the High Breast Cancer Italian Trial (HIBCRIT). Multicenter comparative multimodality surveillance of women at genetic-familial high risk for breast cancer (HIBCRIT Study). Radiology 2007; 242: 698-715. See Evidence Table. Warner E et al. Surveillance of BRCA1 and BRCA2 mutation carriers with magnetic resonance imaging, ultrasound and mammography, and clinical breast examination. JAMA 2004; 292: 1317-1325. See Evidence Table.

The use of MRI in the screening of high risk patients for breast cancer and breast lesions does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/08/2008: MTAC REVIEW
MRI in the Diagnosis of Breast Cancer and Breast Lesion
Evidence Conclusion: *Diagnostic accuracy:* It is hard to determine the diagnostic accuracy of imaging studies used to assess the integrity of breast implants. Visual inspection of the implant after its surgical removal is considered the gold standard for ruptured implants. However, this would not apply to asymptomatic women, as it would not be appropriate or ethical to remove an implant with no evidence of leak or rupture. The majority of the studies on the diagnostic accuracy of MRI or other imaging tests were thus conducted among symptomatic women who requested or were advised to remove the implants. The meta-analysis and the studies reviewed show wide variations in the accuracy of MRI and its predictive values in detecting an implant rupture in symptomatic women. The studies had differences in the equipment used, imaging protocol, description of positive MRI, and surgical criteria for a diagnosis of rupture. There were also some interobserver variations as seen in Collis and colleagues' study (2007). Different generations of implants were used. These varied by manufacturer, model, longevity, long-term integrity of the implant, as well as the implantation site and position. The authors of the majority of studies did not indicate the generation of implants used. Only one study (Collis 2007) included patients who exclusively received the third-generation implants. Holmich (2005) also provided the proportion of women receiving each of the three implant generations. Results of studies among women who received earlier generation of implants might not be generalized to the generation(s) currently used. One other limitation of the studies is the inclusion of self-selected symptomatic women who were requesting removal or replacement of the implants. The higher prevalence of rupture among these women would overestimate the accuracy of the tests, and limit generalization of the results to similar groups of patients. The overall results of the published studies show that the sensitivity of MRI in detecting an implant rupture among symptomatic women ranged from 64% to 90%. The specificity of the test ranged from 43% to 100%, the positive predictive value from 57% to 100% and the negative predictive values from 79% to 90%. Ultrasound came next in its accuracy with a sensitivity ranging from 30% to 69% and specificity ranging from 64% to 81%. Mammography was found to have the lowest sensitivity ranging from 20% to 69%, but with a specificity of 82% to 93%. Collis et al's study among asymptomatic who responded to the invitation for MRI testing showed a wide variation in sensitivity (71-86%) and specificity (48-95%) depending on the radiologist who interpreted the test. This assessment was based only on implants that were surgically removed. *Diagnostic impact*: There is insufficient evidence to determine that MRI may influence the management decisions for detected implant leak. *Therapeutic impact:* There are no published studies on the impact of MRI detection of implant leak on health outcomes.
Conclusions:

- MRI is moderately to highly sensitive, and more specific in detecting implant rupture among self-selected groups of symptomatic women**.** i.e. in confirming ruptures when suspected.

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- There is insufficient evidence on the accuracy of MRI as a screening tool for detecting leak or rupture among asymptomatic women.
- There is insufficient evidence to determine that MRI may influence the management decisions for detected implant leak.
- There is insufficient evidence on the impact of MRI detection of implant leak on health outcomes.

Articles: The literature search revealed over 120 articles. Many were review articles or studies on and safety and durability of the silicone gel implants. The following questions were considered in screening the published articles:

1. What is the diagnostic accuracy of MRI in detecting silicone gel breast implant leak/rupture in asymptomatic and symptomatic women?
2. Would the detection of the implant rupture be using MRI influence management decisions?
3. Does the detection of the implant rupture using MRI have an impact on health outcome?

1. Diagnostic accuracy

The literature search revealed several studies dating back to the early 1990s. There were 2 meta-analyses, and a systematic review on the diagnostic accuracy of MRI for detecting implant rupture among symptomatic women. The more recent meta-analysis, as well as studies that were not included in the analysis and that verified MRI findings with visual inspection of implant after surgical removal were critically appraised. Two studies that included asymptomatic women with a breast implant were identified (Brown 2000, and Collis 2007). In Brown and colleagues' (2000), study, the majority (92%) of the implants was second generation implants, and in Collis et al's study all were 3rd generation implant type. Collis' study was selected for critical appraisal as the second-generation implants are known to be more prone to rupture, and the results of Brown's study may not be generalized to the other generations that are more commonly used.

2. Diagnostic impact

A small study on the clinical impact of MRI was identified and critically appraised.

3. Therapeutic impact

No studies on the impact of technology on patient outcomes were identified by the search.

The following studies were critically appraised:

Cher DJ, Conwell JA, Mandel JS. MRI for detecting silicone breast implant rupture: Meta-analysis and implications. *Ann Plast Surg* 2001; 47:367-380. See Evidence Table. Reynolds HE, Buckwalter KA, Jackson VP, et al. Comparison of mammography, sonography, and magnetic resonance imaging in the detection of silicone-gel breast implant rupture. *Ann Plast Surg.*1994; 33:247-257. See Evidence Table. Beekman WH, Hage JJ, van Amerongen AHM, et al. Accuracy of ultrasonography, and magnetic resonance imaging in detecting failure of breast implants filled with silicone gel. *Scand J Plast Reconstr Hand Surg* 1999; 33:415-418. See Evidence Table. Scaranelo AM, Marques AF, Smialowski EB, et al. Evaluation of the rupture of silicone breast implants by mammography, ultrasonography, and magnetic resonance imaging in asymptomatic patients: correlation with surgical findings. *Sao Paulo Med J* 2004; 122:41-47. See Evidence Table. Holmich LB, Vejborg I, Conrad C, et al. The diagnosis of breast rupture: MRI findings compared with findings of explanation. *Europ J Radiol*. 2005:213-225. See Evidence Table. Collis N, Phil M, Litherland J, et al. Magnetic resonance imaging and explantation investigation of long-term silicone gel implant integrity. *Plast Reconstr Surg* 2007; 120:1401-1406. See Evidence Table. Dobke MK, Middleton MS. Clinical impact of breast implant magnetic resonance imaging. *Ann Plast Surg.*1994; 33:241-246. See Evidence Table

The use of MRI in the detecting leakage from silicone implants does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/03/2009: MTAC REVIEW

MRI in the Diagnosis of Breast Cancer and Breast Lesion

Evidence Conclusion: Published studies by two research groups comparing the specificity of breast MRI with and without CAD assistance for distinguishing between benign and malignant lesions were reviewed. Williams et al. (2007) evaluated 155 breast lesions detected by MRI and found a statistically significant reduction in the false-positive rate (reduced 23%) with CAD enhancement at 100%. Meinel et al. (2006) evaluated 80 lesions and found a statistically significant increase in specificity (from 51% to 81%) when human readers were aided by CAD. A higher specificity (and corresponding low false-positive rate) would contribute to improved diagnosis since fewer women would be subject to unnecessary follow-up tests or procedures. No published studies, however, evaluated whether there was a reduction in the number of biopsies or other procedures, or whether use of CAD contributed to a change in diagnosis. The above findings are insufficient to draw conclusions about the use of CAD systems with breast MRI and its impact on health outcomes. The quantity of published studies is low, and sample sizes of individual studies are small. Only one research group, Williams et al. (2007) did a comparative analysis with a

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commercially available CAD system. Moreover, no studies are available on the impact of CAD-enhanced MRI on follow-up procedures or diagnosis.
Articles: The Pubmed search yielded 79 articles. One additional article was identified on the CADStream website (Lehman et al., 2006). BCBSA TEC conducted an assessment in 2006; their search in March of that year identified the same articles as the PubMed search. Most of the articles in the PubMed search were either review articles, dealt with related topics such as other types of cancer, or addressed CAD development of other technical aspects of CAD systems or MRI. Three empirical studies were identified that compared breast MR imaging with and without a CAD system. Two of the articles were published by the same research group (T. Lehman, W DeMartini, S Peacock and others) and the later article (2007) appears to also include lesions included in the earlier article (2006). The 2007 article by this group and the other comparative study were both critically appraised. References are as follows: Williams TC, DeMartini WB, Partridge SC et al. Breast MR imaging: Computer-aided evaluation program for discriminating benign from malignant lesions. Radiol 2007; 244: 94-103. See Evidence Table. Meinel LA, Stolpen AH, Berbaum KS et al. Breast MRI lesion classification: Improved performance of human readers with a backpropagation neural network computer-aided diagnosis (CAD) system. J Magn Reson Imaging 2007; 25: 89-95. See Evidence Table.

The use of computer-aided detection (CAD) applied to breast MRI does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Breast MRI surveillance in women with personal history of breast cancer
Date: 07/13/2020
Evidence Conclusion:

- There is insufficient evidence for or against annual surveillance breast MRI in less than 50 years old women with personal history of breast cancer who were diagnosed with invasive breast cancer.
- High-quality randomized controlled trials comparing annual surveillance breast MRI vs mammography in women <50 years old (even in women aged 50 years and older) with personal history of breast cancer who were diagnosed with invasive breast cancer are rare.
- In women (age 18+) with personal history of breast cancer, (some in this population had heterogeneously & extremely dense breast tissue, genetic/family history) who were diagnosed were invasive breast cancer or DCIS:
  - Although one cohort study indicates no difference in performance between annual surveillance MRI and mammography, retrospective studies suggest that MRI performance may be higher than mammography.
  - In addition, MRI results in increased recall and biopsy rates as well as false positive.
  - Cancer detection rate may be higher in patients undergoing MRI than in that undergoing mammography.
  - The findings also suggest that mammography combined with MRI may be more effective (with low specificity) than mammography alone but recall rate and biopsy rate are high.
  - It is also not clear who may benefit from surveillance breast MRI.
- Impact of MRI on survival was not assessed.

Articles: PubMed was searched through February 14, 2020 with the following search terms (with variations): (((Magnetic Resonance Imaging OR MRI)) AND (breast neoplasm OR breast cancer)) AND (follow-up OR postoperative). Search terms also included surveillance, follow-up, and breast MRI surveillance. The search was limited to English language publications and human populations. The search was filtered by RCTs, systematic review & meta-analysis, and observational studies. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Breast MRI for surveillance in women with a personal history of breast cancer, diagnosed under the age of 50 does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral

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77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed0	Date Last Revised
02/13/2002	06/07/2011 MDCRPC, 04/03/2012MDCRPC, 05/01/2012MDCRPC, 08/07/2012MDCRPC, 03/05/2013MDCRPC, 09/03/2013MPC, 05/06/2014MPC, 03/03/2015MPC, 08/04/2015MPC, 06/07/2016MPC, 04/04/2017MPC, 02/06/2018MPC, 01/08/2019MPC, 01/07/2020MPC, 01/05/2021MPC, 01/04/2022MPC, 01/10/2023MPC	06/06/2023

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/14/2015	Changed Breast Cancer Diagnosis criteria to include language that clarifies cancer must be newly diagnosed within the last 3 months.
08/04/2015	Criteria was modified for clarifications regarding requests for MR biopsies
09/02/2016	Added indication, “it is not being requested for routine surveillance of a silicone implant,” to criteria
01/09/2017	Revised indication to “evaluate response to neoadjuvant chemotherapy”
10/18/2018	Criteria was modified for clarifications under breast abnormality evaluation
01/28/2019	Computer-aided detection applied to breast MRI No longer requires review
12/27/2019	Codes deleted 77058, 77059, C8904, C8907, 0159T
03/02/2021	Added July 2020 MTAC Review. MPC approved to adopt Breast MRI criteria for members with a personal history of breast cancer diagnosed at the age of 50 or younger and elected to have a lumpectomy or partial mastectomy. Requires 60-day notice, effective date 08/01/2021.
05/03/2022	MPC approved to revise the criteria to include educational additions for *Breast Cancer Diagnosis*
10/17/2022	Clarification of breast center protocols
06/06/2023	MPC approved modifications to the existing MRI Breast criteria to align with recommendations from multiple guideline statements, including NCCN, regarding certain types of nipple discharge and the need for breast MRI to detect cancer. Requires 60-day notice, effective date 11/01/2023.

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Clinical Review Criteria
Cervical Spine MRI

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (220.2)
Local Coverage Determinations (LCD)	MRI and CT Scans of the Head and Neck (L35175) *Medical necessity review not required
Local Coverage Article (LCA)	Billing and Coding: MRI and CT Scans of the Head and Neck (A57215)

For Non-Medicare Members

Adapted from Washington State Department of Labor & Industries Final Imaging Guidelines: Cervical Spine MRI. Retrieved 9/3/2020 from https://lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/_docs/CervicalSpineChecklist.pdf

**Note – most acute cervical radicular pain will resolve with time and conservative management. Bulging discs will retract away from the affected nerve root spontaneously in a high percentage of cases. Acute or chronic non-radicular or non-myelopathy neck pain may be associated with painful paresthesia's diffusely in one or both arms; MRI imaging is of low value for sensory symptoms alone.*

Effective until September 1, 2023

I. Acute cervical pain (onset within past 6 weeks)

A. Acute cervical radicular pain (radiating into one or both arms) without red flags – cervical spine MRI **not** indicated, medical management should be the initial approach

B. Acute cervical pain with radiating pain from the neck into arm **AND 1 or more** of the following red flag conditions present, where the result is likely to lead to emergent surgery: - cervical MRI may be indicated

Red Flags:

1. **Progressive (objective) neurological signs on repeat in-person examination** (i.e. progressive motor weakness present) *(MRI without contrast)*
2. **Evidence of spinal instability or spinal fracture on any other imaging test** (e.g. plain films or cervical spine CT) *(MRI without contrast)*
3. **Radiating pain from the neck with compelling clinical argument for one of the following:** *(MRI with or without contrast)*
   a. Malignancy

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b. Infection
c. Immunosuppression
d. Bone disc margin destruction on plain radiographs
e. Trauma with neck pain, on anticoagulants

4. **Evidence of neurologic signs suggestive of spinal cord involvement** (e.g. myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia) where the result is likely to lead to immediate surgery or similar intensive intervention

II. Subacute cervical pain (>6 weeks), no prior MRI for the same episode of cervical pain: *(MRI without contrast)*

A. Patient has had **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months, minimum of 3 visits) for *current episode* of neck pain with no significant improvement (remote past history of physical therapy does not qualify)

AND

B. Clinical evaluation demonstrates **1 or more** of the following:
   a. Abnormal reflexes or motor deficits in the C5, C6, C7, T1 nerve territory on one side
   b. Prior neck surgery and significant **new** neurological signs or symptoms, compared to maximal post-op recovery baseline, as defined in a. and b. above
   c. Evidence of spinal instability or spinal fracture on any other imaging test
   d. Complex congenital anomaly or deformity of the spine
   e. Strong suspicion for cervical spinal cord stenosis (e.g. myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia)

OR

C. Patient's clinical presentation indicates need for urgent surgery or other intensive intervention as determined by a surgeon or interventional specialist, even without 6 weeks of physical therapy.

III. Chronic cervical pain

A. **Chronic cervical pain (> 3 months) with no prior MRI of cervical spine**: (MRI without contrast) for any of the criteria under subacute cervical spine pain (section II above)

   1. *Including* **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months) for *current episode* of neck pain with no significant improvement (remote past history of physical therapy does not qualify)

B. **Chronic or recurrent cervical pain (> 3 months) with prior MRI of cervical spine for the same episode of cervical pain with 1 or more of the following:** *(MRI without contrast)*

   1. *Should have* **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months) for *current episode* of neck pain with no significant improvement (remote past history of physical therapy does not qualify)

   2. Patient has not been determined to be a surgical candidate in the past:
      a. Documented significant objective worsening of neurological status on current in-person physical exam (e.g. documented sensory loss, motor weakness, abnormal reflexes in the C5, C6, C7, T1 nerve territory) compared to baseline *OR* electrodiagnostic testing confirming *new* radiculopathy *OR* myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia *OR*
   3. Patient has been determined to be a definite candidate for cervical spine surgery by neurosurgery/orthopedics, (and **ONE** of the following):
      a. Progressive changes in objective neurological findings (see 1 above)
         OR
      b. If no objective neurological findings: the surgeon is requesting another MRI prior to surgery and it has been at least 1 year since last cervical MRI
   4. Prior cervical spine surgery with **1 or more** of the **following** *(MRI without contrast)*:

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a. Objective and new or worsening neurological signs on physical exam compared with maximum post-op recovery baseline (e.g. documented sensory loss, motor weakness, abnormal reflexes in the C5, C6, C7, T1 nerve territory, or new radiculopathy on electrodiagnostic studies *OR* myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia)

OR

b. Other imaging *OR* clinical findings suggest new adverse effects of surgery (e.g., hardware failure or concern for epidural scarring/arachnoiditis)

IV. Suspect Cervical Multiple Sclerosis (MS) *(MRI with contrast)* if patient has been already evaluated by neurology:

A. Approved for staging (along with MRI of brain) at time of initial presentation
B. Known MS diagnosis (confirmed by neurology)—approved for annual surveillance along with Brain MRI

Effective September 1, 2023

I. Acute cervical pain (onset within past 6 weeks)

A. Acute cervical radicular pain (radiating into one or both arms) without red flags – cervical spine MRI **not** indicated, medical management should be the initial approach
B. Acute cervical pain with radiating pain from the neck into arm **AND ONE or more** of the following red flag conditions present, where the result is likely to lead to emergent surgery: - cervical MRI may be indicated

Red Flags:

1. **Progressive (objective) neurological signs on repeat in-person examination** (i.e., progressive motor weakness present) *(MRI without contrast)*
2. **Evidence of spinal instability or spinal fracture on any other imaging test** (e.g., plain films or cervical spine CT) *(MRI without contrast)*
3. **Radiating pain from the neck with compelling clinical argument for one of the following:** *(MRI with or without contrast)*
   a. Malignancy
   b. Infection
   c. Immunosuppression
   d. Bone disc margin destruction on plain radiographs
   e. Trauma with neck pain, on anticoagulants
4. **Evidence of neurologic signs suggestive of spinal cord involvement** (e.g., Bilateral "cape-like" sensory loss to suggest syrinx, myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia) where the result is likely to lead to immediate surgery or similar intensive intervention

II. Subacute cervical pain (>6 weeks), no prior MRI for the same episode of cervical pain: *(MRI without contrast)*

A. Patient has had **at least 6** weeks medical/conservative treatment (must include **at least 4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up, within the last 3 months) for *current episode* of neck pain with no significant improvement (remote past history of physical therapy does not qualify)

AND

B. Clinical evaluation demonstrates **ONE or more** of the following:
   a. Abnormal reflexes or motor deficits in the C5, C6, C7, T1 nerve territory on one side
   b. Prior neck surgery and significant **new** neurological signs or symptoms, compared to maximal post-op recovery baseline, as defined in a. and b. above
   c. Evidence of spinal instability or spinal fracture on any other imaging test
   d. Complex congenital anomaly or deformity of the spine
   e. Strong suspicion for cervical spinal cord stenosis (e.g., myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia)

OR

C. Patient's clinical presentation indicates need for urgent surgery or other intensive intervention as determined by a surgeon or interventional specialist, even without 6 weeks of physical therapy.

III. Chronic cervical pain

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A. **Chronic cervical pain (> 3 months) with no prior MRI of cervical spine**: (MRI without contrast) for any of the criteria under subacute cervical spine pain (section II above)
   1. *Including* **at least 6** weeks medical/conservative treatment (must include **at least 4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up within the last 6 months) for *current episode* of neck pain with no significant improvement (remote past history of physical therapy does not qualify)

B. **Chronic or recurrent cervical pain (> 3 months) with prior MRI of cervical spine for the same episode of cervical pain with 1 or more of the following:** *(MRI without contrast)*
   1. *Should have* **at least 6** weeks medical/conservative treatment (must include **at least 4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up within the last 6 months) for *current episode* of neck pain with no significant improvement (remote past history of physical therapy does not qualify)
   2. Patient has not been determined to be a surgical candidate in the past:
      a. Documented significant objective worsening of neurological status on current in-person physical exam (e.g., documented sensory loss, motor weakness, abnormal reflexes in the C5, C6, C7, T1 nerve territory) compared to baseline *OR* electrodiagnostic testing confirming *new* radiculopathy *OR* myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia *OR*
   3. Patient has been determined to be a definite candidate for cervical spine surgery by neurosurgery/orthopedics, (and **ONE** of the following):
      a. Progressive changes in objective neurological findings (see 1 above)
         OR
      b. If no objective neurological findings: the surgeon is requesting another MRI prior to surgery, and it has been at least 1 year since last cervical MRI
   4. Prior cervical spine surgery with **1 or more** of the **following** *(MRI without contrast)*:
      a. Objective and new or worsening neurological signs on physical exam compared with maximum post-op recovery baseline (e.g., documented sensory loss, motor weakness, abnormal reflexes in the C5, C6, C7, T1 nerve territory, or new radiculopathy on electrodiagnostic studies *OR* myelopathy signs such as bowel or bladder changes, abnormally increased reflexes, positive Babinski sign, spastic gait ataxia)
      OR
      b. Other imaging *OR* clinical findings suggest new adverse effects of surgery (e.g., hardware failure or concern for epidural scarring/arachnoiditis)

IV. Suspect Cervical Multiple Sclerosis (MS) *(MRI with contrast)* if patient has been already evaluated by neurology:
   A. Approved for staging (along with MRI of brain) at time of initial presentation
   B. Known MS diagnosis (confirmed by neurology)—approved for annual surveillance along with Brain MRI

V. Interval follow up of known neurosurgical disease clinical indication for repeat imaging is documented (e.g., intermedullary or extramedullary tumors, bony spine tumors, syrinx, vascular malformation) when ordered by or in consultation with neurosurgery.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

References

American College of Radiology (2008). ACR appropriateness criteria: chronic neck pain. Available at: http://www.acr.org/Quality-Safety/Appropriateness-Criteria/Diagnostic/MusculoskeletalImaging.

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American College of Radiology (2009). ACR appropriateness criteria: suspected spine trauma. Available at: http://www.acr.org/Quality-Safety/Appropriateness-Criteria/Diagnostic/MusculoskeletalImaging.

Bussieres AE, Peterson C, Taylor JAM. Diagnostic imaging guideline for musculoskeletal complaints in adults- an evidence-based approach—part 3: spinal disorders. J Manipulative Physiol Ther 2008; 31: 33-87.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
72141	Magnetic resonance (e.g., proton) imaging, spinal canal and contents, cervical; without contrast material
72142	Magnetic resonance (e.g., proton) imaging, spinal canal and contents, cervical; with contrast material(s)
72156	Magnetic resonance (e.g., proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed04/	Date Last Revised
09/18/2020	10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	04/04/2023

[MPC] Medical Policy Committee

Revision History	Description
10/06/2020	MPC approved to adopt new clinical criteria. Requires 60-day notice, effective date 2/1/2021.
04/01/2021	Added clarifying language to clinical criteria.
04/30/2021	Added clarifying language and formatting changes
10/04/2022	MPC approved to include quantifying number of 3 visits for physical therapy of subacute low back pain. 60-day notice required; effective March 1, 2023.
11/01/2022	MPC approved the minor change for MRI-Cervical Spine criteria to include language for MS patients.
04/04/2023	MPC approved to modify MRI criteria with 4 weeks of physical therapy (instead of 6 weeks) and updated indications for cervical spine imaging.

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Clinical Review Criteria
Lumbar Spine MRI

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Lumbar MRI (L37281) *Medical necessity review not required
Local Coverage Article (LCA)	Billing and Coding: Lumbar MRI (A57207)

For Non-Medicare Members

Adapted from Washington State Department of Labor & Industries Guidelines for Advanced Imaging Studies: Lumbar spine checklist. Retrieved 4/22/2020 from https://lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/_docs/LBchecklist.pdf

Lumbar spine MRI is NOT indicated for the following:
Uncomplicated acute (<6 weeks) low back pain with or without suspected radiculopathy (no red flags) does not warrant the use of MRI, X-ray, CT, myelography or CT xylography, NUC Tc-99m bone scan with SPECT. Nonspecific lumbar disc abnormalities are commonly found in asymptomatic patients. (Chou, Qaseem et al. 2007) (American College of Radiology 2007)

**Note – most acute lumbar radicular pain will resolve with time and conservative management. Bulging discs will retract away from the affected nerve root spontaneously in a high percentage of cases. Most patients will respond to 6 weeks medical/conservative treatment including physical therapy.*

If advanced imaging is needed, lumbar spine MRI is the preferred imaging modality for the following circumstances unless contraindicated or not tolerated by the patient (i.e., due to presence of ferrous metal in body, or severe anxiety) or unavailable.

Effective until September 1, 2023

I. Acute low back pain (onset within past 6 weeks)

Lumbar spine MRI not indicated unless **ONE or more** of the following red flag conditions are present:

Red Flags:

1. **Progressive (objective) neurological signs on repeat in-person examination** (i.e., progressive motor weakness present) *(MRI without contrast)*

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2. **Suspect Cauda Equina syndrome** *(MRI without contrast)* due to the following:
   - New onset bilateral neurologic signs and symptoms of cauda equina (e.g., saddle numbness with acute bladder or bowel dysfunction)

> *ACR appropriateness recommendation ranks MRI without contrast highest (rating = 9). MRI with and without contrast (rating = 8) depends on clinical circumstances. Other methods: Myelography and postmyelography CT (rating = 6), CT with and without contrast (rating = 5)-may be indicated if MRI is confusing or contraindicated, x-ray, NUC Tc-99m bone scan with SPECT and x-ray myelography are rated < 5.

3. **Strong clinical suspicion of spine infection** *(MRI with and without contrast)* and **TWO or more** of the following:
   - Fever
   - Immunosuppression (e.g., chronic steroid use, diabetes)
   - IV drug use
   - Known bacteremia
   - Elevated sedimentation rate/c-reactive protein

4. **History or strong clinical suspicion of cancer with new onset of low back pain and non-diagnostic plain films** and **TWO or more** of the following *(MRI with and without contrast)***:**
   - Unexplained weight loss
   - Failure of back pain to improve after one month
   - Age over 50

> *ACP recommends plain radiography for unexplained weight loss, MRI or plain radiography if multiple risk factors present. ACR Guidelines for suspicion of cancer, infection or immunosuppression rate MRI without and with contrast highest (rating = 8). CT without contrast (rating = 6)-useful if MRI is contraindicated or unavailable. Other imaging methods: use of x-ray, NUC Tc-99m bone scan whole body with optional targeted SPECT, myelography and postmyelography CT (appropriateness rating < 6 for these).

5. **Suspected vertebral fracture in a patient with pain and non-diagnostic plain films** *(MRI without contrast)*
   - Low velocity trauma (e.g., fall from height or struck by object) OR
   - Osteoporosis OR
   - Age >70 years with other acute fracture(s)

> *ACP Guideline recommends: if vertebral compression fracture is suspected due to history of osteoporosis, use of steroids, or age ≥ 70 plain radiography should be completed prior to MRI.
>
> *For low velocity trauma, ACR Guidelines do not support use of NUC Tc-99m bone scan with SPECT, MRI with and without contrast, myelography and postmyelography CT, or x-ray myelography (appropriateness ratings < 5 for these)

II. Subacute Low back pain >6 weeks: *(MRI without contrast)*

A. Patient has had **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months, minimum of 3 visits) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify)

AND

- **ONE or more** of the criteria under acute low back pain met (from section I above)

OR

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- Suspected radiculopathy with **ALL of the following** documented in notes:
  - Leg pain is > than back pain present in nerve root distribution (e.g., L5, S1, etc.) **ONE** or more of the following:
    - Positive supine straight leg raising test - radicular leg pain reproduced when the leg is extended >30° and <70° (pain reproduced only in the back is a negative test) or positive crossed straight leg raising test

    OR
    - Motor weakness or sensory loss in a radicular distribution (must be in a specific radicular distribution)

    OR
    - EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

*ACP recommendation: consider EMG/NCS testing if symptoms > 1 month. For suspected radiculopathy, ACR Guidelines rate MRI without contrast as most appropriate. CT without contrast may be useful if MRI is not available or contraindicated. MRI with and without contrast may be indicated if noncontrast MRI is nondiagnostic or indeterminate. MRI is preferred over myelography and postmyelography CT but may be indicated if MRI is nondiagnostic. In some circumstances (facet arthropathy, stress fracture and spondylolysis) NUC Tc-99m bone scan with SPECT may be useful. Least appropriate x-ray (appropriateness rating 2).

III. Chronic low back pain

A. **Chronic low back pain (> 3 months) with no prior MRI of lumbar spine:** *(MRI without contrast)*
All patients should have **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify) **and must meet ONE of the following:**

1. Any of the criteria under subacute low back pain (section II above)
2. Strong clinical suspicion of lumbar spinal stenosis, with documentation of neurogenic claudication (bilateral or unilateral leg pain upon standing that is temporarily relieved by forward flexion or sitting)

B. **Chronic low back pain (> 3 months) with prior MRI of lumbar spine:** *(MRI without contrast)*:

All patients should have **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months) for *current episode* of back pain with no significant improvement (remote history of physical therapy does not qualify)

1. Patient has not been determined to be a surgical candidate in the past
   a. Documented objective worsening of neurological status on current physical exam (e.g. absence of reflexes, dermatomal sensory changes, radicular motor weakness, etc.) *OR* electrodiagnostic testing confirming new radiculopathy *OR*
2. Patient has been determined to be a definite candidate for spine surgery by neurosurgery/orthopedics, (and **ONE** of the following):
   a. Progressive changes in objective neurological findings
   b. If no objective neurological findings: the surgeon is requesting another MRI prior to surgery and it has been at least 1 year since last lumbar MRI

* ACR Guidelines rate MRI without contrast as most appropriate. CT without contrast may be useful if MRI is not available or contraindicated. MRI with and without contrast may be indicated if noncontrast MRI is nondiagnostic or indeterminate. MRI is preferred over myelography and postmyelography CT but may be indicated if MRI is nondiagnostic. In some circumstances (facet arthropathy, stress fracture and spondylolysis) NUC Tc-99m bone scan with SPECT may be useful. Least appropriate x-ray (appropriateness rating 2).

3. Prior lumbar surgery with **ONE or more** of the following *(MRI with and without contrast)*:

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a. Objective and/or new or worsening neurological signs on physical exam (new absence of reflexes, dermatomal sensory changes, radicular motor weakness, or new radiculopathy on electrodiagnostic studies, etc.)
b. Plain radiography OR clinical findings suggest new adverse effects of surgery
   - (e.g., hardware failure or concern for epidural scarring/arachnoiditis)
c. New changes to electrodiagnostic studies

*ACR appropriateness rates MRI with and without contrast highest (rating =8), CT without contrast(rating=6) may be indicated in postfusion patients or when MRI is contraindicated or indeterminate. Other methods rated lower: MRI without contrast (rating=6) as contrast is often necessary, myelography and postmyelography CT (rating= 5, x-ray (rating = 5)-flex/extension may be useful, NUC Tc-99m bone scan with SPECT (rating=5)-helps detect and localize pseudoarthrosis, x-ray myelography (rating = 2).

C. **Indication not listed: provide clinical justification**
Indications here should be well documented. For example, while the vast majority of true radiculopathy cases would meet the criteria, specific syndromes (lateral stenosis, L1-L3 syndromes) may only meet some of these criteria. In these cases, clinical correlation should be clearly documented.

IV. There is no indication for Lumbar MRI for initial or subsequent evaluation of suspected or confirmed MS.

Effective September 1, 2023

I. Acute low back pain (onset within past 6 weeks)

Lumbar spine MRI not indicated unless **ONE or more** of the following red flag conditions are present:

Red Flags:

1. **Progressive (objective) neurological signs on repeat in-person examination** (i.e. progressive motor weakness present) *(MRI without contrast)*

2. **Suspect Cauda Equina syndrome** *(MRI without contrast)* due to the following:
   - New onset bilateral neurologic signs and symptoms of cauda equina (e.g., saddle numbness with acute bladder or bowel dysfunction)

*ACR appropriateness recommendation ranks MRI without contrast highest (rating = 9). MRI with and without contrast (rating = 8) depends on clinical circumstances. Other methods: Myelography and postmyelography CT (rating = 6), CT with and without contrast (rating = 5)-may be indicated if MRI is confusing or contraindicated, x-ray, NUC Tc-99m bone scan with SPECT and x-ray myelography are rated < 5.

3. **Strong clinical suspicion of spine infection** *(MRI with and without contrast)* and **TWO or more** of the following:
   - Fever
   - Immunosuppression (e.g., chronic steroid use, diabetes)
   - IV drug use
   - Known bacteremia
   - Elevated sedimentation rate/c-reactive protein

4. **History or strong clinical suspicion of cancer with new onset of low back pain and non-diagnostic plain films** and **TWO or more** of the following *(MRI with and without contrast)***:**
   - Unexplained weight loss
   - Failure of back pain to improve after one month
   - Age over 50

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*ACP recommends plain radiography for unexplained weight loss, MRI or plain radiography if multiple risk factors present. ACR Guidelines for suspicion of cancer, infection or immunosuppression rate MRI without and with contrast highest (rating = 8). CT without contrast (rating = 6)-useful if MRI is contraindicated or unavailable. Other imaging methods: use of x-ray, NUC Tc-99m bone scan whole body with optional targeted SPECT, myelography and postmyelography CT (appropriateness rating < 6 for these).

5. **Suspected vertebral fracture in a patient with pain and non-diagnostic plain films** *(MRI without contrast)*
   - Low velocity trauma (e.g., fall from height or struck by object) OR
   - Osteoporosis OR
   - Age >70 years with other acute fracture(s)

*ACP Guideline recommends: if vertebral compression fracture is suspected due to history of osteoporosis, use of steroids, or age ≥ 70 plain radiography should be completed prior to MRI.

*For low velocity trauma, ACR Guidelines do not support use of NUC Tc-99m bone scan with SPECT, MRI with and without contrast, myelography and postmyelography CT, or x-ray myelography (appropriateness ratings < 5 for these)

II. Subacute Low back pain >6 weeks: *(MRI without contrast)*

A. Patient has had **at least 6 weeks** medical/conservative treatment (must include **at least 4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up, within the last 3 months) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify)

AND

- **ONE or more** of the criteria under acute low back pain met (from section I above)
  OR
- Suspected radiculopathy with **ALL of the following** documented in notes:
  - Leg pain is > than back pain present in nerve root distribution (e.g., L5, S1, etc.) **ONE** or more of the following:
    - Positive supine straight leg raising test - radicular leg pain reproduced when the leg is extended >30° and <70° (pain reproduced only in the back is a negative test) or positive crossed straight leg raising test

    OR
    - Motor weakness or sensory loss in a radicular distribution (must be in a specific radicular distribution)

    OR
    - EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

*ACP recommendation: consider EMG/NCS testing if symptoms > 1 month. For suspected radiculopathy, ACR Guidelines rate MRI without contrast as most appropriate. CT without contrast may be useful if MRI is not available or contraindicated. MRI with and without contrast may be indicated if noncontrast MRI is nondiagnostic or indeterminate. MRI is preferred over myelography and postmyelography CT but may be indicated if MRI is nondiagnostic. In some circumstances (facet arthropathy, stress fracture and spondylolysis) NUC Tc-99m bone scan with SPECT may be useful. Least appropriate x-ray (appropriateness rating 2).

III. Chronic low back pain

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A. **Chronic low back pain (> 3 months) with no prior MRI of lumbar spine:** *(MRI without contrast)*
All patients should have **at least 6 weeks** of medical/conservative treatment (must include at least **4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up within the last 6 months) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify **and must meet ONE of the following:**
1. Any of the criteria under subacute low back pain (section II above)
2. Strong clinical suspicion of lumbar spinal stenosis, with documentation of neurogenic claudication (bilateral or unilateral leg pain upon standing that is temporarily relieved by forward flexion or sitting)

B. **Chronic low back pain (> 3 months) with prior MRI of lumbar spine:** *(MRI without contrast)*:
All patients should have **at least 6 weeks** medical/conservative treatment (must include at least **4 weeks** of physical, including an initial evaluation with PT and at least one follow up therapy within the last 6 months) for *current episode* of back pain with no significant improvement (remote history of physical therapy does not qualify)
1. Patient has not been determined to be a surgical candidate in the past
   a. Documented objective worsening of neurological status on current physical exam (e.g. absence of reflexes, dermatomal sensory changes, radicular motor weakness, etc.) *OR* electrodiagnostic testing confirming new radiculopathy *OR*
2. Patient has been determined to be a definite candidate for spine surgery by neurosurgery/orthopedics, (and **ONE** of the following):
   a. Progressive changes in objective neurological findings
   b. If no objective neurological findings: the surgeon is requesting another MRI prior to surgery and it has been at least 1 year since last lumbar MRI

* ACR Guidelines rate MRI without contrast as most appropriate. CT without contrast may be useful if MRI is not available or contraindicated. MRI with and without contrast may be indicated if noncontrast MRI is nondiagnostic or indeterminate. MRI is preferred over myelography and postmyelography CT but may be indicated if MRI is nondiagnostic. In some circumstances (facet arthropathy, stress fracture and spondylolysis) NUC Tc-99m bone scan with SPECT may be useful. Least appropriate x-ray (appropriateness rating 2).

3. Prior lumbar surgery with **ONE or more** of the following *(MRI with and without contrast)*:
   a. Objective and/or new or worsening neurological signs on physical exam (new absence of reflexes, dermatomal sensory changes, radicular motor weakness, or new radiculopathy on electrodiagnostic studies, etc.)
   b. Plain radiography OR clinical findings suggest new adverse effects of surgery (e.g., hardware failure or concern for epidural scarring/arachnoiditis)
   c. New changes to electrodiagnostic studies

*ACR appropriateness rates MRI with and without contrast highest (rating =8), CT without contrast(rating=6) may be indicated in postfusion patients or when MRI is contraindicated or indeterminate. Other methods rated lower: MRI without contrast (rating=6) as contrast is often necessary, myelography and postmyelography CT (rating= 5, x-ray (rating = 5)-flex/extension may be useful, NUC Tc-99m bone scan with SPECT (rating=5)-helps detect and localize pseudoarthrosis, x-ray myelography (rating = 2).

C. **Indication not listed: provide clinical justification**
Indications here should be well documented. For example, while the vast majority of true radiculopathy cases would meet the criteria, specific syndromes (lateral stenosis, L1-L3 syndromes) may only meet some of these criteria. In these cases, clinical correlation should be clearly documented.

IV. There is no indication for Lumbar MRI for initial or subsequent evaluation of suspected or confirmed MS.

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Chou, R., A. Qaseem, et al. (2007). "Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society." Ann Intern Med 147(7): 478-91.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Summary of Recommendations

- Uncomplicated acute LBP and/or radiculopathy are benign, self-limited conditions that do not warrant any imaging studies.
- MRI of the lumbar spine should be considered at any point for those patients presenting with red flags raising suspicion for a serious underlying condition, such as cauda equina syndrome (CES), malignancy, or infection.
- In patients with a history of low-velocity trauma, osteoporosis, or chronic steroid use, initial evaluation with radiographs is recommended.
- In the absence of red flags, first-line treatment for chronic LBP remains conservative therapy with both pharmacologic and nonpharmacologic (eg, exercise, remaining active) therapy.
- If there are persistent or progressive symptoms during or following 6 weeks of conservative management and the patient is a surgery or intervention candidate or diagnostic uncertainty remains, MRI of the lumbar spine has become the initial imaging modality of choice in evaluating complicated LBP.
- MRI is the imaging procedure of choice in patients suspected of cord compression or spinal cord injury.
- Patients with recurrent low back pain and history of prior surgical intervention should be evaluated with contrast-enhanced MRI.

Applicable Codes

Medicare – Medical Necessity review not required
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
72148	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; without contrast material
72149	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; with contrast material(s)
72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/05/2020	05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	04/04/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	MPC approved to adopt new clinical criteria. Requires 60-day notice, effective date 9/1/2020.
04/30/2021	Added clarifying language and formatting changes
10/04/2022	MPC approved to include quantifying number of 3 visits for physical therapy of subacute low back pain. 60-day notice required.
04/04/2023	MPC approved to modify MRI criteria with 4 weeks of physical therapy (instead of 6 weeks)

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Clinical Review Criteria
Thoracic Spine MRI

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (220.2)
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None

For Non-Medicare Members

Effective until May 1, 2023

No review required

Effective until September 1, 2023

I. Acute thoracic back pain (onset within past 6 weeks)

Thoracic spine MRI not indicated unless **ONE or more** of the following red flag conditions are present:

Red Flags:

A. Objective neurological signs of thoracic myelopathy (leg weakness and incontinence with +/- spasticity) *(MRI without contrast)*

B. Progressive (objective) neurological signs of thoracic myelopathy (leg weakness and incontinence with +/- spasticity) on repeat examination during a course of conservative care (i.e., progressive motor weakness present) *(MRI without contrast)*

C. Strong clinical suspicion of spine infection with strong clinical concern for thoracic myelopathy or myelitis *(MRI with and without contrast)* and **TWO or more** of the following:

- Fever
- Immunosuppression (e.g., chronic steroid use, diabetes)
- IV drug use
- Known bacteremia
- Elevated sedimentation rate/c-reactive protein

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D. **History or strong clinical suspicion of cancer (by examination, lab and other ancillary testing) with new onset of thoracic back pain/myelopathy and non-diagnostic plain films** and **TWO or more** of the following *(MRI with and without contrast)***:**
- Unexplained weight loss
- Failure of back pain to improve after conservative management
- Back pain worse when supine is common in thoracic metastasis
- Age over 50

> *ACP recommends plain radiography for unexplained weight loss, MRI or plain radiography if multiple risk factors present. ACR Guidelines for suspicion of cancer, infection or immunosuppression rate MRI without and with contrast highest (rating = 8). CT without contrast (rating = 6)-useful if MRI is contraindicated or unavailable. Other imaging methods: use of x-ray, NUC Tc-99m bone scan whole body with optional targeted SPECT, myelography and postmyelography CT (appropriateness rating < 6 for these).

E. **Suspected vertebral fracture in a patient with pain and non-diagnostic plain films** *(CT should be done first and MRI can be considered based on clinical findings/possible surgical intervention)*
- Low velocity trauma (e.g., fall from height or struck by object) OR
- Osteoporosis OR
- Age >70 years with other acute fracture(s)

> *ACP Guideline recommends: if vertebral compression fracture is suspected due to history of osteoporosis, use of steroids, or age ≥ 70 plain radiography should be completed prior to MRI.
> *For low velocity trauma, ACR Guidelines do not support use of NUC Tc-99m bone scan with SPECT, MRI with and without contrast, myelography and postmyelography CT, or x-ray myelography (appropriateness ratings < 5 for these)

II. Subacute Thoracic back pain >6 weeks (with no red flags above): *(MRI without contrast)*

A. Patient has had **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months, minimum of 3 visits) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify); if diabetic should be well controlled

AND
- **ONE or more** of the criteria under acute thoracic back pain met (from section I above)
  OR
- Suspected thoracic radiculopathy (band of numbness, pain or sensitivity around midsection)
  OR
- Motor weakness or sensory loss in a spinal cord distribution (e.g., bilateral sensory loss from mid or low abdomen down, and/or leg weakness, and/or bowl or bladder incontinence)

III. Chronic thoracic back pain (> 3 months) with no prior MRI of thoracic spine (with no red flags above): *(MRI without contrast)*

A. All patients should have **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify) **and must meet ONE of the following:**
- Any of the criteria under subacute thoracic back pain (section II above)

IV. Chronic thoracic back pain (> 3 months) with prior MRI of thoracic spine (with no red flags above): *(MRI without contrast)*:

A. All patients should have **at least 6** weeks medical/conservative treatment (must include 6 weeks of physical therapy within the last 3 months) for *current episode* of back pain with no significant improvement (remote history of physical therapy does not qualify)

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- Any of the criteria under subacute thoracic back pain (section II above). If clinical exam is unchanged from prior, should not be repeated more than once every 12 months.

V. **Suspect Thoracic Multiple Sclerosis (MS)** *(MRI with contrast)* patient must have been already evaluated by neurology who specifically advises thoracic MRI:

A. Should not be part of initial staging unless there are specific findings attributable to the thoracic cord (e.g., MS "hug" or sensory loss beginning mid thorax)

B. Not routinely indicated for subsequent imaging for MS

VI. Inflammatory or demyelinating process, suspected (e.g., transverse myelitis, spinal cord abscess, clinically isolated syndrome, conditions mimicking MS, other demyelinating disease), as indicated by **ONE or more** of the following (ordered with specific recommendation by neurology/neurosurgery):

- Ascending numbness or tingling (e.g., from foot to trunk)
- Brown-Sequard syndrome
- Autoimmune inflammatory disorders known to affect spinal cord (Sjogren syndrome, systemic lupus erythematosus, antiphospholipid syndrome)
- MS strongly suspected but MRI of brain and cervical spine nondiagnostic, after consultation with Neurology
- Signs or symptoms strongly indicative of myelopathy (leg weakness and incontinence with +/- spasticity) or myelitis (pain with weakness and incontinence and +/- spasticity)

VII.

A. Pediatric/Adolescent Scoliosis, as indicated by **ONE or more** of the following:

- Congenital scoliosis
- Early-onset scoliosis (age 9 years or younger)
- Neurofibromatosis
- Presurgical planning for adolescent idiopathic scoliosis to assess possible neural axis malformation, as indicated by **ONE or more** of the following:
  - Abnormal neurologic findings on clinical examination
  - Age at first visit 10 years or younger
  - Kyphosis at curve apex
  - Left-sided thoracic curvature
  - Male gender
  - Pain, moderate to severe
  - Rapid curve progression (i.e., more than 1 degree per month)
  - Short segment curve (i.e., less than 6 vertebral segments)
  - Thoracic kyphosis 30 degrees or greater
  - Vertebral abnormalities (e.g., hemivertebrae, block vertebrae) detected on x-ray

B. Adult Scoliosis as indicated by **ONE or more** of the following:

- Abnormal neurologic findings on clinical examination
- Kyphosis at curve apex
- Pain, moderate to severe
- Rapid curve progression (i.e., more than 1 degree per month)
- Short segment curve (i.e., less than 6 vertebral segments)
- Thoracic kyphosis 30 degrees or greater
- Vertebral abnormalities (e.g., hemivertebrae, block vertebrae) detected on x-ray
- Presurgical planning

VIII. Spinal stenosis of thoracic spine, suspected, as indicated by **ALL** of the following):

- Patient being considered for invasive treatment
- Progressive or disabling symptoms of thoracic spine stenosis, as indicated by **ONE or more** of the following:
  - Hyperactive reflexes
  - Muscle weakness
  - Sensory loss
  - Spasticity

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IX. Stereotactic spine radiotherapy treatment planning

X. Syringomyelia in thoracic spine, suspected, as indicated by **ONE or more** of the following:
- Muscle wasting in appropriate thoracic spine dermatomes
- Sensory loss in appropriate thoracic spine dermatomes
- Weakness in appropriate thoracic spine dermatomes
- Bowel/bladder dysfunction

XI. Tethered cord, suspected, as indicated by **ONE or more** of the following:
- Anorectal malformation
- Cutaneous manifestations of occult spina bifida (e.g., nevus, lipoma, tufts of hair, hemangioma, dimple overlying spine, asymmetric gluteal cleft, dermal sinus tract)
- Gait abnormality or difficulty
- Urinary dribbling or lack of bladder control
- Urodynamic tests abnormal

XII. Indication not listed: provide clinical justification
- Indications here should be well documented.

Effective September 1, 2023

I. Acute thoracic back pain (onset within past 6 weeks)

Thoracic spine MRI not indicated unless **ONE or more** of the following red flag conditions are present:

Red Flags:

A. Objective neurological signs of thoracic myelopathy (leg weakness and incontinence with +/- spasticity) *(MRI without contrast)*

B. Progressive (objective) neurological signs of thoracic myelopathy (leg weakness and incontinence with +/- spasticity) on repeat examination during a course of conservative care (i.e., progressive motor weakness present) *(MRI without contrast)*

C. Strong clinical suspicion of spine infection with strong clinical concern for thoracic myelopathy or myelitis *(MRI with and without contrast)* and **TWO or more** of the following:
- Fever
- Immunosuppression (e.g., chronic steroid use, diabetes)
- IV drug use
- Known bacteremia
- Elevated sedimentation rate/c-reactive protein

D. History or strong clinical suspicion of cancer (by examination, lab and other ancillary testing) with new onset of thoracic back pain/myelopathy and non-diagnostic plain films and **TWO or more** of the following *(MRI with and without contrast)***:**
- Unexplained weight loss
- Failure of back pain to improve after conservative management
- Back pain worse when supine is common in thoracic metastasis
- Age over 50

*ACP recommends plain radiography for unexplained weight loss, MRI or plain radiography if multiple risk factors present. ACR Guidelines for suspicion of cancer, infection or immunosuppression rate MRI without and with contrast highest (rating = 8). CT without contrast (rating = 6)-useful if MRI is contraindicated or unavailable. Other imaging methods: use of x-ray, NUC Tc-

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99m bone scan whole body with optional targeted SPECT, myelography and postmyelography CT (appropriateness rating < 6 for these).

E. **Suspected vertebral fracture in a patient with pain and non-diagnostic plain films** *(CT should be done first and MRI can be considered based on clinical findings/possible surgical intervention)*
- Low velocity trauma (e.g., fall from height or struck by object) OR
- Osteoporosis OR
- Age >70 years with other acute fracture(s)

*ACP Guideline recommends: if vertebral compression fracture is suspected due to history of osteoporosis, use of steroids, or age ≥ 70 plain radiography should be completed prior to MRI. *For low velocity trauma, ACR Guidelines do not support use of NUC Tc-99m bone scan with SPECT, MRI with and without contrast, myelography and postmyelography CT, or x-ray myelography (appropriateness ratings < 5 for these)

II. Subacute Thoracic back pain >6 weeks (with no red flags above): *(MRI without contrast)*

A. Patient has had at least 6 weeks medical/conservative treatment (must include **at least 4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up, within the last 3 months) for current episode of back pain with no significant improvement (remote past history of physical therapy does not qualify); if diabetic should be well controlled

AND
- **ONE or more** of the criteria under acute thoracic back pain met (from section I above)
  OR
- Suspected thoracic radiculopathy (band of numbness, pain or sensitivity around midsection)
  OR
- Motor weakness or sensory loss in a spinal cord distribution (e.g., bilateral sensory loss from mid or low abdomen down, and/or leg weakness, and/or bowl or bladder incontinence)

III. Chronic thoracic back pain (> 3 months) with no prior MRI of thoracic spine (with no red flags above): *(MRI without contrast)*

A. All patients should have **at least 6 weeks** medical/conservative treatment (must include **at least 4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up within the last 6 months) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify) **and must meet ONE of the following:**
- Any of the criteria under subacute thoracic back pain (section II above)

IV. Chronic thoracic back pain (> 3 months) with prior MRI of thoracic spine (with no red flags above): *(MRI without contrast)*:

A. All patients should have **at least 6 weeks** medical/conservative treatment (must include at least **4 weeks** of physical therapy, including an initial evaluation with PT and at least one follow up therapy within the last 6 months) for *current episode* of back pain with no significant improvement (remote past history of physical therapy does not qualify) **and must meet ONE of the following:**
- Any of the criteria under subacute thoracic back pain (section II above). If clinical exam is unchanged from prior, should not be repeated more than once every 12 months.

V. Suspect Thoracic Multiple Sclerosis (MS) *(MRI with contrast)* patient must have been already evaluated by neurology who specifically advises thoracic MRI:

A. Should not be part of initial staging unless there are specific findings attributable to the thoracic cord (e.g., MS “hug” or sensory loss beginning mid thorax)

B. Not routinely indicated for subsequent imaging for MS

VI. Inflammatory or demyelinating process, suspected (e.g., transverse myelitis, spinal cord abscess, clinically isolated syndrome, conditions mimicking MS, other demyelinating disease), as indicated by **ONE or more** of the following (ordered with specific recommendation by neurology/neurosurgery):
- Ascending numbness or tingling (e.g., from foot to trunk)

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- Brown-Sequard syndrome
- Autoimmune inflammatory disorders known to affect spinal cord (Sjogren syndrome, systemic lupus erythematosus, antiphospholipid syndrome)
- MS strongly suspected but MRI of brain and cervical spine nondiagnostic, after consultation with Neurology
- Signs or symptoms strongly indicative of myelopathy (leg weakness and incontinence with +/- spasticity) or myelitis (pain with weakness and incontinence and +/- spasticity)

VII.

A. Pediatric/Adolescent Scoliosis, as indicated by **ONE or more** of the following:
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- Presurgical planning for adolescent idiopathic scoliosis to assess possible neural axis malformation, as indicated by **1 or more** of the following:
  - Abnormal neurologic findings on clinical examination
  - Age at first visit 10 years or younger
  - Kyphosis at curve apex
  - Left-sided thoracic curvature
  - Male gender
  - Pain, moderate to severe
  - Rapid curve progression (i.e., more than 1 degree per month)
  - Short segment curve (i.e., less than 6 vertebral segments)
  - Thoracic kyphosis 30 degrees or greater
  - Vertebral abnormalities (e.g., hemivertebrae, block vertebrae) detected on x-ray

B. Adult Scoliosis as indicated by **ONE or more** of the following:
- Abnormal neurologic findings on clinical examination
- Kyphosis at curve apex
- Pain, moderate to severe
- Rapid curve progression (i.e., more than 1 degree per month)
- Short segment curve (i.e., less than 6 vertebral segments)
- Thoracic kyphosis 30 degrees or greater
- Vertebral abnormalities (e.g., hemivertebrae, block vertebrae) detected on x-ray
- Presurgical planning

VIII. Spinal stenosis of thoracic spine, suspected, as indicated by **ALL** of the following):
- Patient being considered for invasive treatment
- Progressive or disabling symptoms of thoracic spine stenosis, as indicated by **ONE or more** of the following:
  - Hyperactive reflexes
  - Muscle weakness
  - Sensory loss
  - Spasticity

IX. Stereotactic spine radiotherapy treatment planning

X. Syringomyelia in thoracic spine, suspected, as indicated by **ONE or more** of the following:
- Muscle wasting in appropriate thoracic spine dermatomes
- Sensory loss in appropriate thoracic spine dermatomes
- Weakness in appropriate thoracic spine dermatomes
- Bowel/bladder dysfunction

XI. Tethered cord, suspected, as indicated by **ONE or more** of the following:
- Anorectal malformation
- Cutaneous manifestations of occult spina bifida (e.g., nevus, lipoma, tufts of hair, hemangioma, dimple overlying spine, asymmetric gluteal cleft, dermal sinus tract)

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- Gait abnormality or difficulty
- Urinary dribbling or lack of bladder control
- Urodynamic tests abnormal

XII. Indication not listed: provide clinical justification

- Indications here should be well documented.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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References

The American College of Radiology (ACR), the American Society of Neuroradiology (ASNR),the Society of Computed Body Tomography and Magnetic Resonance (SCBT-MR), and the Society for Skeletal Radiology (SSR). (2020, October 13). *Search results*. American College of Radiology. Retrieved December 19, 2022, from https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Adult-Spine.pdf

Adapted from Washington State Department of Labor & Industries Final Imaging Guidelines: Thoracic Spine MRI. Retrieved 9/13/2022 from https://lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/_docs/ThoracicSpineChecklist.pdf

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPCS Codes	Description
72146	MRI Thoracic without contrast
72147	MRI Thoracic with contrast
72157	MRI Thoracic without and with contrast

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/06/2022	12/06/2022[MPC],	04/04/2023

[MPC] Medical Policy Committee

Revision History	Description

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12/06/2022	MPC approved to adopt criteria for Thoracic MRI for non-Medicare members. Requires 60-day notice, effective date May 1, 2023.
04/04/2023	MPC approved to modify MRI criteria with 4 weeks of physical therapy (instead of 6 weeks)

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Clinical Review Criteria
Weight-Bearing MRI

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (MRI) (220.2)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Magnetic resonance imaging (MRI) uses magnetic fields and radiofrequency waves to provide images of internal organs and tissues. Among other applications, MRI is widely used to diagnose joint and musculoskeletal disorders especially injuries affecting the knee, shoulder, hip, elbow and wrist.

Conventional MRI may have limits for diagnosing certain conditions such as degenerative cervical spinal disorders in which symptoms are aggravated when patients are standing and relieved when patients are lying down. The closed cylindrical design of standard MRI systems requires patients to be imaged in a supine position. Thus, with conventional non-weight-bearing MRI, the conditions under which symptoms arise are often not reproduced. Biomechanical studies have found a decrease in spinal canal cross-sectional area (or dural sac) and spinal foraminal dimensions with weight-bearing (axial loading) and with flexion and extension. In some cases, MRI findings correlate with patient symptoms. Disk extrusion, disk sequestration and nerve root compression are infrequently seen in asymptomatic patients, leading to the common belief that nerve root compression seen on MRI is clinically relevant. MRI of patients in the supine position may not identify clinically relevant spinal canal and foraminal stenosis, or the degree of nerve root compression (Kumura et al., 2005; Weishaupt & Boxheimer, 2003).

Weight-bearing MRI is proposed as an alternative to conventional MRI imaging. There are two ways to image the weight-bearing spine. One approach is to simulate weight bearing using a special device with conventional MRI machines. A study of patients with symptoms of spinal stenosis (Hiwatashi et al., 2004) found that imaging with axially loaded MR imaging can yield information that results in different treatment decisions than standard MRI.

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The Hiwatashi study used a device, consisting of a harness/jacket with straps connected to a footplate that applies an axial load to the patient's spine during imaging in the supine position.

The other approach is to use a vertically open-configuration MRI that allows the patient to be imaged in a weight-bearing position. There are two FDA-approved devices:

- The Indomitable MRI scanner (Fonar) was approved by the FDA in October 2000 for imaging multiple planes of the head and body. It has an open design and the patient-scanning table can be moved to a variety of positions with the patient on it. Scanning positions include a vertical (upright) position, a horizontal (supine) position and an angled position (angles between -20o and 90o). Fonar, the manufacturer, claims that this is the only MRI system that can scan patients in flexion, extension, rotation and lateral bending (Fonar website; FDA website).
- The G-scan (Esaote) was approved by the FDA in August 2004; its use is limited to imaging the ankle, knee, hip, shoulder joint and spine. The scanning table can also be moved to a variety of positions with the patient on it. The table can be rotated to angles between supine (0o) to fully upright (90o). The system also includes specialized knee, hand/wrist, ankle/foot and shoulder coils (Esaote website; FDA website).

Weight-bearing MRI has not been previously reviewed by MTAC.
Assessment questions:

- Diagnostic accuracy: What is the evidence on the ability of upright MRI to accurately detect problems/pathology compared to conventional MRI?
- Diagnostic impact: What is evidence on whether findings from weight-bearing MRI contribute substantially to improved diagnosis compared to conventional MRI?
- Therapeutic impact: What is the evidence that more appropriate therapy is used after weight-bearing MRI compared to conventional MRI?

Medical Technology Assessment Committee (MTAC)

Weight-Bearing MRI

06/04/2007: MTAC REVIEW

Evidence Conclusion: There are no published studies on the diagnostic accuracy (sensitivity/specificity), diagnostic impact or therapeutic impact of upright MRI compared to conventional MRI. One study with the Fonar Upright MRI system (Perez et al., 2007 in press) compared the diagnostic yield of the new device compared to conventional MRI. There was no gold standard comparison; rather, weight-bearing MRI was compared to conventional MRI. 68 pathologies were identified in 89 symptomatic patients by one or both methods. The authors considered a technology to be "superior" if it identified a pathology not detected by the other method or indicated a herniation or spondylolisthesis that was larger in size. Upright MRI was found to be superior to recumbent MRI in 52 out of 68 pathologies identified, and recumbent MRI was found to be superior to upright MRI in 11 cases. The reports by the Washington State Labor and Industries Department and the Washington State Department of Health both also concluded that there was insufficient evidence on the diagnostic accuracy or utility of weight-bearing MRI.

Articles: Diagnostic accuracy: No studies were identified evaluated the sensitivity and specificity of weight-bearing MRI compared to conventional MRI, using an objective comparison. The empirical articles identified in the search generally involved obtaining spinal measurements with patients in various positions. For example, Hirasawa et al. (2007) examined 20 asymptomatic volunteers with the Fonar Indomitable MRI scanner in supine, sitting and standing positions. The primary outcome measures were differences in spinal measurements, specifically mean dural sac cross-sectional area and diameter. One study was identified that compared clinical diagnoses of patients imaged with weight-bearing MRI versus conventional MRI. This study (Ferreiro Perez et al., in press 2007) was critically appraised. See Evidence Table. Diagnostic accuracy: No studies were identified evaluated the sensitivity and specificity of weight-bearing MRI compared to conventional MRI, using an objective comparison. The empirical articles identified in the search generally involved obtaining spinal measurements with patients in various positions. For example, Hirasawa et al. (2007) examined 20 asymptomatic volunteers with the Fonar Indomitable MRI scanner in supine, sitting and standing positions. The primary outcome measures were differences in spinal measurements, specifically mean dural sac cross-sectional area and diameter. One study was identified that compared clinical diagnoses of patients imaged with weight-bearing MRI versus conventional MRI. This study (Ferreiro Perez et al., in press 2007) was critically appraised. See Evidence Table. Diagnostic impact: No studies were identified that evaluated whether findings from weight-bearing MRI contribute substantially to improved diagnosis compared to conventional MRI. Therapeutic impact: No studies were identified that reported quantitative data on whether more appropriate therapy was used after weight-bearing MRI than conventional MRI.

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The use of weight-bearing MRI does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
06/26/2007	05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/02/2019MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC	05/03/2011

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Magnetic Resonance Spectroscopy (MRS)

- ADHD
- Autism
- Cerebral Tumors
- Differentiating Tumors from Non-Tumors
- Epilepsy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Spectroscopy (220.2.1) **RETIRED** 06/08/2021 NCD Magnetic Resonance Spectroscopy (220.2.1) has been retired. These services still need to meet medical necessity as outlined in the NCD and will require review. NCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most NCDs are not retired because they are incorrect. Therefore, continue to use NCD 220.2.1.
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Magnetic resonance spectroscopy (MRS) is a non-invasive technique that provides chemical information on metabolites in tissues. It uses strong magnetic fields to generate an exchange of energy between external magnetic fields and protons within tissues. The energy exchange is transmitted back to the machine as a radiofrequency signal which is decoded by computer software. The software produces a waveform with peaks corresponding to the relative concentration of various chemicals. In addition, the specific chemicals that are present are identified--they appear at different locations on a horizontal axis. MRS utilizes the magnetic property of atomic nuclei. The proton is the most commonly studied nucleus. Proton (^{1}H) MRS defines approximately 15 brain metabolites. These include lipids, lactate, N-acetylaspartate (NAA), glutamate/glutamine (Glx), creatine (Cr), choline (Cho) and myinositol (mI) (Gulati et al., 2003; Lin et al., 2005; BlueCross BlueShield Association, 2005).

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A potential use of MRS is to diagnose conditions when other tests have been negative or inconclusive, or to refine existing diagnoses. For example, an increased Cho signal is believed to indicate the presence of cancerous cells. MRS can be used alone or in combination with magnetic resonance imaging (MRI) which produces anatomic images. In addition, MRS can be used to monitor metabolites to evaluate the effectiveness of therapy by seeing if levels change from elevated back to normal (Lin et al., 2005).

MRS has been used to study various neurologic diseases, including epilepsy, multiple sclerosis, HIV-related neurologic disorders and brain tumors, as well as cerebrovascular and metabolic diseases. One review article stated that MRS's most important use in neurology is quantifying neuronal loss and demonstrating reversible neuronal damage. (Rudkin & Arnold, 1999).

Other imaging tests used for epilepsy include EEG, MRI, FDG PET and CT scanning. ADHD and autism are diagnosed mainly by clinical evaluation. EEG and MRI are sometimes used to provide additional information on autism.

Cerebral Tumors
More than 190,000 people in the United States are diagnosed with primary or metastatic cerebral tumors annually. It is challenging to diagnose and treat cerebral tumors due to the similarity of these lesions to other types of pathologies on conventional imaging, the inaccessibility of the lesions and their proximity to complex brain structures. An accurate non-invasive method for diagnosing cerebral tumors is desirable, especially one that could replace biopsy which has a reported morbidity of 3-4% (AHRQ, 2003, Sibtain et al., 2007; National Brain Tumor Foundation).

Imaging procedures for diagnosing cerebral tumors include CT, MRI, SPECT and PET. CT uses x-rays and MRI uses non-ionizing radio frequency to acquire images. Both methods can generate multiple two-dimensional cross-sections of tissue as well as three-dimensional reconstructions and are generally used in conjunction with stereotactic biopsy. PET scans measure glucose activity which can be translated to a moving picture of the brain. SPECT imaging uses gamma rays to acquire multiple two-dimensional images from multiple angles, which can produce true three-dimensional information.

Magnetic resonance spectroscopy (MRS), a technique related to MRI, is also proposed for imaging cerebral tumors. MRS is a non-invasive technique that provides chemical information on metabolites in tissues. It uses strong magnetic fields to generate an exchange of energy between external magnetic fields and protons within tissues. The energy exchange is transmitted back to the machine as a radiofrequency signal which is decoded by computer software. The software produces a waveform with peaks corresponding to the relative concentration of various chemicals. In addition, the specific chemicals that are present are identified--they appear at different locations on a horizontal axis. MRS utilizes the magnetic property of atomic nuclei. The proton is the most commonly studied nucleus. Proton (1H) MRS defines approximately 15 brain metabolites. These include lipids, lactate, N-acetylaspartate (NAA), glutamate/glutamine (Glx), creatine (Cr), choline (Cho) and myinositol (mI). A chemical profile that may be characteristic of brain tumors includes an increase in Cho, and a reduction in Cr and NAA (Sibtain et al., 2007; Lin et al., 2005; BlueCross BlueShield Association, 2005).

Potential areas in which MRS may contribute diagnostic information include distinguishing abscesses from tumors, providing a more accurate way to determine the grade of primary tumors than conventional MRI, distinguishing single metastatic brain lesions from primary tumors, providing guidance for biopsy and gamma knife therapy, determining tumor recurrence and differentiating between radiation necrosis and tumor recurrence. MRS can be used alone, or in combination with MRI (AHRQ, 2003; Sibtain et al., 2007).

Several factors may limit the performance of MRS in identifying cerebral tumors. Sudden dramatic changes in the composition of tissue can cause inaccuracies in the magnetic fields. This is relevant for lesions adjacent to bone or air-filled structures such as the sinuses. Moreover, lesions that lie near areas of old infarcts or ischemic changes, or concurrent demyelinatin disease, can distort the chemical ratios used in interpretation. In addition, visual interpretation of spectra is difficult and requires special training (AHRQ, 2003; Sitbain et al., 2007).

Medical Technology Assessment Committee (MTAC)

Magnetic Resonance Spectroscopy (MRS)

12/05/2005: MTAC REVIEW

Evidence Conclusion: No published studies were identified on the accuracy of magnetic resonance spectroscopy for diagnosing ADHD or autism. One study was identified on the accuracy of MRS for lateralization

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of patients with medically refractory temporal lobe epilepsy. This study (Cendes et al., 1997) included 100 patients and used EEG as the gold standard. Lateralization based on MRS agreed with EEG findings in 87% of cases. Lateralization based on the results of MRS and MRI combined agreed with EEG findings in 86% of cases.
Articles: The ideal study of diagnostic accuracy would report the sensitivity and specificity of MRS and compare this to an independent blinded comparison to a "gold standard" diagnosis.
ADHD and autism None of the studies on ADHD, or ADHD and autism reported the sensitivity and specificity of MRS diagnosis compared to a "gold standard" such as clinical evaluation. The empirical studies reported on preliminary research using MRS to measure the concentrations of various chemicals in the brains of children with ADHD compared to healthy children. One of the articles included children with autism, in addition to children with ADHD and healthy controls. *Epilepsy* None of the studies on epilepsy reported the sensitivity and specificity of MRS diagnosis compared to a "gold standard". There were several studies examining the correlations between concentrations of chemicals identified by MRS and seizure duration, seizure severity or surgical outcome. One study compared chemical concentrations in patients with epilepsy and normal controls. These were all descriptive studies and were not evaluated further. One study was identified that compared the performance of MRI, MRS and the combination of the two in the lateralization of temporal lobe epilepsy (TLE). This article (Cendes et al., 1997) was critically appraised. No other studies on the diagnostic accuracy of MRS in patients with epilepsy were identified and no studies were identified on diagnostic or therapeutic impact.
The study critically appraised was: Cendes F, Caramanos Z, Andermann F et al. Proton magnetic resonance spectroscopic imaging and magnetic resonance imaging volumetry in the lateralization of temporal lobe epilepsy: A series of 100 patients. Ann Neurol 1997; 42: 737-746. See Evidence Table.

The use of Magnetic resonance spectroscopy (MRS) in diagnosing autism, ADHD and epilepsy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/02/2006: MTAC REVIEW
Magnetic Resonance Spectroscopy (MRS)
Evidence Conclusion: No new published studies were identified on the accuracy of magnetic resonance spectroscopy for diagnosing ADHD, epilepsy or autism. No new studies were identified that validate specific chemical profiles that are diagnostic of particular conditions.
Articles: The ideal study of diagnostic accuracy would report the sensitivity and specificity of MRS and include an independent blinded comparison to a "gold standard" diagnosis. *ADHD and autism* - 2005 Review: None of the studies on ADHD, or ADHD and autism reported the sensitivity and specificity of MRS diagnosis compared to a "gold standard" such as clinical evaluation. The empirical studies reported on preliminary research using MRS to measure the concentrations of various chemicals in the brains of children with ADHD compared to healthy children. One of the articles included children with autism in addition to children with ADHD and healthy controls. 2006 Review: The newer studies were similar to those identified in the 2005 search. Studies reported on use of MRS to measure the concentrations of chemicals (i.e. Cho, CR and NAA) in children with autism or ADHD compared to healthy children. None of the studies reported the ability of MRS to diagnose autism or ADHD (i.e. sensitivity and specificity of MRS findings). *Epilepsy* - 2005 Review: None of the studies on epilepsy reported the sensitivity and specificity of MRS diagnosis compared to a "gold standard". Several studies examined the correlations between concentrations of chemicals identified by MRS and seizure duration, seizure severity or surgical outcome. One study compared chemical concentrations in patients with epilepsy and normal controls. These were all descriptive studies and were not evaluated further. One study compared the performance of MRI, MRS and the combination of the two in the lateralization of temporal lobe epilepsy (TLE). This article (Cendes et al., 1997) was critically appraised. 2006 Review: One meta-analysis was identified. This study (Willmann et al., in press, 2006) assessed the pre-operative value of MRS in identifying the epileptogenic zone (EZ) for epilepsy surgery. Preoperative evaluation of epilepsy patients is outside the scope of the current review and the study was thus not evaluated further.

The use of Magnetic resonance spectroscopy (MRS) in diagnosing autism, ADHD and epilepsy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

12/03/2007: MTAC REVIEW
Magnetic Resonance Spectroscopy (MRS)
Evidence Conclusion: Three studies were reviewed that reported the sensitivity and specificity of MRS for distinguishing brain tumors from non-tumors, compared to a reference standard. All had relatively small sample sizes, especially as regards the number of patients without tumors, so estimates may not be reliable. One of the studies used combined MRS/MRI findings. Sensitivity ranged from 81% to 90% and specificity from 86% to 100%. The size of the studies was too small to draw conclusions about the accuracy of MRS for differentiating between brain tumors and any specific alternate condition such as radiation necrosis or abscess. There is a lack of

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evidence on the diagnostic accuracy of MRS alone compared to conventional imaging, or on MRS plus conventional imaging versus conventional imaging alone. Thus, it is difficult to draw conclusions about the ability of MRS to replace other diagnostic tests. Two studies addressed the impact of MRS on clinical decision-making. Both were case series; Lin et al., 1999 was limited in that it had only 15 patients, and Adamson et al. was retrospective. In the Adamson et al., study, MRS was seen as having a potential positive impact on treatment in 23/78 (29%) of cases. In 2 cases, MRS was seen as having a potential negative impact on treatment. For the remainder of the cases, MRS was viewed as neutral, or patients were lost to follow-up. In the Lin study, which only included 15 patients, MRS was used in place of biopsy in 7 cases, and MRS was correlated with clinical course in 6 cases. MRS did not correlate with clinical course in only 1 patient.

Articles: *Accuracy of MRS* the ideal study of diagnostic accuracy would report the sensitivity and specificity of MRS and include an independent blinded comparison to a "gold standard" diagnosis. Several studies met these criteria and were critically appraised. All had relatively small sample sizes. Rand et al., 1997 and McKnight et al., 2002 evaluated MRS alone and Gajewicz et al., 2003 evaluated MRS in combination with MRI. Rand SD, Prost P, Haughton V et al. Accuracy of single-voxel proton MR spectroscopy in distinguishing neoplastic from nonneoplastic brain lesions. AJRN 1997; 18: 1685-1704. See Evidence Table. McKnight TR, von dem Bussche BS, Vigneron DB. et al., Histopathological validation of a three-dimensional magnetic resonance spectroscopy index as a predictor of tumor presence. J Neurosurg 2002; 97: 794-802. See Evidence Table. Gajewicz W, Papierz W, Szymczak W et al. The use of proton MRS in the differential diagnosis of brain tumors and tumor-like processes. Med Sci Monit 2003; 9: MT97-105. See Evidence Table. Diagnostic impact (does MRS contributes substantially to improved diagnosis and/or replace other diagnostic tests or procedures). There were no studies comparing diagnosis with MRS to diagnosis with conventional imaging. Therapeutic impact of MRS (is more appropriate therapy is used after application of MRS than would be used if the test were not available). Two studies that evaluated the impact of MRS on clinical decision-making were identified and critically appraised: Adamson AJ, Rand SD, Prost RW et al. Focal brain lesions: Effect of single-voxel proton MR spectroscopic findings on treatment decisions. Radiol 1998; 209: 73-78. See Evidence Table**.** Lin A, Blum s, Mamelak AN. Efficacy of proton magnetic resonance spectroscopy in clinical decision making for patients with suspected malignant brain tumors. J Neuro-Oncol 1999; 45: 69-81. See Evidence Table.

The use of Magnetic resonance spectroscopy (MRS) in diagnosing cerebral tumors and differentiating tumors from non-tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
76390	Magnetic resonance spectroscopy

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/23/2005	05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC, 12/02/2014MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/02/2019MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC	11/18/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
02/04/2020	MPC approved to remove MCG guideline A-0482 and to retain policy of non-coverage. Also added language that states, Clinical Review physician should consult with KP Neuroradiology on any requests received.
11/18/2021	Medicare Retired NCD (220.2.1) Magnetic Resonance Spectroscopy

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Clinical Review Criteria
Myocardial Perfusion Imaging

- Exercise Nuclear Stress Test
- Pharmacologic Nuclear Stress Test

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Criteria

For Medicare* Members **Medical necessity review not required for Medicare members*

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Cardiovascular Stress Testing, Including Exercise and/or Pharmacological Stress and Stress Echocardiography (L36889)
Local Coverage Article (LCA)	Billing and Coding: Cardiovascular Stress Testing, Including Exercise and/or Pharmacological Stress and Stress Echocardiography (A57184)

For Non-Medicare Members

Service	Criteria Used
Exercise Nuclear Stress Test	Kaiser Permanente has elected to use the Myocardial Perfusion Imaging, Exercise Stress (A-0078) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Pharmacologic Nuclear Stress Test	Kaiser Permanente has elected to use the Myocardial Perfusion Imaging, Pharmacologic Stress (A-0079) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

ASCVD Risk Estimator Plus (American College of Cardiology): please click here

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If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Myocardial perfusion exercise stress imaging, such as stress SPECT, involves intravenous injection of a radioactive tracer (eg, thallium, sestamibi, or tetrofosmin), which is taken up by myocardial cells and visualized by a digital gamma camera, thereby reflecting the distribution of blood perfusion throughout the myocardium. A defect in the image with exercise that is not present at rest usually indicates an area of myocardial ischemia. Myocardial perfusion imaging synchronized with ECG (eg, gated SPECT) can assess ventricular function, including ejection fraction, in addition to myocardial perfusion. Myocardial perfusion imaging has been noted by specialty societies to have the most clinical utility in patients who are at intermediate risk for coronary artery disease, in those requiring management or prognostic information, and in those with unexplained and persistent symptoms. Myocardial perfusion imaging systems that combine SPECT and CT technology (also known as "hybrid" systems) are now widely available. It has been noted that myocardial perfusion scans contribute at least 20% of the estimated annual collective radiation dose in the United States, although the lifetime cancer risk from a single myocardial perfusion imaging study is thought to be small. Best-practice methods to maximize diagnostic quality while minimizing radiation exposure have been proposed.

Pharmacologic stress myocardial perfusion imaging, such as pharmacologic stress SPECT, involves intravenous injection of a radioactive tracer (eg, thallium, sestamibi, or tetrofosmin), which is taken up by myocardial cells and visualized by a digital gamma camera, thereby reflecting the distribution of blood perfusion throughout the myocardium. Coronary hyperemia is induced by a vasodilator, such as adenosine, dipyridamole, or regadenoson, or an adrenergic agent such as dobutamine, in lieu of stress via exercise or in addition to submaximal exercise. A defect in the image with stress that is not present at rest usually indicates an area of myocardial ischemia. Myocardial perfusion imaging synchronized with ECG (eg, gated SPECT) can assess ventricular function, including ejection fraction, in addition to myocardial perfusion. Pharmacologic stress testing using the vasodilator agent's adenosine and dipyridamole is contraindicated in patients with severe reactive airway disease (eg, asthma or chronic obstructive pulmonary disease) because of provocation of bronchospasm; regadenoson or dobutamine may be substituted in this population.

Myocardial perfusion imaging has been noted by specialty societies to have the most clinical utility in patients who are at intermediate risk for coronary artery disease, in those requiring management or prognostic information, and in those with unexplained and persistent symptoms. Myocardial perfusion imaging systems that combine SPECT and CT technology (also known as "hybrid" systems) are now widely available. It has been noted that myocardial perfusion scans contribute at least 20% of the estimated annual collective radiation dose in the United States, although the lifetime cancer risk from a single myocardial perfusion imaging study is thought to be small. Best-practice methods to maximize diagnostic quality while minimizing radiation exposure have been proposed.

Applicable Codes

Medicare – Medical necessity review not required
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Myocardial Perfusion Imaging, Exercise or Pharmacologic Stress

CPT® or HCPC Codes	Description
78451	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78452	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study,

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	at rest or stress (exercise or pharmacologic)
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection

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Date Created	Date Reviewed	Date Last Revised
01/05/2021	01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	08/24/2022

[MPC] Medical Policy Committee

Revision History	Description
05/20/2021	Updated policy effective date to 7/1/2021. Medical necessity review requirement does not apply to Medicare.
02/16/2022	Updated applicable codes
08/24/2022	Added Cardiac Risk Calculator link

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KAISER PERMANENTE®

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Clinical Review Criteria
Myocardial Strain Imaging
- Speckle-tracking echocardiography

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Criteria
For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Myocardial Strain Imaging*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members
Myocardial strain imaging is considered medically necessary:
- Prior to, during, or following exposure to oncology medications* that could result in cardiotoxicity

*Including but not limited to – doxorubicin (Adriamycin); trastuzumab (Herceptin, Kanjinti); pertuzumab (Perjeta); ado-trastuzumab emtansine (Kadcyla); fam-trastuzumab deruxtecan (Enhertu); mitoxantrone (Novantrone); liposomal doxorubicin (Doxil)

Myocardial strain imaging is considered experimental, investigational or unproven for all other indications.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

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Background
Technology Description
Myocardial strain imaging (MSI) involves a sophisticated analysis of images from echocardiography. Reflection of ultrasonic waves from myocardial tissue creates stable patterns of brighter and darker spots (speckles) that can

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serve as "fingerprints" to identify specific segments of the myocardial walls. Image processing computer software tracks the movement of these patterns to assess the severity of myocardial damage and abnormal heart function.

Quality of the Evidence
The body of evidence concerning diagnostic and prognostic use of MSI was large in size and overall low in quality. The overall low-quality rating for the body of evidence reflects individual study limitations, wide variability in the MSI parameters used for diagnosis or prognosis in DCM, and the absence of studies evaluating the clinical utility of MSI in patients with DCM. Overall quality was determined based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of data to general practice.

Conclusion
The available studies have not provided sufficient evidence to evaluate diagnostic uses of MSI in DCM patients due to the small number and diverse applications of MSI in diagnostic studies. Although some prognostic studies found that certain MSI parameters had statistically significant correlations with health outcomes, results were not consistent across studies and the parameter that appeared most accurate for prognosis (early DSR) was measured in only 1 study. Furthermore, no studies of the clinical utility of MSI were identified to evaluate whether the diagnostic and prognostic information obtained from MSI can be used to improve patient management. MSI does not pose any safety concerns. Additional studies are needed to identify the optimal MSI parameters for diagnosis and prognosis in DCM patients and to demonstrate that guidance of care with MSI provides meaningful improvements in health outcomes for DCM patients.

Insights
- MSI can be used to measure many types of changes and rates of change in myocardial length, shape, and rotation in each of the 4 heart chambers. More research is needed to evaluate which of these measurements are most useful for all of the potential diagnostic and prognostic uses of MSI.

- Although the equipment needed to perform echocardiographic MSI is much less complicated than the equipment needed for cardiac magnetic resonance imaging (MRI), MSI may be less accurate and there is little evidence addressing the relative accuracy of these techniques. Only 1 study compared MSI with cardiac MRI; therefore, additional studies are needed to evaluate the relative accuracy of these techniques in patients with DCM.

- MSI may provide some useful diagnostic or prognostic information if cardiac MRI is not available or not feasible.

- Two studies that included exercise testing or cardiac stress testing obtained results that greatly differed from results of measurements obtained solely in resting patients, suggesting that additional MSI studies incorporating exercise and stress testing are needed.

Reference
Hayes. Hayes Health Technology Assessment. Myocardial Strain Imaging by Speckle-Tracking Echocardiography for Evaluation of Dilated Cardiomyopathy. Dallas, TX: Hayes; September 24, 2020. Retrieved January 7, 2022 from https://evidence.hayesinc.com/report/dir.myocardialstrain4712.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPCS Codes	Description
93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/18/2022	02/01/2022[MPC],02/07/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
02/01/2022	MPC approved to adopt criteria for Myocardial Strain Imaging. Requires 60-day notice, effective date 07/01/2022.

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KAISER PERMANENTE®

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Clinical Review Criteria
Naturopathy

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Criteria

For Medicare Members

Naturopathy is not covered by Medicare and is considered a supplemental benefit. Please check member contract for specific coverage language.

For Non-Medicare Members

I. Authorizations for covered naturopathic treatments beyond three visits require prior approval by the health plan for those plans with alternative medicine benefits.

II. Clinical review criteria for naturopathy are as follows:
   A. The patient has an established, documented diagnosis of **ONE of the following**:
      1. Fibromyalgia (The patient has an established, documented diagnosis of fibromyalgia consistent with the 1990 American College of Rheumatology Criteria.)
      2. Chronic arthritis
      3. Chronic fatigue syndrome
      4. Premenstrual syndrome
      5. Irritable bowel syndrome
      6. Menopausal symptoms
      7. Headaches (persistent sinus, muscle tension, migraine)
      8. Chronic sinusitis, defined as persistent sinusitis
      9. Chronic serious otitis media, defined as persistent middle ear fluid for greater than three months
      10. Atopic dermatitis/chronic eczema
      11. Asthma that is mild to moderate in severity and not dependent on oral steroids
   B. Treatment progress reports submitted to the health plan after the second visit, or at intervals as specified in the referral, must demonstrate the benefit of treatment for continuation of care to be approved.

Review Services will consider each referral request on a case-by-case basis and will consider requests outside the above criteria based on, among other things, clear documentation of objective improvement by the licensed naturopathic physician or the patient's personal physician, as well as a detailed treatment plan.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Naturopathic medicine is a distinct profession of health care that has been in existence since the late nineteenth century. The philosophical approach includes the following principles:

- Utilization of therapies that first do no harm.
- Prevention of disease through healthy lifestyle and control of risk factors.
- Recognition and encouragement of the body's inherent healing abilities.

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- Treatment of the whole person – physical, emotional, mental, and spiritual.
- Patient education and cultivation of an attitude of personal responsibility for one's health.

Education standards for naturopathic medicine require at least three years of college level work followed by a four-year curriculum with over 4,000 hours of instruction at an accredited training institution (such as Bastyr University). In addition to conventional basic science courses, students receive training in botanical medicine, therapeutic nutrition, and various physical medicine modalities. Naturopathic physicians are licensed in the state of Washington and in ten other states.

Evidence and Source Documents

There is a small body of literature that supports some of the interventions that naturopaths provide.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
Service Specialty: Naturopathy; TOS 320	

Date Created	Date Reviewed	Date Last Revised
11/15/2002	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	11/25/2002

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Negative Pressure Wound Therapy

- Pumps
- PICO (non-powered)
- SNAP (non-powered)
- Single Use Negative Pressure Wound Therapy (s-NPWT) for the Prevention of Surgical Site Infections (SSIs) in Closed Surgical Incisions

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Negative Pressure Wound Therapy Pumps (L33821) for traditional NPWT covered under DME Wound Care (L37228) *Mentions disposable NPWT (dNPWT)*
Local Coverage Article	Negative Pressure Wound Therapy Pumps (A52511) for traditional NPWT covered under DME
MLN Matters Article	Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy Using a Disposable Device *For disposable NPWT provided by Home Health Agency*

For Non-Medicare Members

Initial Coverage:

1) Traditional Negative Pressure Wound Therapy Pumps (tNPWT)
   A traditional NPWT (tNPWT) pump and supplies are covered for wound edema, exudate management and stimulation of granulation for an initial 14-day course when the following main criteria are met:
   A. Must complete the Kaiser Permanente initial coverage request form and fax it to the DME staff at 877-290-4632.
   B. Ulcers and Wounds in the Home Setting:
      1. The patient has a Stage III or IV pressure ulcer, neuropathic/diabetic ulcer, venous insufficiency or arterial ulcer, or a chronic ulcer of mixed etiology. These wounds should have exudate, size and depth to require this specialized therapy. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried for 30 days unless edema and/or exudate mandates NPWT.
         i. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures prior to application of NPWT:
            (a) Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional.
            (b) Consideration of the following risk factors is addressed in the documentation
               (i) Risk for bleeding and hemorrhage
               (ii) Active treatment with anticoagulants or platelet aggregation inhibitors
               (iii) Presence of:
               - Friable vessels and infected blood vessels

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- Vascular anastomosis
- Infected wounds
- Osteomyelitis
- Exposed organs, vessels, nerves, tendons, and ligaments
- Sharp edges in the wound (i.e. bone fragments)
- Spinal cord injury (stimulation of sympathetic nervous system)
- Enteric fistulas

(c) Requirement for:
- MRI
- Hyperbaric chamber
- Defibrillation
- Size and weight
- Use of device near the vagus nerve
- Use of circumferential dressing application
- Mode of therapy – intermittent versus continuous negative pressure

(d) Application of dressings to maintain a moist wound environment.
(e) Debridement of necrotic tissue if present.
(f) Evaluation of and provision for adequate nutritional status.

ii. For Stage III or IV pressure ulcers:
(a) The patient has been appropriately turned and positioned.
(b) The patient's moisture and incontinence have been appropriately managed.

iii. For neuropathic/diabetic ulcers:
(a) The patient with diabetes has been on a comprehensive diabetic management program, **and**
(b) A foot ulcer has been appropriately off-loaded.

iv. For venous insufficiency ulcers:
(a) Compression bandages and/or garments have been consistently applied only after Ankle-Brachial Index has been done per guidelines, and
(b) Leg elevation with alternating ambulation has been encouraged.

C. Goal of therapy is clearly stated

D. Ulcers and Wounds Encountered in an Inpatient Setting:
1. An ulcer or wound (described in section A above) is encountered in the inpatient setting and, after wound treatments described under sections A-a through A-d have been tried or considered and ruled out, NPWT may be initiated.
2. The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).
In either of the above situations, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.
3. Skin-flaps or grafts approved as covered by the health plan in advance of the procedure.

E. Contraindications for use:
1. The presence in the wound of necrotic tissue with eschar, if debridement has not been carried out
2. Untreated osteomyelitis within the vicinity of the wound
3. Possibility of malignant cells present in the wound
4. The presence of a fistula to an organ or body cavity within the vicinity of the wound
5. Exposed vascular in the wound
6. Exposed nerves in the wound
7. Exposed anastomotic site
8. Exposed organs
9. Recent lab value for albumin equal to or less than 2.5.
10. Pediatric patients (newborns, infants and children)

2) Disposable, single-use Negative Pressure Wound Therapy for chronic wound and ulcers

A. The SNAP™ Therapy System (Acelity/KCI) may be used instead of traditional NPWT if **ALL** of the following criteria are met:

B. Must complete the Kaiser Permanente initial coverage request form and fax it to the DME staff at 877-290-4632.

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C. These wounds should have exudate, size and depth to require this specialized therapy. A complete wound therapy program described by criterion 1.B.1.i and criteria 1.B.1.ii, 1.B.1.iii, or 1.B.1.iv, as applicable depending on the type of wound, should have been tried for 30 days.
   1. Wound size < 13 cm x 13 cm
   2. Wound drainage ≤ 180 mL/week (20mL/day)
   3. Change dressing 2x/week at minimum; dispose of cartridge when full (typical cartridge holds 60 mL)

D. Contraindications for use of disposable NPWT (SNAP)
   1. Inadequately drained wounds
   2. Necrotic tissue such as eschar or adherent slough
   3. Exposed blood vessels, anastomotic sites, organs, tendons, or nerves
   4. Wounds containing malignancy
   5. Fistulas
   6. Untreated osteomyelitis
   7. Actively bleeding wounds

3) Single Use Negative Pressure Wound Therapy (s-NPWT) for the Prevention of Surgical Site Infections (SSIs) in Closed Surgical Incisions (*device must be FDA approved for this indication*)

A. When applied in the operating room after revision of total hip arthroplasty (rTHA) or total knee arthroplasty (rTKA), member must meet **ONE or more of the following:**
   1. Body mass index (BMI) > 35kg/m2
   2. Use of non-aspirin blood thinners postoperatively
   3. Current/previous diagnosis of peripheral vascular disease (established through history of intermittent claudication, generalized atherosclerosis, or compromised blood flow on doppler ultrasound)
   4. Current tobacco use (within 30 days)
   5. History of prior infection history at operative site (not within the last 4 weeks)
   6. Operative limb lymphedema
   7. Diabetes
   8. Current use of immunomodulators or corticosteroids
   9. Ongoing malignancy excluding localized skin cancer
   10. Rheumatoid Arthritis
   11. Renal failure or dialysis
   12. Malnutrition (supported by laboratory values of albumin<3.5 g/dL, a total lymphocyte count<1500 cells/mm3, and/or a transferrin level<200 mg/dL
   13. Liver disease (defined as ongoing chronic infectious or noninfectious liver pathology with associated abnormalities in liver functions)
   14. History of organ transplant
   15. Human immunodeficiency virus infection

B. Not medically necessary and/or contraindicated for **ONE or more of the following**:
   1. Known hypersensitivity to device components
   2. Surgical glue used for wound closure (those patients would not be able to receive ciNPT per the instructions of the manufacturer)

Continued Coverage (TNPWT/SNAP):

For wounds and ulcers described under sections 1 and 2 of Initial Coverage, once placed on any type of NPWT pump with supplies, for coverage to continue a licensed medical professional must do the following:

1) Must complete the Kaiser Permanente continued coverage request form and fax it to the DME staff at 877-290-4632.
2) On a regular basis:
   A. Directly assess the wound(s) being treated with the NPWT pump
   B. Supervise or directly perform the NPWT dressing changes
3) On at least a weekly basis, document changes in the ulcer's dimensions and characteristics and the degree of granulation and management of exudate
   A. If using SNAP: If wound increases in size or is producing amounts of exudate above the parameters for SNAP, may need to evaluate the need for tNPWT or other wound management strategies.
4) Laboratory values at monthly intervals to show a contraindication does not exist

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
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5) If these criteria are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary

When Coverage Ends for tNPWT/SNAP:

1) For wounds and ulcers described under sections A and B of Initial Coverage, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:
   A. Criteria for Continued Coverage cease to occur.
   B. In the judgment of the treating physician, adequate wound granulation has occurred to the degree that NPWT may be discontinued.
   C. Wound is not healing progressively
      1. Progressive wound healing has failed to occur over the prior 14 days. There must be documented in the patient's medical records quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from week to week.
      2. If using SNAP: If progressive wound healing has failed to occur, or wound increases in size or is producing amounts of exudate above the parameters for SNAP.
   D. NPWT should be ordered for a 2-week period of time as wounds are expected to change with this therapy. Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order, the provided should be directly contacted and the delivery of further supplies stopped. Traditional NWPT Pumps must be returned to the provider for billing purposes and cleaning.

Supplies for tNPWT:

1) Coverage for tNPWT is provided up to a maximum of 6 dressing kits (A6550) per wound per 14-day period unless there is documentation that the wound size requires more than one dressing kit for each dressing change. Dressings should be changed based on the patient's condition and the condition of the wound but normally not more frequently than 3 times a week.
2) Coverage for tNPWT is provided up to a maximum of 2 canister sets (A7000) per 14-day period unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary.

Supplies for SNAP replacement:

1) Coverage for SNAP is provided up to a maximum of 4 devices per 14-day period unless there is documented evidence of a larger volume of drainage requiring more frequent replacement.
2) The two codes of 97607 and 97608 should only be used when the provider is either initially applying an entirely new SNAP device or removing a SNAP device and replacing it with an entirely new one as clinically required. These codes may not be used if only a dressing change is performed for a SNAP system.

Service: Negative Pressure Wound Therapy: non-powered other than SNAP	Criteria Used
PICO	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KAISER PERMANENTE will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Negative pressure wound therapy (NPWT) is a wound dressing system that was designed to promote wound healing through the use of subatmospheric pressure to the wound surface. NPWT systems include a vacuum

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pump, drainage tubing, and a dressing set. To place the device, the wound is covered or packed with a foam or gauze dressing and then secured using an adhesive film drape. A vacuum pump connected to the draining tube(s) in the wound dressing is used to apply pressure to the wound surface in the range of -50 to -125 mmHg. The precise mechanism through which NPWT aids the healing process is not fully understood; however, it has been suggested that NPWT may aid in the healing process through increasing local blood flow, increasing granulation tissue, reducing bacterial contamination, reducing wound area, reducing edema and exudate, and changes to the microenvironment (AHRQ 2009, Webster 2011).

Negative pressure therapy has been used in clinical applications for over five decades.
The concept of applying topical negative pressure in the management of wounds emerged in the late 1980s and is increasingly used for a wide variety of wounds. The technique is also known as vacuum assisted closure (VAC), negative pressure wound therapy (NPWT), vacuum sealing technique (VST), sealed surface wound suction (SSS), subatmospheric pressure therapy or dressing, foam suction dressing, and vacuum pack technique (VPT). The technology generally involves putting a dressing (foam or gauze) into the wound cavity, connecting it to a vacuum pump, and sealing the area with an adhesive film. The vacuum pump creates and maintains a subatmospheric pressure (intermittent or continuous) in the range of -50 to -125 mmHg. The default setting is -125 mmHg, and the pressure may be titrated up by 25 mmHg increments when there is excessive drainage or a large wound volume, or titrated down when the patient is elderly, nutritionally compromised, or has a risk of excessive bleeding. Dressings are usually changed every 48 hours, or every 12-24 hours if the wound is infected. The mechanism by which NPWT is believed to promote wound healing is unclear. In theory it may increase dermal perfusion, stimulate granulation tissue formation, reduce the edema and interstitial tissue fluid, reverse tissue expansion, and/or reduce bacterial colonization. It is also thought that the vacuum pressure may act as an effective skin graft splint over irregular surfaces. The therapy cannot be used as a replacement for surgical debridement, but as a complementary treatment. It is contraindicated for use in wounds with necrotic tissue, exposed vital structures, untreated osteomyelitis, unexplored fistulae and malignant wounds. Adverse effects include pain and damage to the skin around the wound (Braakenburg 2006, Bovill 2008, Wild 2008, Preston 2008).

Acute and chronic wounds and are a major cause of morbidity and impaired quality of life. They affect at least 1% of the population and represent a significant risk factor for hospitalization, amputation, sepsis, and even death. Wound healing is a complex series of events, broadly classified into inflammatory, proliferative, and remodeling phases. The healing process may be compromised by arterial or venous insufficiency which can prevent or delay healing and/or increase the risk of recurrent wound infections. The treatment of difficult-to-manage and chronic wounds remains a significant challenge to practitioners, a cause of pain and discomfort to the patients, and costly (Gregor 2008, Sadat 2008).

For centuries, gauze has been used in local wound care, mainly due to its low price and simplicity. In 1950s, a new concept, that wound healing is optimal when it is kept in a moist environment rather than air dried, was introduced. Since then, a large variety of occlusive or semi-occlusive dressings, topical applications, and other products were developed for the treatment of all kinds of wounds. Modern wound-healing agents include hydrocolloidal, alginates, hydrogels, hydrofiber, paraffin gauze dressings, as well as many other types of moist dressings and topical agents. The choice of the ideal regimen remains controversial due to the lack of good evidence from well conducted RCTs and depends mainly on the clinicians' preference (Chaby 2007, Gregor 2008, Ubbink 2009).

Skin grafts are used to promote healing in complex wounds with tissue loss. Successful skin grafting relies on the ability of the skin graft to integrate with the recipient wound bed. Bolstering the graft to the wound bed by applying a dressing along with positive pressure is used to improve integration with the wound bed and minimize seroma formation. NPWT is an alternative to standard bolstering techniques. It has been suggested that NPWT offers all of the advantage of standard bolstering in addition to other advantages such as active fluid removal and easier patient mobilization (Runkel 2011).

NPWT systems are FDA approved for use in patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers, flaps, and grafts. The device is contraindicated for use in wounds with exposed vital structures, devitalized tissue, malignant tissue, untreated osteomyelitis, or in patients with untreated coagulopathy or allergy to any component required for the procedure (AHRQ 2009). NPWT was reviewed by MTAC in 1999, 2003, and 2008 for the management of chronic wounds and did not meet MTAC evaluation criteria. It is being re-reviewed for a new indication.

Evidence Source Documents

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Vacuum Assisted Closure for the Treatment of Wounds
Vacuum Assisted Closure in the Treatment of Non-Healing Wounds
Negative Pressure Wound Therapy in the Treatment of Skin Grafts and Flaps
SNAP & PICO Device

Medical Technology Assessment Committee (MTAC)

Vacuum Assisted Closure for the Treatment of Wounds

02/10/1999: MTAC REVIEW

Evidence Conclusion: The efficacy of the VST cannot be determined from the combination of these widely disparate studies/case series because of the widely heterogeneous samples, varying methods and application of the technique; small sample sizes, possible selection and observation bias, and the absence of comparison groups. In addition, there are a number of unresolved issues surrounding this technique, including but not limited to:

- which wounds are ideally suited for the application of this technique;
- the optimal conditions in which the technique can/should be applied;
- the ideal pressure required;
- ideal delivery of the negative pressure, e.g., by vacuum pump or bottle;
- when the wound dressing should be applied.

Further studies, preferably blinded, randomized control trials are warranted to determine the efficacy of this technique/device.

Articles: Articles were selected based on study type. There was one prospective clinical trial (Mullner et al, 1997), no meta-analyses or cohort studies, and a few case series. An evidence table for the clinical trial. No evidence tables were created for the case series, as the sample sizes were either too small, or the not described in sufficient detail. Case series were reviewed by abstract, and a brief summary of their findings is included. Mullner T, Mrkonjic L, Kwasny O, Vecsei V. The use of negative pressure to promote the healing of tissue defects: a clinical trial using the vacuum sealing technique. British Journal of Plastic Surgery 1997 Apr;50(3):194-9. See Evidence Table.

The use of Vacuum Assisted Closure for the treatment of wounds to promote healing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Vacuum Assisted Closure in the Treatment of Non-Healing Wounds

08/13/2003: MTAC REVIEW

Evidence Conclusion: The best evidence on VAC consists of two RCTs, each with fewer than 30 patients. Both are limited by their small sample sizes which makes selection bias likely and results in low statistical power. The two studies had different findings. Ford found no significant differences in wound healing between VAC and gel. Joseph found a statistically significant greater reduction in wound volume, width and depth with VAC compared to traditional saline wet-to-moist (WM) dressings. Joseph had the stronger methodology—more complete follow-up and consistency between the unit of randomization and the unit of analysis. Although the Joseph RCT suggests that VAC may be superior to traditional WM dressings, additional research is needed with larger sample sizes and consideration of potential selection bias/confounding.

Articles: The search yielded 144 articles. Many of these were review articles, opinion pieces, dealt with technical aspects of wound closure techniques or were on related procedures. There were two small randomized controlled trials using the VAC system. No non-randomized comparative studies were identified. The two RCTs were critically appraised. Ford CN, Reinhard ER, Yeh D. et al. Interim analysis of a prospective, randomized trial of Vacuum-Assisted Closure versus the Healthpoint System in the management of pressure ulcers. *Ann Plast Surg* 2002; 49: 55-61. See Evidence Table. Joseph E, Hamori CA, Bergman S. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. *Wounds* 2000; 12: 60-67. See Evidence Table.

The use of vacuum assisted closure in the treatment of non-healing wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/06/2009: MTAC REVIEW

Vacuum Assisted Closure in the treatment of Non-Healing Wounds

Evidence Conclusion: There is a lack of high quality randomized controlled trials on the use of negative pressure therapy for wound healing. The best published clinical evidence consists of few RCTs with flawed methodology. The majority of the studies were small, had inadequate power to detect differences between treatment groups, were unblinded, and had little or no information on the baseline characteristics of the

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participants, or causes of dropouts. The trials mainly used surrogate outcomes as reduction in wound size and formation of granulation tissue, rather than complete healing of the ulcer. The largest published trial to date (Blume et al, 2008) randomized 341 patients with diabetic foot ulcers to receive negative pressure wound therapy (NPWT) or advanced moist wound therapy (AMWT). All participants in the two groups also underwent wound debridement and off-loading. The results of the trial showed a significantly higher rate of complete ulcer closure in the patients receiving NPWT vs. AMWTs. The study was randomized and controlled; however, it had several limitations including unblinding of the patients and physicians which is a potential source of bias as it could influence the patient motivation and the care provided. Patients were treated at home or in a hospital setting and there is no indication whether they were given the same care and therapy e.g. equal pressure relief, intermittent or continuous negative atmospheric pressure, debridement, antibiotics, and other potentially confounding factors. Moreover, the study had a high drop-out rate and was financially supported by the manufacturer of the device.
Conclusions: There is insufficient published evidence to date to determine whether topical negative pressure therapy is more effective than alternative wound dressings as regards rate of healing, pain management and quality of life. There is insufficient published evidence to date to determine that topical negative pressure therapy is safe to use in patients with acute or chronic wounds.
Articles: The search yielded over 300 articles on negative pressure wound therapy. Many were review articles, opinion pieces, dealt with technical aspects of wound closure techniques, or were unrelated to the current review. There were four systematic reviews with or without meta-analyses, four RCTs, and a number of case series published after the last MTAC review of the technology. Gregor et al's 2008 review included both randomized and non-randomized trials but pooled the results of each group of studies for only one surrogate outcome. In two Cochrane reviews (Ubbink 2008, Wasiak 2007), the authors could not pool the results in meta-analyses due to the small number of studies, poor reporting, heterogeneity in endpoints and comparator treatments. Another published meta-analysis (Sadat et al, 2008) included two small negative trials (total of 70 participants) on the use of VAC for various types of ulcers, and one positive larger trial (N= 162) on its use after diabetic foot amputation, which skewed the results of the meta-analysis. Only one RCT (Blume 2008) had clinically important outcomes, relatively large sample size, and generally valid methodology. Both the review with a meta-analysis as well as the RCT with generally valid methodology were selected for critical appraisal: Gregor S, Maegele M, Sauerland S, et al. Negative pressure wound therapy. A vacuum of evidence? Arch Surg 2008; 143:189-196. See Evidence Table.
Blume PA, Ayala J, Walters J, et al. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers. A multicenter randomized controlled trial. Diabetes Care 2008;31: 631-636. See Evidence Table.

The use of vacuum assisted closure in the treatment of non-healing wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Negative Pressure Wound Therapy in the Treatment of Skin Grafts and Flaps
12/19/2011: MTAC REVIEW
Evidence Conclusion: An RCT that included 60 subjects with acute traumatic injuries and skin loss evaluated the effectiveness of NPWT compared to dressings without NPWT. Results from this study suggest that NPWT may lead to less graft loss, less frequent regrafting, and reduced time from patient intervention to discharge compared to with dressings without NPWT (Llanos 2006).

	NPWT	Control	P-value
	Median (range)		
Loss of grafted area (cm^2)	0.0 (0-12)	4.5 (0-53)	0.001
Percentage of graft loss	0.0 (0-62)	12.8 (0-76)	<0.001
Days from grafting to discharge	8 (7-13)	12 (7-23)	0.001
	Number (%)		
Need for 2nd coverage procedure	5 (16.7)	12 (40.0)	0.045

Conclusion: There is some evidence to support the use of NPWT as a splint or bolster for skin grafts.
Articles: NPWT for skin grafts or skin substitutes was reviewed in 2010 by NHS Quality Improvement Scotland (NHS QIS). This review found some evidence to support the use of NPWT for wounds caused by burns or trauma that require a skin graft as treatment and certain types of venous leg ulcers with split-thickness pinch skin graft. The recommendations from NHS QIS were based on evidence from two high-quality and two low-quality randomized controlled trials (RCTs) as well as several observational studies (NHS QIS 2010). Since the NHS QIS review, the literature search revealed two additional RCTs that evaluated the safety and efficacy of NPWT for skin grafts or skin substitutes. These studies were not selected for review due to methodological limitations (i.e., small

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sample size, high loss to follow-up, etc.) (Chio 2010, Petkar 2011). One of the high-quality trials evaluating the use of NPWT was not used for bolstering and therefore was not selected for review (Vuerstaek 2006). The other high-quality trial included in the NIH QIS was selected for review. The following study was selected for critical appraisal:
Llanos S, Danilla S, Barraza C, et al. Effectiveness of negative pressure closure in the integration of split thickness skin grafts. *Ann Surg.* 2006; 244:700-705. See Evidence Table.

The use of negative pressure wound therapy in the treatment of skin grafts and flaps does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

SNAP & PICO Device

02/09/2015: MTAC REVIEW

Evidence Conclusion: First and foremost, it should be established that there is a lack of evidence to support the general use of NPWT. Previous MTAC critical appraisals have cited a lack of high-quality RCTs evaluating the use of NPWT for wound healing. To date, the best published clinical evidence consists of a few RCTs with flawed methodology due to limitations such as small sample size and inadequate power. Generally speaking, NPWT has been applied to a wide variety of wounds in varying locations, complexity and underlying pathology limiting the ability to make comparisons across studies. This limitation is demonstrated in a various systematic reviews with attempted meta-analyses that have failed to reach any definitive conclusions due to variable endpoints (Mendonca, Papini et al. 2006; Pham, Middleton et al. 2006; Sjögren, Malmsjö et al. 2006; Kanakaris, Thanasas et al. 2007; Wasiak and Cleland 2007; Bovill, Banwell et al. 2008; Group 2008; Noble-Bell and Forbes 2008; Ubbink, Westerbos et al. 2008; Ubbink, Westerbos et al. 2008; Dumville, Hinchliffe et al. 2013). *Effectiveness*: In 2011 and 2012, Armstrong and colleagues published an interim and final analysis with the overall aim of comparing NPWT with an ultraportable mechanically powered device with a traditional electrically powered device. Overall, the study enrolled 132 patients with lower-extremity diabetic and venous wounds. The primary outcome measurement was wound size reduction, however, data assessing the time for dressing change and user experience was also collected. The primary end point results indicated that the SNaP treated subjects were non-inferior to the VAC-treated patients at all follow-up points 4, 8, 12 and 16 weeks (p-value of 0.0054, 0.0047, <0.0001, and <0.0001, respectively). Exit surveys addressing quality of life (QoL) and activity were completed by 105 patients (79.5%) with the SNaP group consistently reporting less impact on activities such as sleep, mobility and socializing. Patient reporting of pain and discomfort associated with treatment, however, was similar in both groups with no statistical difference (Armstrong, Marston et al. 2011; Armstrong, Marston et al. 2012). [Evidence Table 1] *Safety:* In terms of safety, device related adverse events (AE) were similar in both groups with maceration being the most commonly reported complication. The investigators ultimately concluded that the treatment of wounds with a mechanically powered NPWT device resulted in similar wound healing outcomes as treatment with a traditional, electrically powered, NPWT device with less impact on the patient's quality of life. The evidence is limited by a variety of factors most notably, the use of an inadequate comparator. While NPWT is widely used, the current body of evidence is limited in supporting its effectiveness in promoting wound healing. Beyond that, limitations of the study's methodology include small sample size, as well as significant differences between groups in terms of wound size and age prior to treatment. Finally, it should be noted that the study was sponsored by Spiracur, Inc. the manufacturers of the SNaP® device. In addition, two of the investigators, Armstrong and Marston, have received research funding from both Spiracur and K.C.I. Conclusions: There is insufficient evidence to support the safety of the non-powered NPWT devices for treatment of patients with wounds. There is insufficient evidence to support the effectiveness of the non-powered NPWT devices for treatment of patients with wounds.

Articles: The literature search revealed a variety of articles relating to the general use of NPWT. Only a few articles were directly related to the use of non-powered or non-electrically powered NPWT devices including a small pilot trial (n=30) of the effect of the PICO device on surgical wound healing in patients with Crohn's disease (Pellino, Sciaudone et al. 2014), a small case series (n=20) describing experience with the PICO device (Hudson, Adams et al. 2013), and a small retrospective case-control study (n=78) comparing the SNaP™ device to a variety of other wound therapies (Lerman, Oldenbrook et al. 2010). There were no randomized control trials (RCTs) identified that compared non-powered/electrical NPWT to conventional wound care. Two publications were revealed that presented the interim and final results of a small RCT comparing the SNaP device with a standard powered VAC (Armstrong, Marston et al. 2011; Armstrong, Marston et al. 2012). The following articles were selected for critical appraisal: Armstrong DG, Marston WA, Reyzelman AM et al. Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered device for the treatment of chronic lower extremity ulcers: A multicenter randomized-controlled trial. Wound Rep Reg. 2011; 19(2):173-180. Evidence Table 1.Armstrong DG, Marston WA, Reyzelman AM et al. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. 2012;20(3):332-341. Evidence Table 1

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The use of SNAP & PICO device in the treatment of negative wound pressure therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/14/2019: MTAC REVIEW
Evidence Conclusion:

- There is low-moderate quality evidence from a single open-label RCT suggesting that s-NPWT is superior to the traditional NPWT in treating venous leg ulcers (VLUs), or diabetic foot ulcers (DFUs) as regards reducing the wound area, and the ulcer depth and volume as well as time to complete closure in highly selected patients with chronic lower extremity ulcers.

- Low quality evidence from a sub-analysis of one open-label RCT suggests that SNaP may be superior to the traditional NPWT as regards wound size reduction and 50% wound closure when used in a highly selected group pf patients with venous leg ulcers.

- There is insufficient evidence to determine the safety of the single use NPWT in patients with lower extremity chronic wounds.

Articles: The literature search for studies on single use NPWT published after the last MTAC review of the technology, revealed one RCT that directly compared the efficacy of PICO versus traditional NPWT in the treatment of chronic ulcers in the lower extremities, and another RCT that compared a single use mechanically powered SNaP Wound Care System versus a traditional NPWT system for the management of venous leg ulcers. The rest of the published studies that evaluated the single use NPWT were either observational studies or RCTs that compared the devices versus conventional wound dressing (such as sterile gauze dressing, absorbent dressings, and silver-impregnated occlusive dressings). The results of these studies were pooled in five meta-analyses (MAs) identified by the search; three of which (Semsarzadeh et al, 2015, Watts et al, 2015, and De Vries et al, 2016) compared the outcomes of NPWT (t-NPWT and s-NPWT combined) versus conventional wound care. One MA (Strugala and Martin 2017); evaluated the effect of s-NPWT versus traditional dressing on the prevention of surgical site complications. and another (Singh et al, 2018) compared the effect of closed incision NPT (using PRAVENA system) also versus traditional dressing on reducing surgical site infections.

The following two RCTs that compared the single use NPWT versus the traditional NPWT were selected for critical appraised. None of the identified meta-analyses or the trials comparing the single use NPWT versus conventional/standard wound care was included as the aim of the current review is to compare the single use NPWT versus the traditional NPWT. See Evidence Table.

The use of SNAP & PICO device in the treatment of negative wound pressure therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

tNPWT - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A7000	Canister, disposable, used with suction pump, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable
K0743	Suction pump, home model, portable, for use on wounds
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq. in or less
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq. in but less than or equal to 48 sq. in
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq. in

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Disposable NPWT (including, but not limited to: SNAP, Prevena, V.A.C. VIA) - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
***not covered by Medicare**

CPT/HCPC Codes	Description
97607	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
A9272*	Wound suction, disposable, includes dressing, all accessories and components, any type, each

PICO - Considered Not Medically Necessary:
***not covered by Medicare**

CPT/HCPC Codes	Description
97607	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
A9272*	Wound suction, disposable, includes dressing, all accessories and components, any type, each

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

******To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
12/12/2000	06/01/2010 MDCRPC, 04/05/2011 MDCRPC, 01/03/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013MPC, 08/05/2014MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC, 10/04/2022MPC	03/01/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
10/26/2015	Changed codes for PICO and SNAP
06/02/2015	Codes Added
09/18/2017	Removed the requirement for Hemoglobin and Hematocrit
09/27/2017	Added LCA and MLN Matters Article
03/03/2020	MPC approved to adopt coverage policy for SNAP; Added October 2019 MTAC Review
04/07/2020	MPC approved to adopt new coverage criteria for SNAP
03/01/2022	MPC approved to adopt coverage criteria for dNPWT for SSI Prevention. 60-day notice required; effective 08/01/2022.

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Clinical Review Criteria
New and Emerging Medical Technologies and Procedures

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Criteria

The following are new and emerging medical technologies which are considered to have unproven benefit because the current scientific evidence is not yet sufficient to establish the impact of these technologies on health outcomes:

CPT® Codes	Description
98975	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)
0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
0015M	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy
0016M	Oncology (bladder), mRNA, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)
0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked

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	immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
0166U	Liver disease, 10 biochemical assays (a2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation
0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)
0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons
0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1
0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10
0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19
0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2
0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4
0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2
0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2
0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4
0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2
0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3
0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6
0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9

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0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26
0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8
0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)
0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3
0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1
0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5
0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12
0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3
0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2
0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness
0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected
0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements
0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease
0207U	Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)
0208U	Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities
0210U	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)
0211U	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association
0212U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
0213U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling)
0214U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva,

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	identification and categorization of genetic variants, each comparator exome (eg, parent, sibling)
0216U	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
0217U	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
0218U	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
0219U	Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
0221U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene
0222U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia
0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue
0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens
0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report
0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma
0252U	Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including

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	urethral measurement
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours
0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment
0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days
0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days
0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional
0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis
0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report
0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed
0614T	Removal and replacement of substernal implantable defibrillator pulse generator
0615T	Eye-movement analysis without spatial calibration, with interpretation and report
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery,

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	including transrectal ultrasound and fluoroscopy, when performed
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed
0621T	Trabeculostomy ab interno by laser
0622T	Trabeculostomy ab interno by laser; with use of ophthalmic endoscope
0623T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report
0624T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography
0626T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0631T	Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity
0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0633T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material
0634T	Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)
0635T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)
0636T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)
0637T	Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)
0638T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)
0639T	Wireless skin sensor thermal anisotropy measurement(s) and assessment of flow in cerebrospinal fluid shunt, including ultrasound guidance, when performed
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound

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0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed
0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor
0665T	Donor hysterectomy (including cold preservation); open, from living donor
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor
0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation;

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	arterial anastomosis, each
HCPC Codes	**Description**
C1761	Catheter, transluminal intravascular lithotripsy, coronary
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (e.g., intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed
C9760	Non-randomized, non-blinded procedure for NYHA class II, III, IV heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, transesophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
C9768	Endoscopic ultrasound-guided direct measurement of hepatic portosystemic pressure gradient by any method (list separately in addition to code for primary procedure)
C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed
C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (ICG) (list separately in addition to code for primary procedure)
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)
C9778	Colpopexy, vaginal; minimally invasive extraperitoneal approach (sacrospinous)
G2170	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed
G2171	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures

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	(e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, veinography, and/or ultrasound, with radiologic supervision and interpretation, when performed
K1009	Speech volume modulation system, any type, including all components and accessories
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist
K1019	Monthly supplies for use of device coded at K1018
S1091	Stent, noncoronary, temporary, with delivery system (Propel)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
7/7/2020	07/07/2020[MPC] ,07/06/2021[MPC], 07/05/2022[MPC]	06/15/2022

[MPC] Medical Policy Committee

Revision History	Description
07/07/2020	Created document including new codes from 04/2020 and 07/2020.
01/01/2021	Added new codes from 10/2020 and 01/2021.
07/06/2021	Updating applicable coding, including new codes released 04/01/21 and 07/01/2021.
06/15/2022	Updated codes for remote therapeutic monitoring

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Next Generation Sequencing for Advanced Cancer (somatic/tissue testing)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2)
Local Coverage Determinations (LCD)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230) (Guardant360®)
Local Coverage Article (LCA)	MolDX: Plasma-Based Genomic Profiling in Solid Tumors (A58975) (Guardant 360®)
Decision Memo	Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.) MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets))

For Non-Medicare Members

Effective until 02/01/2023

I. Next Generation Sequencing can **only be covered for the following solid cancer types:**
   1. stage III (Effective 01/01/2023) or IV non-small cell lung cancer (RCW 48.43.810)

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2. stage IV pancreatic carcinoma
3. stage IV colon carcinoma
4. stage IV prostate (Effective 01/01/2023)
5. stage IV ovarian (Effective 01/01/2023) (RCW 48.43.810)
6. stage IV endometrial (Effective 01/01/2023) (RCW 48.43.810)
7. stage IV biliary (Effective 01/01/2023) (RCW 48.43.810)
8. stage IV gastric (Effective 01/01/2023) (RCW 48.43.810)
9. stage IV esophageal (adeno and squamous) gastroesophageal (Effective 01/01/2023) (RCW 48.43.810)
10. stage IV breast (ER or PR positive) (Effective 01/01/2023) (RCW 48.43.810)

II. In addition, the member must meet **ALL of the following**:
   1. The individual is a candidate for a targeted therapy associated with a specific tumor biomarker or disease site
   2. Results of testing will directly impact clinical decision making
   3. The testing method is considered to be scientifically valid and proven to have clinical utility based on prospective evidence

1. **EITHER** of the following:
   - Identification of the specific biomarker or risk assessment using a Gene Expression Classifier (GEC)/Next Generation Sequencing is required in order to initiate a related therapy and the therapy has been validated by the National Comprehensive Cancer Network™ (NCCN Guidelines™) as a category 1, 2A, or 2B recommendation for the individual's tumor type or disease site **OR**
   - Identification of the specific biomarker or use of a GEC/Next Generation Sequencing has been demonstrated in published peer-reviewed literature to improve diagnosis, management or clinical outcomes for the individual's condition being addressed

III. The following panels meet Kaiser Permanente coverage criteria in regard to actionable mutations**:**

A. SymGene Focus – NGS Lung Cancer Panel (CellNetix) **-**
ALK ARAF BRAF EGFR ERBB2 KRAS MAP2K1 MET MTOR NRAS RET ROS1 TP 53

B. SymGene Focus - NGS Colon Cancer Panel (CellNetix) -
BRAF KRAS MLH1 MSH2 MSH6 NRAS PIK3CA PMS2 POLD1 POLE

C. SymGene NGS Cancer Panel (CellNetix) **-**

AKT1	**ALK**	**APC**	**ARAF**	**ATM**	**BCL2L11**	**BRAF**
BRCA1	**BRCA2**	**BTK**	**CCND1**	**CDK4**	**CDK6**	**CDKN2A**
CSF1R	**CTNNB1**	**DDR2**	**EGFR**	**EPHA2**	**ERBB2**	**ERBB4**
ESR1	**FGFR1**	**FGFR2**	**FGFR3**	**FLT1 (VEGFR1)**	**FLT3**	**FLT4**
FOXL2	**FYN**	**GLI2**	**GNA11**	**GNAQ**	**GNAS**	**HDAC2**
HRAS	**IGF1R**	**JAK2**	**JAK3**	**KDR (VEGFR2)**	**KIT**	**KRAS**
LCK	**LYN**	**MAP2K1 (MEK1)**	**MAP2K2 (MEK2)**	**MDM2**	**MET**	**MLH1**
MSH2	**MSH6**	**MST1R (RON)**	**MTOR**	**NOTCH1**	**NRAS**	**NTRK2**

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PDGFRA	**PDGFRB**	**PIK3CA**	**PMS2**	**POLD1**	**POLE**	**PTCH1**
PTEN	**RAF1**	**RB1**	**RET**	**ROS1**	**SMAD4**	**SMO**
SRC	**STK11**	**TEK**	**TERT**	**TP53**	**TSC1**	**TSC2**
VHL	**YES1**					

*If the submission is for a different vendor, it will be redirected to SymGene for HMO. For POS and PPO, a similar narrow panel limited to the genes above can be considered on a case by case basis.

IV. Molecular testing for hematology-oncology indications is **considered experimental, investigational or unproven in the following situations:**
- there is insufficient evidence to support molecular testing for the specific tumor type or disease site
- the requested gene(s) or biomarker(s) are correlated with a known therapy, but that therapy has not been validated for the specific tumor type or disease site

Individual or targeted gene testing can be covered for specific, actionable mutations for cancer types that panel testing is not covered.

Please see the list of ***non-covered*** genetic panels on the KPWA criteria page – Genetic Panel Testing. This includes, but is not limited to:

- FoundationOne
- Caris Life Sciences – MI Profile
- Guardant360

Repeat testing is non-covered.

Effective 02/01/2023

I. Next Generation Sequencing can **only be covered for the following solid cancer types:**
1. Stage III or IV non-small cell lung cancer
2. stage IV pancreatic carcinoma
3. stage IV colon carcinoma
4. stage IV prostate
5. stage IV ovarian
6. stage IV endometrial
7. stage IV biliary
8. stage IV gastric
9. stage IV esophageal (adeno and squamous) gastroesophageal
10. stage IV breast (ER or PR positive)

II. In addition, the member must meet **ALL of the following**:
1. The individual is a candidate for a targeted therapy associated with a specific tumor biomarker or disease site
2. Results of testing will directly impact clinical decision making
3. The testing method is considered to be scientifically valid and proven to have clinical utility based on prospective evidence
4. **EITHER** of the following:
   - Identification of the specific biomarker or risk assessment using a Gene Expression Classifier (GEC)/Next Generation Sequencing is required in order to initiate a related therapy and the therapy has been validated by the National Comprehensive Cancer Network™ (NCCN Guidelines™) as a category 1, 2A, or 2B recommendation for the individual's tumor type or disease site **OR**

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- Identification of the specific biomarker or use of a GEC/Next Generation Sequencing has been demonstrated in published peer-reviewed literature to improve diagnosis, management or clinical outcomes for the individual's condition being addressed

III. The following panels meet Kaiser Permanente coverage criteria in regard to actionable mutations —any of these three labs can be used:
- CellNetix SymGene Panel
- Oncoplex (University of Washington)
- Caris Life Sciences

*If the submission is for a different vendor, it will be redirected to one of the above preferred labs A-D for HMO. For POS and PPO, a similar narrow panel limited to the genes above can be considered on a case-by-case basis if labs A-D are unacceptable.

IV. Molecular testing for hematology-oncology indications is **considered experimental, investigational or unproven in the following situations:**
- there is insufficient evidence to support molecular testing for the specific tumor type or disease site
- the requested gene(s) or biomarker(s) are correlated with a known therapy, but that therapy has not been validated for the specific tumor type or disease site

Individual or targeted gene testing can be covered for specific, actionable mutations for cancer types that panel testing is not covered.

Please see the list of ***non-covered*** genetic panels on the KPWA criteria page – Genetic Panel Testing. This includes, but is not limited to:

- FoundationOne
- Guardant360

Repeat testing is non-covered.

If requesting this these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Symgene 79 NGS Cancer Panel:

CPT® or HCPC Codes	Description
88374 (x2)	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
88381	Microdissection (ie, sample preparation of microscopically identified target); manual
G0452	Molecular pathology procedure; physician interpretation and report

Symgene Focus- Targeted NGS Cancer Panel (Lung):

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CPT® or HCPC Codes	Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
88374 (x2)	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure
88360	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual
88381	Microdissection (ie, sample preparation of microscopically identified target); manual
G0452	Molecular pathology procedure; physician interpretation and report

Symgene Focus- Targeted NGS Cancer Panel (Colon):

CPT® or HCPC Codes	Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
88381	Microdissection (ie, sample preparation of microscopically identified target); manual
G0452	Molecular pathology procedure; physician interpretation and report

Caris Life Sciences – Effective 02/01/2023

CPT® or HCPC Codes	Description
81479	Unlisted molecular pathology procedure

Oncoplex (University of Washington) - Effective 02/01/2023

CPT® or HCPC Codes	Description
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed

FoundationOne® (Foundation Medicine) –
Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Considered Not Medically Necessary, use preferred vendors above

CPT® or HCPC Codes	Description
0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations *FoundationOne® Liquid CDx*
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden *FoundationOne CDx™*

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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
08/04/2020	08/04/2020 MPC, 08/03/2021 MPC, 08/02/2022MPC, 09/06/2022MPC	01/24/2023

MPC Medical Policy Committee

Revision History	Description
08/04/2020	MPC approved to adopt new clinical criteria. Requires 60-day notice, effective date 01/01/2021.
11/13/2020	Added codes from CellNetix
09/06/2022	MPC approved to expand solid cancer types to include: stage IV prostate, stage IV ovarian , stage IV endometrial , stage IV biliary , stage IV gastric, stage IV esophageal (adeno and squamous) gastroesophageal, stage IV breast (ER or PR positive). Also approved Caris and Oncoplex as contracted lab vendors. 60-day notice required; effective 2/1/2023.
10/26/2022	Refiled 60 day notice. Adjusted effective dates for advanced cancers to 1/1/23 per RCW 48.43.810
01/24/2023	Added Applicable codes for FoundationOne® NGS testing

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Neonatal Facility Level of Care Guidelines

- NICU

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Neonatal Facility Level of Care Guidelines*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the following Neonatal Facility Levels of Care Guidelines from MCG* for medical necessity determinations.

- Neonatal Facility, Level II (LOC-005)
- Neonatal Facility, Level III (LOC-006)
- Neonatal Facility, Level IV (LOC-007)

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Based on the Kaiser National Payment Integrity Clinical Review processes, these medical criteria provide guidance for NICU and neonatal care levels 2 through 4. Level 1 admission and discharge criteria was intentionally omitted as it now replaces routine nursery care. Specific information regarding neonatal level of care may be requested through National Clinical Review.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- All clinical notes from requesting provider

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

This chart follows the American Academy of Pediatrics recommendation to use uniform, nationally applicable definitions and consistent standards of service to improve neonatal outcomes.

Definitions, Capabilities, and Provider Types[1]

Level of Care	Capabilities	Provider Types
Level I *Well Newborn Nursery*	✔ Provide neonatal resuscitation at every delivery ✔ Evaluate and provide postnatal care to stable term newborn infants ✔ Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable ✔ Stabilize newborn infants who are ill and those born at <35 wk gestation until transfer to a higher level of care	✔ Pediatricians ✔ Family physicians ✔ Nurse practitioners ✔ Other advanced practice registered nurses
Level II *Special Care Nursery*	**Level I Capabilities plus:** + Provide care for infants born ≥32 wk gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis + Provide care for infants convalescing after intensive care + Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both + Stabilize infants born before 32 wk gestation and weighing less 1500 g until transfer to a neonatal intensive care facility	**Level I Providers plus:** + Pediatric hospitalists + Neonatologist + Neonatal nurse practitioners as appropriate
Level III *NICU*	**Level II Capabilities plus:**[3] + Provide sustained life support + Provide comprehensive care for infants born <32 wks gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness + Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists + Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide + Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography	**Level II Providers plus:** + Pediatric medical subspecialists + pediatric anesthesiologists + Pediatric surgeons + Pediatric ophthalmologists with appropriate qualifications
Level IV *Regional NICU*	**Level III Capabilities plus:** + Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions + Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site + Facilitate transport and provide outreach education	**Level III Providers plus:** + Pediatric surgical subspecialists

Washington State Perinatal and Neonatal Level of Care (LOC) Guidelines | March 2018 | 3

Retrieved 5/13/2020 from https://www.doh.wa.gov/Portals/1/Documents/Pubs/950154.pdf

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/21/2020	05/21/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC]	05/21/2020

[MPC] Medical Policy Committee

Revision History	Description

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05/21/2020	MPC approved to adopt new clinical criteria. Requires 60-day notice, effective date 9/1/2020.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Recombinant Activated Factor VII (NovoSeven®)

- Glanzmann's Disease
- Hemophilia
- Post-Partum Hemorrhage
- Cardiac Surgery Hemorrhage

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Criteria

For Non-Medicare Members

Kaiser Permanente has elected to use the Coagulation Factor VIIa – (NovoSeven) (KP-0452) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 12 months of clinical notes from requesting provider &/or specialist (hematology, primary care physician)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Glanzmann's disease (aka Glanzmann's thrombasthenia) is a platelet disorder characterized by a deficiency in the platelet membrane glycoproteins (GP) IIb-IIIa. It is one of several hereditary platelet disorders typified by normal platelet numbers and a prolonged bleeding time. NovoSeven® may also be appropriate for use with patients who have other bleeding disorders such as Glanzmann's thrombasthenia or Bernard-Soulier's thrombasthenia.

NovoSeven® (manufactured by Novo Nordisk, Denmark) is a product containing recombinant coagulation Factor VII. It has been used to prevent bleeding and treat hemorrhage during surgery in patients with hemophilia A with a Factor VIII inhibitor, hemophilia B with a Factor IX inhibitor and acquired deficiencies in Factors VIII or IX.

NovoSeven® has been approved by the FDA as a biological product.

People with hemophilia A (approximately 85% of hemophilia patients) lack the blood clotting protein, factor VIII and people with hemophilia B lack factor IX. The severity of the condition varies, depending on the amount of clotting factor in the blood. About 70% of individuals with hemophilia A have less than 1 percent of the normal amount of clotting factor and are considered to have severe disease. Treatment of hemophilia A or B consists of replacement of the deficient factor.

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Approximately 20-50% of severe hemophilia A patients and 1.5-3% of hemophilia B patients (Kulkarni, 2001) develop antibodies called inhibitors that block the activity of the replacement clotting factor. Management of hemophilia patients with inhibitors is challenging. Injection of high quantities of clotting factors is sometimes effective at neutralizing the inhibitors and allowing sufficient quantities of the factors to circulate. Another treatment is injection of porcine factor VIII, which is often sufficiently different from human factor VIII to go unrecognized by inhibitors. However, many patients have cross-reactive antibodies to Porcine FVIII concentrates. Removing the antibody from the plasma (plasmapheresis), in combination with injections of clotting factor, is sometimes used.

Another approach to treatment is the use of bypassing agents, treatments that induce hemostasis independent of the presence of factors VIII and IV. Prothrombin complex concentrates (PCCs) and activated prothrombin complex concentrates (aPCC) were developed in the 1970s. They are derived from human plasma and contain the vitamin K-dependent coagulation proteins.

Recombinant activated Factor VII (rFVIIa) or NovoSeven is also a bypassing agent. This product is derived from cultured baby hamster kidney cells using recombinant DNA technology. Because it does not any human serum or proteins, NovoSeven has a low risk of infecting patients with human viruses that could be present in plasma-derived products. NovoSeven has a relatively short half-life and injections must be given frequently. The initial recommended dose is 90 ug/kg every two hours until cessation of bleeding. PCCs and aPCCs have been associated with thromboembolic side effects and it is also possible that there is a risk of thrombosis with NovoSeven (Kulkarni, 2001).

NovoSeven (manufactured by Novo Nordisk, Denmark) has been available in the European Union since 1996. In 1999, NovoSeven was approved by the FDA for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to factors VIII or IX. It is available in the US through Novo Nordisk Pharmaceuticals, New Jersey.

Major bleeding is a common and potentially serious complication in high-risk **cardiovascular surgeries** and is a well-known risk factor for postoperative morbidity and mortality. Excessive blood loss frequently requires the transfusion of allogenic blood, blood products, and surgical re-exploration when appropriate. Re-exploration may not reveal a surgically repairable source of bleeding in up to 50% of cases. Both massive blood transfusion and re-exploration are associated with longer intensive care and hospital stay, wound infection, higher morbidity, and reduced survival rates. The high risk of bleeding and its consequences have prompted cardiac surgeons to explore the off-label use of recombinant factor VIIa as an alternative haemostatic agent for postoperative bleeding (Murphy 2007, Zangrillo 2009, Goksedef 2010, Chapman 2011).

Recombinant factor VIIa (rFVIIa; NovoSeven®, NovoNordisk, Copenhagen, Denmark) is a recombinant DNA preparation of activated blood coagulation factor VII. It is an engineered preparation of factor VIIa produced in cultured baby hamster kidney cells and is nearly identical to plasma-derived factor VIIa in structure and function. At the pharmacological level, it is to some degree different from the natural FVIIa (nFVIIa). Its pharmacologic action induces thrombin generation on locally activated platelets and contributes to the formation of a stabilized clot at the site of vessel injury. NovoSeven received market approval by the US Food and Drug Administration (FDA) in 1999 for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX respectively. In 2005, it was further approved by the FDA for the treatment of bleeding episodes and for the prevention of bleeding in surgical interventions or invasive procedures in patients with acquired hemophilia. NovoSeven is licensed in Europe for the treatment of congenital factor VII deficiency and Glanzmann's thrombasthenia refractory to platelet administration (Ratko 2004, Al-Ruzzeh 2008, Gill 2009, Zangrillo 2009, Logan 2011, Goksedef 2012, Guzette 2012).

Over the last decade, rFVIIa (NovoSeven) has been increasingly used off-label for a wide range of disorders including life threatening bleeding after body and brain trauma, intracranial hemorrhage, major abdominal surgeries, drug-induced coagulopathy, platelet disorders, intraoperative or postoperative hemorrhage, and a number of other conditions. The vast majority of adults and pediatric patients who have received rFVIIa received it for an off-label indication. It is also being used off-label for pediatric and adult cardiac surgery. However, its use in these patients is controversial and widely debated due to the concern about its safety especially for the potential increase the risk of thromboembolic events. Cardiac surgery patients are already at high risk of myocardial ischemia, arterial and venous thrombosis before, during, and after the surgery due to either or both the underlining pathology and the surgery performed with cardiopulmonary bypass or cross clamping. The reported mortality and complication rate among cardiac surgery patients receiving rFVIIa ranged from 19-40%. The issue of the appropriate dosing is also a major concern (Ratko 2004, Al-Ruzzeh 2008, Gelsomino 2008, Gill 2009, Zangrillo 2009, Logan 2011, Goksedef 2012, Guzette 2012).

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Medical Technology Assessment Committee (MTAC)

NovoSeven®

10/10/2001: MTAC REVIEW

Evidence Conclusion: There is insufficient published scientific evidence on which to base conclusions about the effect of NovoSeven® on health outcomes in people with Glanzmann's disease.

Articles: The search yielded 7 articles. Two were review articles, two were case studies (report on only one patient) and three were case series, each of which included five or fewer patients with Glanzmann's disease. Due to the small sizes of the case series, no evidence tables created.

The use of NovoSeven® in the treatment of Glanzmann's disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

NovoSeven®

12/10/2003: MTAC REVIEW

Evidence Conclusion: There are no studies comparing NovoSeven to another treatment for hemophilia patients with inhibitors. A comparison to the alternative bypass agents, prothrombin complex concentrates (PCCs) or activated prothombin complex concentrates (aPCC), might be feasible. In the Scharrer study, 7 (25%) of the patients had failed PCCs/aPCCs, but neither of the other two studies attempted to select patients who had failed treatment with another bypass agent. Non-comparative clinical data suggests that NovoSeven is effective at achieving hemostasis in 80-90% of bleeding episodes. There are data on both in-home and surgical use of NovoSeven. There was a low rate of thrombosis associated with treatment in the published data.

Articles: The search yielded 71 articles, many of which were reviews, opinion pieces, overviews or dealt with technical aspects of the treatment. There were no randomized or non-randomized studies with hemophilia patients with inhibitors that compared NovoSeven to an alternate treatment. One randomized controlled trial was identified with hemophilia patients, but this compared two doses of NovoSeven. The remaining empirical studies were case series. The RCT was critically appraised, not for comparative data, but because it was a reasonably well-designed study with the target population. In addition, two of the largest case series using NovoSeven to treat hemophilia patients with inhibitors were critically appraised. The articles reviewed are as follows: Shapiro AD, Gilchrist S, Hoots WK. Prospective, randomized trial of two doses of rFVIIa (NovoSeven) in hemophilia patients with inhibitors undergoing surgery. *Thromb Haemost* 1998; 80: 773-778. See Evidence Table. Key NS Aledort LM, Beardsley D. Home treatment of mild to moderate bleeding episodes using recombinant factor VIIa (NovoSeven) in hemophiliacs with inhibitors. *Thromb Haemost* 1998; 80: 912-918. See Evidence Table. Scharrer I et al. Recombinant factor VIIa for patients with inhibitors to factor VIII or IX or factor II deficiency. *Hemophilia* 1999; 5: 253-259. See Evidence Table.

The use of NovoSeven® in the treatment of Hemophilia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

NovoSeven®

02/11/2013: MTAC REVIEW

Evidence Conclusion: There is a lack of published high-quality studies on the off-label use of rFVIIa in cardiac surgery. To date only two RCTs evaluated the use of rFVIIa in adult cardiac surgery; one was a very small pilot study with 20 patients that assessed the prophylactic use of the therapy, and the other was conducted among 172 patients (Gill 2009, evidence table 3) to evaluate the effectiveness and safety of rFVIIa in 172 patients bleeding after cardiac surgery requiring cardiopulmonary bypass. Both trials lacked statistical power to detect significant differences between the study groups. The rest of the published studies were observational with or without matched comparison groups. A number of these observational studies compared outcomes of patients receiving rFVIIa to matched groups using propensity score (PS) analysis. This method is used to adjust for selection bias in observational studies of causal effect, when RCTs are unfeasible, unethical, or too costly to conduct. PS matching adjusts for observed variables and can only decrease but not eliminate the selection bias. It may also reduce the study's external validity as only a subset of the treated patients is used in the analysis. The majority of the published studies were conducted over a long period of time; the administration of rFVIIa was based on the guidelines of each institution, but was ultimately made by at the discretion of the operating team, and may have evolved throughout the study period as the experience with using the therapy increased (Anderson 2012). There were no consistent well-defined and measurable endpoints to evaluate the efficacy of the therapy. In addition, the published studies followed different protocols for the threshold for using rFVIIa and its dose. This ranged from prophylactic use as a haemostatic agent in the operating room, to a rescue therapy for

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patients with refractory bleeding. Rescue therapy is defined as situations in which rFVII is used when patients continue to bleed excessively despite having received maximal standard haemostatic therapy, the definition of which varied between institutions (Guzette 2012).The dosage of rFVIIa ranged between studies from 9-192 µg/kg, and was used either repeatedly or a in a single dose.The results of the RCTs and the four comparative observational studies on the use of rFVIIa in adult cardiac surgery were pooled in three meta-analyses (Zangrillo 2009, Ponschab 2011, and Yank 2011). The pooled results of the two more recent meta-analyses comprising a total 470 patients, showed no significant effect of rFVIIa on reducing mortality compared to usual care, but a statistically significant increase in the occurrence of stroke (calculated number needed to harm of 26). The meta-analyses showed a lower but statistically insignificant rate of re-exploration and a trend towards the lower blood loss and need for transfusion with the use of rFVIIa. Gill and colleagues' RCT found a statistically significant lower rate of re-operation rates and need for blood transfusion, and a statistically insignificant increase in serious adverse events in the adult cardiac surgery patients who received rFVIIa. In conclusion, the available evidence suggests that rFVIIa use in adult cardiac surgery patients may result in an increased risk of stroke and lower re-exploration rate without a significant mortality benefit. Larger randomized controlled trials with sufficient power are needed to verify the results of the meta-analyses and clearly assess the benefits and risks of the off-label use of rFVIIa in cardiac surgery patients.

Articles: The literature search for studies on the use of rFVIIa (NovoSeven) for adults undergoing cardiac surgery revealed two meta-analyses, two randomized controlled trials, and a number of observational prospective and retrospective studies with or without comparison groups. The search also identified an updated Cochrane review and other meta-analyses and systematic reviews that included trials on the use of rFVII for any off-label indication including cardiac surgery. Among these, there was one review (Yank 2011) prepared for the agency for Healthcare Research and Quality (AHRQ) that included a meta-analysis of studies on the use of the rFVIIa for adult cardiac surgery. The two meta-analyses on the use of rFVIIa or cardiac surgery patients were conducted by the same group of authors, but the more recent analysis included an additional RCT and focused on the rates of thromboembolic events associated with the use of rFVIIa. Two meta-analyses of trials using rFVII for adult patients undergoing cardiac surgery as well as the most recent RCT among cardiac surgery patients were selected for critical appraisal. Zangrillo A, Mizzi A, Biondi-Zoccai G, et al. Recombinant activated factor VII in cardiac surgery: a meta-analysis. J Cardiothoracic Vasc Anesth. 2009.23:34-40. Evidence Table. Ponschab M, Landoni G, Biondi-Zoccai G, etal. Recombinant activated factor VII increases stroke in cardiac surgery: a meta-analysis. J Cardiothoracic Vasc Anesth. 2011.25:804-810. Evidence Table.Gill Ravi, Herbertson M, Vuylsteke A, et al. Safety and efficacy of recombinant activated factor VII A randomized placebo-controlled trial in the setting of bleeding after cardiac surgery. Circulation 2009; 120:21-27. Evidence Table.

The use of NovoSeven® in the prevention of cardiac surgery bleeding does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
J7189	Factor VIIa (antihemophilic factor, recombinant), (NovoSeven RT), 1 mcg

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/10/2001	10/10/2001, 12/10/2003, Reinstitute criteria set on 03/05/2013[MDCRPC] 03/05/2013[MDCRPC], 01/07/2014[MDCRPC], 11/04/2014 [MPC], 09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	03/05/2013

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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Observation Level of Care

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PURPOSE

To provide a regional standard for appropriate utilization of observation care that ensures consistent application of the outpatient and acute care benefits for Kaiser Permanente of Washington members regardless of where care is delivered.

POLICY

A. Observation care will be utilized, when in the judgment of the admitting physician, the patient's presenting medical condition requires services which are reasonable and necessary to evaluate a patient's condition or determine the need for a possible inpatient admission.

   Observation care is a set of specific, clinically appropriate services, not a location. Therefore, a patient can be in observation status regardless of where the services are performed, i.e. critical care unit, emergency room, recovery room, telemetry, or on a medical floor. MCG Care Guidelines and the CMS "Two Midnight Rule" may serve as guidance for the attending physician in determining the appropriate use of observation care. (See MCG white paper on "Observation Care 101", by Bill Rifkin, M.D.) Observation services are defined by Centers for Medicare and Medicaid (CMS). See definition on following page.

B. CMS Manual- "When a physician orders observation care, the patient's status is that of an outpatient. The purpose of observation care is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation care may improve and be released or be admitted as an inpatient. A physician's order must specify, "admit to observation" or "observation status" and signed electronically.

   Conversion to inpatient status must meet medical necessity for admission and be documented at the time of conversion from observation to inpatient status. A physician's order must specify, "admit to inpatient status" and be signed electronically.

   Medical records may be evaluated by Kaiser Permanente of Washington to determine the consistency between the physician order (physician intent), the services actually provided (inpatient or outpatient), and the medical necessity of those services, including the medical appropriateness of the inpatient or observation stay.

C. A patient in observation care may improve and be released or be admitted as an inpatient. In most instances a placement in observation care a will result in a disposition being implemented within 48 hours-either to discharge or continued hospitalization under inpatient status.

D. If a patient is retained in observation care for 48 hours without being admitted as an inpatient, further observation services may be denied as not reasonable and necessary for the diagnosis or treatment of illness or injury.

E. Conversion from observation status to inpatient status must meet medical necessity

F. Medicare does not consider use of observation as a convenience of the patient, the patient's family, or a physician to be appropriate. For example, a decision to keep the patient overnight due to transportation issues or because the procedure could not be scheduled in a timely manner would not qualify.

DEFINITIONS

Medicare CMS definition:

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.

Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient tests. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours.

In only rare and exceptional cases do reasonable and necessary outpatient observation care span more than 48 hours. For coverage requirements, see the Medicare Benefit Policy manual, Chapter 6.

Medicare Outpatient Observation Notice (MOON):

The MOON informs all Medicare beneficiaries when they are an outpatient receiving observation services and are not an inpatient of the hospital or critical access hospital (CAH).

Beneficiary Notices Initiative (BNI)

RESPONSIBILITIES

TIMELINESS

A. MOON - The MOON must be delivered to beneficiaries in Original Medicare (fee-for-service) and Medicare Advantage plans. Enrollees who receive observation services as outpatients for more than 24 hours will be issued a MOON by the facility. The hospital or CAH must provide the MOON no later than 36 hours after observation services as an outpatient begin.

B. If the attending physician intends to place or retain a patient in observation care longer than 48 hours for:
   1. a non-medical reason,
   2. or the patient and/or family are unable or unwilling to make other arrangements for care

   A coverage determination should be requested of the Health Plan to determine if the stay is approved or denied.

PROCESS

Primary Responsibility	Actions
Facility or CAH	1. Must deliver verbal & written MOON no later than 36 hours after observation services as an outpatient begin.
KP Physician (Kaiser Permanente of Washington) and Contracted MD) (Attending/Admitting Physician)	1. Utilizing clinical judgment and CMS 2 Midnight Rule, admits the patient to observation status. (see MCG white paper "Observation Care 101" by Bill Rifkin, M.D.) 2. The KP Physician's order must specify, "admit to observation" and be electronically signed. 3. The history and physical must clearly document the medical intent of the use of observation care and be supported by the patient's presenting medical condition (severity of illness) and plan for observation/treatment (intensity of service). 4. Medical necessity for admission must be met and documented at the time of

Primary Responsibility	Actions
	conversion from observation to inpatient status. 5. The KP Physician may change admission status prior to discharge. The patient must be informed before they are transferred or discharged from the hospital if their status is Observation care only for Medicare patients. 6. The KP Physician may convert a patient from inpatient status to observation status. This will cancel the inpatient admission prior to discharge if the physician determines: a. that the inpatient admission is unnecessary b. or the original order was ambiguous and the KP Physician clarifies that order. 7. Any change in admission status must be supported by medical records (KP Physician notes and orders) and be supported by medical necessity. 8. The KP Physician may change or clarify the admission status through a direct written order, a verbal order given to a CMLN and subsequently signed by the KP Physician. 9. Notification of the Care Management department is required in this instance. **The KP Physician/attending physician may not change the patient's status (i.e., inpatient vs. observation) after discharge.* *** Through Provider Reconsideration or other review process, coverage decision can be made and/or changed after the patient discharges.*
CMLN (Care Management Liaison Nurse)	**Rounded and Non-Rounded Facilities:** • CMLN will communicate Observation/Inpatient status decision to hospital UM office within 24 hours after hospital services begin or from time of notification. • Medicare Observation stays over 24 hours are communicated to hospital UM office. **For Rounded Facilities** 1. When working directly with KP Physician during admission, will discuss status based on CMS 2 Midnight Rule and medical necessity. 2. Based upon the review, the KP Physician may provide additional documentation to support the admission status, or convert the admission status to the identified appropriate status 3. If the patient does not meet Inpatient criteria for the admission status, the CMLN will contact the physician and discuss the results of the review. 4. The CMLN may accept a verbal order from the physician to either clarify or change the admission status. The CMLN must notify the Hospital UM Office of the changes. 5. In the event the attending physician does not provide additional documentation to support the admission status or convert the patient to the appropriate status, the CMLN will: a. contact the Clinical Review Unit (CRU) physician for further review, b. arrange for a "Peer to Peer" discussion before the patient discharges. 6. If the peer-to-peer results in a change from IP to Obs, notification of the status change to the hospital UM Office before hour 36 will allow for timely MOON delivery. **Non- Rounded Facilities** 1. When not working directly with KP Physician, CMLN will conduct a review for all patients admitted as inpatient utilizing MCG Care Guidelines. 2. CMLN will communicate Observation/Inpatient status decision to hospital UM office within 24 hours after hospital services begin or from time of notification.

Primary Responsibility	Actions
Clinical Review Unit (CRU) (UM Physician Advisor)	1. CRU may contact the KP Physician and review the recommended level of care determination. If additional clinical information is needed to make a determination. 2. CRU will advise the CMLN of the results of the contact. • The decision from the Peer-to-Peer discussion will be entered into Care Management workflow system and the outcome communicated to the Hospital UM office for the appropriate actions.

Date Created	Date Reviewed	Date Last Revised
04/04/2017	04/04/2017, 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	06/06/2017

[MPC] Medical Policy Committee

Revision History	Description
06/06/2017	MPC approved revised policy to further clarify language

Date Sent: 6/28/23
1029
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Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Occipital Nerve Stimulation (ONS) for Primary Headache

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Peripheral Nerve Stimulation (L37360)
Local Coverage Article	Billing and Coding: Peripheral Nerve Stimulation (A55531) Response to Comments: Peripheral Nerve Stimulation (A56042)

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Occipital Nerve Stimulation (A-0716) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

See related policy: Deep Brain Stimulation for Primary Headache

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Headache is a major worldwide health problem disabling millions of people and resulting in considerable economic burden. Up to 40% of patients seen in major headache clinics suffer from chronic daily headache. Chronic headache disorders include migraine, cluster headache, cervicogenic headache, occipital neuralgia, and other types of primary headache (Maizels 1998, Jasper 2008).

Cluster headache (CH), an excruciating headache syndrome, is the most common type of trigeminal autonomic cephalalgias, and is thought to be the most severe primary headache disorder. 10-20% of CH patients develop a chronic form in which the attacks persist for more than one year without remissions, or with remissions lasting less than a month. Acute treatment for the attacks includes injectable or intranasal triptans or oxygen inhalation. About one percent will become refractory to medical treatment and fulfill the criteria of intractable headaches. These patients may get some relief with attack treatments, but the disorder could be disabling and may be associated with depression and suicidality (Magis 2007, Leroux 2008).

Migraine headache is a chronic headache that affects about 15% of the population and is one of the most common problems seen in emergency departments and doctors' offices. Migraine is believed to result from changes in the brain and surrounding blood vessels. The attacks typically last from 4-72 hours and vary in

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frequency from daily to less than one per year. Transformed migraines are chronic daily or almost daily headaches (>15/month) that lasts more than 4 hours. There is no cure for migraine, and medications can only help reduce the frequency and severity of disorder (Bigal 2008).
Cervicogenic headache is a chronic hemicranial pain that usually occurs daily. It usually begins at the suboccipital region and spreads anteriorly to the ipsilateral orbital, frontal, and temporal areas. It is typically unilateral bur occasionally affects the two sides. It is believed to be due to convergence of upper cervical and trigeminal sensory pathways allowing pain signals to refer from the neck to the trigeminal sensory fields of the head and face. Treatments with pain medication, physical therapy, manipulative treatment, and surgical interventions may provide only some inconsistent temporary relief of pain (Naja 2006).

Various ablative surgical procedures targeting the trigeminal nerve, or the cranial parasympathetic outflow have been tried to treat these patients with intractable headaches. These include gamma knife surgery or root section of the trigeminal nerve, trigeminal tractotomy, microvascular decompression of the trigeminal nerve, glycerol injection of the Gasserain ganglion, and others. However, none of these procedures has a consistent effect, and many are associated with serious complications (Magis 2007).

Electrical stimulation of the brain was first attempted late in the 19th century, but its application for pain control began in the 1960s with spinal cord stimulation. The neurostimulation technique for ablating pain is based on the theory that peripheral nerve stimulation can produce specific focal analgesia and anesthesia. In addition, the technique may alter perception of pain by blocking cell membrane depolarization and axonal conduction with directly applied current (Shealy 1967, Lim 2007, Trentman 2008).

In the early 2000s, neurostimulation therapy emerged as a potential treatment option for a variety of different intractable primary headache disorders. This is an invasive device- based approach that has two broad types:

1. Peripheral therapy that involves branches of the occipital nerve: occipital nerve stimulation (ONS), and supraorbital nerve stimulation.
2. Central which refers to deep-brain stimulation (DBS) approaches e.g. hypothalamic deep brain stimulation used for chronic cluster headache (Schwedt 2009).

The occipital nerve stimulators (ONS) are implanted surgically in a 3-phase procedure: Phase 1. An incision is made over the occipital region at the level of the first cervical vertebra for the subcutaneous implantation of bilateral electrodes. These are tunneled in a cephalad direction so that they come to lie across the path of the greater occipital nerve on each side of the head. Phase 2. Confirmation of the electrode position by testing each separately by an external stimulator. The operator gradually increases the amplitude delivered to the electrodes from 0 to 4 v, and the patient is asked to locate and describe any sensation he /she feels. Correct placement is confirmed by the patient describing a vibrating sensation that radiates at least 4 cm cephalad from the base of the skull, on the side of the tested electrode, and Phase 3. Implantation of the stimulator battery in the pectoral, abdominal, or gluteal region, and connecting it to the electrodes via subcutaneously tunneled leads. The procedure is performed under sedation or general anesthesia, however during the second phase the patients are required to be awake and to be able to identify the position of the occipital electrodes when the electric stimulus is applied. Potential complications of the procedure include lead migration, infection, localized pain, muscle spasm, and lack or loss of effect (Lim 2007, Trentman 2008).

The deep brain stimulation (DBS) of the posterior hypothalamus has been investigated in patients with chronic cluster headaches or SUNCT (short-lasting, unilateral, neuralgiform headache attacks with conjunctival injection and tearing). DBS involves MRI guided stereotactic placement of an electrode into the brain (e.g. thalamus, globus pallidus, or subthalamic nucleus). It is typically implanted unilaterally on the side corresponding to the most severe symptoms. The use of bilateral stimulation using two electrodes has been investigated in patients with bilateral, severe symptoms. Initially, the electrode(s) is/are attached to a temporary transcutaneous cable to validate treatment effectiveness and, if effective, the patient returns to surgery several days later for permanent subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. After implantation, noninvasive programming of the neurostimulation can be adjusted to control the patient's symptoms. The procedures can be performed only by a highly experienced neurosurgeon and may be associated with a small risk of mortality due to intra-cerebral hemorrhage. Before implantation, all patients must undergo complete preoperative neuro-imaging to exclude disorders associated with increased hemorrhagic risk (Leon 2006, Bartsch 2008).

Neither the occipital nerve stimulation nor the deep brain stimulators are approved to date by the U.S. Food and Drug Administration for the treatment or prevention of primary headaches.

Medical Technology Assessment Committee (MTAC)

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Occipital Nerve Stimulation (ONS)

08/03/2009: MTAC REVIEW

Evidence Conclusion: The literature on brain stimulation for the treatment of chronic primary headache is limited and does not provide sufficient evidence to determine the efficacy or safety of either occipital or deep brain stimulation therapy for the prevention or treatment of chronic headache. There are no published randomized or nonrandomized controlled trials on the intervention to date. The empirical studies consist of a few very small case series with no comparison groups and a number of case reports. The outcome measures varied between studies as some reported change in pain and others reported on headache frequency intensity, disability and/or medication use. Popeney and Alo's (2003), the largest series on ONS studied the response to occipital nerve stimulation in a series 25 consecutive patients with transformed migraine. A comparison between pre- and post-implant measurements, showed significant reductions in headache frequency, severity, and disability after the implant. The study was only an observational case series with potential biases, and with no control or comparison group to rule out the placebo effect of the implant.

Articles: The search yielded almost four hundred articles. The majority was review articles, opinion pieces, or dealt with technical aspects the procedure. ONS: There were around 15 small prospective and retrospective case series with patient sizes ranging from 3-25, and a number of case reports on peripheral nerve stimulation. Popeney CA, Alo KM. Peripheral neurostimulation for the treatment of chronic disabling transformed migraine. Headache 2003,43:369-375. See Evidence Table.

The use of Occipital Nerve Stimulation (ONS) for the treatment of primary headache does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Non-Medicare - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

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L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
09/16/2009	Added to the annual review because of the Medicare criteria 04/11/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC ,10/01/2013 MPC,08/05/2014 MPC,06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC , 10/05/2021MPC , 10/04/2022MPC	10/05/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
04/05/2016	Adopted MCG A-0716
10/05/2021	Updated applicable codes

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Kaiser Foundation Health Plan of Washington

Patient Referral Guidelines
Pancreas Transplant Alone

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pancreas Transplants (260.3)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, accepted guidelines for Pancreas Transplant Alone and Pancreas After Kidney transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. It is important to note that these are guidelines and should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection is a contraindication to transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low.[1,2,3] Exceptions may be made on a case-by-case basis.
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
   g. Patients must be able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
   h. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
   i. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

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j. Evidence of such non adherence may be: failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list
k. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. PANCREAS TRANSPLANT ALONE (PTA/PAK)
   a. Indications for PTA/PAK Transplant
      i. Type 1 DM with disabling and potentially life threatening complications as seen in brittle diabetes with severe and recurrent episodes of either hypoglycemia (involving seizures, loss of consciousness and/or calls to 911) and or hyperglycemia (episodes of DKA) or hypoglycemic unawareness in which the individual requires constant supervision.
      ii. Optimally and intensively managed by an endocrinologist for at least 12 months[4].
      iii. Age 18 - 55 except under special clinical circumstances.
      iv. Native or transplanted kidney must be functioning well as evidenced by an accepted formula for GFR or a 24-hour urine for creatinine clearance of >50 ml per minute[5,6,7]
3. Contraindications for PTA/PAK Transplant
   a. Significant irreversible coronary artery disease and/or left ventricular dysfunction, and irreversible pulmonary disease.
   b. Irreversible peripheral vascular disease, including carotid vascular disease (Amputation alone is not a contraindication).
   c. Uncontrolled hypertension.

   Relative Contraindications
   a. BMI ≥ 35. Patients may be referred to the COE for individual consideration.
      i. May be concurrently referred for weight loss intervention.
   b. Cachexia and/or malnourishment

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1. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
2. *Liver Transplant Surg,*. 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
4. National Coverage Determination (NCD) for Pancreas Transplants (260.3) version 3. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?
5. An assessment of the effect on renal function of a calcineurin inhibitor may be required for a creatinine clearance or GFR between 50 and 70 ml/minute.
6. As determined by direct measurement or calculated by an accepted formula, such asthe CKD-EPI creatinine equation (2021) that are refitted without race.
7. National Kidney Foundation, eGFR Calculator: https://www.kidney.org/professionals/kdoqi/gfr_calculator

If requesting these services, please send the following documentation to support medical necessity:

- Copy of final summary report from multidisciplinary transplant team

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Pancreas transplantation is used in patients with type 1 diabetes. After a successful transplantation, many diabetic patients no longer require insulin. Due to the danger of organ rejection in the short- or long-term, pancreas transplant recipients need to take immunosuppressive drugs.

Most pancreas transplants are done in conjunction with (at the same time or following) a kidney transplant. A reason for this combination transplant is that the pancreas induces a strong immune response and therefore requires larger doses of immunosuppressive drugs that can jeopardize kidney function and the transplanted pancreas.

The first clinical pancreas transplant (of any type) was done in 1966. Initially there was a low success rate but clinical outcomes improved in the 1980s due to advances in surgical techniques and the introduction of

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cyclosporine for immunosuppression. Newer immunosuppressants, Tacrolimus and mycophenolate mofetil, were introduced in 1994 and 1995, respectively. Since 1994, there have been improved graft survival rates in patients receiving pancreas transplants alone (PTA).

Medical Technology Assessment Committee (MTAC)

Pancreas Transplant

12/12/2001: MTAC REVIEW

Evidence Conclusion: Only one article reported data on patients receiving pancreas transplants alone. The methodology was not well described, and the intervention procedures varied dramatically over time. The article reported on the experience of the institution; it was primarily a review article rather than a research study. The case series portion of this article had inadequately described methodology and is subject to selection and observation biases. Due to lack of quality scientific data, the evidence is insufficient to draw conclusions about the effect of this technology on health outcomes.

Articles: The search yielded 36 articles, many of which were review articles, opinion pieces or dealt with pancreas transplantation in conjunction with kidney transplantation. There were no empirical studies that presented separate data on the outcomes of PTA. There were several case series that included both pancreas transplantation in conjunction with kidney transplantation and PTA, but the data were not divided by type of procedure. Only one article presented some data separately for patients receiving PTA. This was primarily a review article and included case series data. This study was critically appraised:

Sutherland DER, Gruessner RWG, Dunn DL, Matas AJ, Humar A, Kandaweamy R, Mauer M, Kennedy WR, Goetz FC, Robertson RP, Gruessner AC, Najarian JS. Lessons learned from more than 1,000 pancreas transplants at a single institution. Ann Surg 2001; 233: 463-501.

The use of Pancreas Transplant alone in the treatment of Juvenile Diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/12/2001	10/05/2010 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 11/03/2015 MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/02/2019MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC	01/10/2022

MDCRPC Medical Director Clinical Review and Policy Committee

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Revision History	Description
05/07/2019	MPC approved KP National criteria for Pancreas Transplant.
03/03/2020	MPC approved proposed changes from KP National Transplant Services
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”
01/10/2022	MPC approved proposed changes from KP National Transplant Services. 60-day notice is not required.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Loss-of-Heterozygosity Topographic Genotyping with PathfinderTG®

- PancraGEN

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	MolDX: Molecular Diagnostic Tests (MDT) (L36256)
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Integrated Molecular Pathology (Topographic Genotyping) - PathFinderTG (A-0632) MCG* guideline for medical necessity determinations. This test is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider
- Genetics consult if applicable & requesting provider is not a geneticist

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Background

Pathologic analysis of tissue samples is central to the diagnosis of cancer; however, there are some instances when these results may by inconclusive. Pathfinder TG® is a molecular DNA-based cancer diagnostic test that can aid diagnosis when pathology results are inconclusive. The Pathfinder TG® test uses a method known as topographic genotyping that combines pathology and molecular analysis using specific genetic marker panels to identify acquired mutations in a variety of difference types of cancer.

Medical Technology Assessment Committee (MTAC)

Pathfinder TG®

06/18/2012: MTAC REVIEW

Evidence Conclusion: Analytic validity - No studies were identified that evaluated the analytic validity of loss-of-heterozygosity based topographic genotyping with Pathfinder TG® (AHRQ 2010). Clinical validity- Fifteen

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retrospective studies with methodological limitations were identified that evaluated the clinical validity of loss-of-heterozygosity based topographic genotyping with Pathfinder TG®. Details on patient characteristics, treatments, clinical definitions, and statistical methods were limited. Additionally, only 3 studies had more than 50 patients and it is possible that these publications analyzed the same patient population. There is insufficient high-quality evidence to determine the clinical validity of loss-of-heterozygosity based topographic genotyping with Pathfinder TG® (AHRQ 2010). Clinical utility - No studies were identified that evaluated the clinical utility of loss-of-heterozygosity based topographic genotyping with Pathfinder TG® (AHRQ 2010). Conclusion:
There is insufficient evidence to determine the analytic validity, clinical validity, and clinical utility of loss-of-heterozygosity based topographic genotyping with Pathfinder TG®.
Articles: The literature search revealed a 2010 AHRQ technology assessment that evaluated the analytic validity, clinical validity, and clinical utility of loss-of-heterozygosity based topographic genotyping with Pathfinder TG®. Studies were excluded if they had less than 25 subjects. No relevant articles were identified after the 2010 ARHQ review. The following technology assessment was selected for review: Trikalinos TA, Terasawa T, Raman G et al. A systematic review of loss-of-heterozygosity based topographic genotyping with PathfinderTG®. AHRQ Technology Assessment Program (Project ID GEND0308). March 2010. See Evidence Table.

The use of Pathfinder TG® does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
No Specific Codes – *often submitted as 81479 Unlisted molecular pathology procedure*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
07/03/2012	07/03/2012[MDCRPC], 05/07/2013[MDCRPC], 03/04/2014[MDCRPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC]	03/04/2014

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Positron Emission Mammography (PEM)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	*Medicare has not specifically addressed this technology in its coverage decision documents. See PET Scan criteria.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Breast cancer is the most common non-skin cancer among women in the United States, and one of the leading causes of cancer death among women of all races. Although the incidence rate has increased, there has been a steady decline in the breast cancer death rate since the early 1990s, mostly due to screening, better awareness, and improved treatment. Early detection and accurate staging and restaging of recurrent breast cancer are important to define appropriate therapeutic strategies and increase the chance of a cure (Bartella 2006, CDC 2010, Pan 2010).

Mammography remains the gold standard screening method for women at average risk for breast cancer. It is relatively inexpensive, requires a low dose of radiation, and reliably identifies malignant tumors especially those that are too small to feel. It can also be used to investigate breast lumps and other symptoms. Although the benefit of mammographic screening is widely accepted, its limitations and failure to detect all breast cancers are also recognized. It is reported that the false negative rate of screening mammography ranges between 20-30%. It also has a low specificity resulting in a large number of unnecessary procedures. It is reported that only 25-45% of the biopsies done based on mammographic abnormalities result in a diagnosis of carcinoma. Diagnostic mammography is commonly used to identify possible breast cancers in women with signs and symptoms and has a higher sensitivity (85-93%) compared with screening mammography (Bartella 2007).

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Ultrasound (US) imaging may be used to evaluate abnormalities detected during a breast exam or mammogram and is useful in differentiating solid tumors from fluid filled cysts. It is considered the imaging technique of choice for evaluating palpable masses in women younger than 30 years as well as in pregnant and lactating women. It can also be used for the guidance of interventional procedures and treatment planning for radiation therapy. US is easily accessible, relatively low in cost, and does not involve the use of ionizing radiation. However, it cannot detect microcalcifications, can be time consuming, and its performance is operator dependent (Ferrara 2010).

Breast MRI using a special receiver and injected contrast material is more sensitive and accurate than mammography and ultrasound in detecting invasive lobular cancer. MRI detects blood flow to lesions and does not expose the patient to radiation. The increased blood flow is indicative of vascularization frequently found in cancer. MRI however, has some disadvantages; it can lead to false positive results as both benign and malignant lesions can absorb the contrast, it is less sensitive in detecting in situ cancers, and its interpretation is challenged when the breast is under estrogen modulation during menstrual cycle or HRT use, which affects the glandular tissue of the breast. In addition, MRI is not indicated and/or tolerated by many patients due to renal disease, metallic implants, claustrophobia, large body size, or general medical condition. It is a costly test to use for screening and is not a substitute for mammography. MRI is recommended for screening women at very high risk of breast cancer especially for the BRCA1 and BRCA2 subgroups. Other accepted indications include patients presenting with axillary adenopathy and an unknown primary, patients with equivocal mammograms, the differentiation of scar versus recurrence at lumpectomy site, as well as other indications (Tafreshi 2010, Philpotts 2011, Schilling 2011).

Nuclear breast imaging refers to functional imaging of the breast through the use of radiopharmaceuticals such as 18 F-fluorodeoxyglucose (18FDG) or 99mTc-sestamibi. It takes advantage of the differences in metabolic activity between tumor and normal tissue. Functional imaging can thus show changes in cell metabolism that are due to malignancies as the majority of primary and metastatic cancers take up more glucose than the adjacent normal tissues. Positron emission tomography (PET) with the radiotracer FDG may be able to detect cancer even before vascularization as cancer cell metabolism is usually heightened prior to the stimulation of new vessel growth. It has the potential of improving detection of cancer in dense breasts, illustrating the extent of the disease for surgical planning, and distinguishing between recurrent cancer and scar tissue (Schilling 2011).

The use of whole-body PET (WB- PET) and PET/CT is limited due to the low sensitivity and positive predictive value in detecting early stage breast cancer, invasive lobular and ductal carcinoma in situ, as well regional lymphadenopathy. The reasons reported for this low sensitivity include low spatial resolution, and lower level of FDG tracer uptake in some breast malignancies compared to other cancers (Schilling 2011).

Positron emission mammography (PEM) is a modification of PET that allows for a much more spatial resolution by putting the photon detectors directly on the breast. PEM uses similar principles as PET but is a breast specific imaging tool. Both work through the introduction and detection of a positron-emitting glucose analog 18F-FDG as the imaging radiotracer. The 18F-FDG analog decays by emitting a positron that is annihilated within a few millimeters resulting in emission of two gamma rays that radiate in opposite directions and are detected by the PET instrument. The resolution of PEM is increased by allowing the detectors to be directly placed on the breast. Gentle compression provides the advantage of spreading out the breast tissue for imaging. PEM devices use 2 moving detector heads mounted on compression paddles, with a similar configuration and size as a traditional mammography system. This allows direct correlation of the initial and recurrence images obtained by both devices. PEM images can also be reconstructed into 3D for localization of abnormalities. It is reported that the technique used allows capturing sharp detailed images of breast lesions as small as 2 mm, and the detection of small foci of ductal carcinoma in situ without depending on the presence of calcification for its identification. The whole-body radiation dose the patient receives from PEM is approximately three times higher than that of a mammogram, which may be a barrier to using it as a screening modality in the general population. PEM also cannot take the place of breast cancer staging performed with whole-body PET because PEM is limited to breast views only. It is reported that the same benign conditions that cause high FDG uptake in PET (e.g. infection, inflammation and fat necrosis) may cause false positive results in PEM. Glucose control is another problem with PEM as it is with PET; women with inadequately controlled diabetes cannot undergo either procedure (Tafreshi 2010, Ferrara 2010, Moadel 2011).

PEM 2400 PET scanner and PEM Flex devices have received FDA clearance to perform PET imaging of the breast under gentle compression for patients with confirmed breast cancer.

Medical Technology Assessment Committee (MTAC)

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Positron Emission Mammography (PEM)

08/15/2011: MTAC REVIEW

Evidence Conclusion: Berg et al (2006) study (Evidence table 1) evaluated PEM diagnostic performance in 77 women with 77 index and 15 incidentally discovered lesions, all histologically proven breast cancer. PEM identified 91% of DCIS, and had an overall sensitivity of 93% for the index cancers, and 90% when incidental cancers were included. Combined with conventional imaging (mammography and ultrasonography) the sensitivity of PEM improved to 98%, but with a reduced specificity. The study had its limitations and used nonstandard method for calculating the standardized uptake value (SUV). Berg et al, 2011 (Evidence table 2) examined the diagnostic performance of PEM and its impact on surgical management compared with MRI in 388 women with newly diagnosed, histologically proven breast cancer. The results of the study showed that PEM and MRI had an overall similar accuracy. MRI was more sensitive and less specific than PEM at the lesion level and in detecting incidental additional cancers. MRI was also more accurate than PEM in assessing disease extent and need for mastectomy. Still, as the authors indicate, "the combination of both MRI and PEM did not fully depict the disease extent, particularly in cases with extensive intraductal component, multifocal disease, or multicentric disease, the patient population that would benefit from accurate assessment of the disease extent". Schilling et al, 2011 (Evidence table 3) also compared the performance of FDG-PEM vs. MRI, including their effect on presurgical planning in 208 patients with newly diagnosed, biopsy proven breast cancer. Only 76% or the participants were included in the analysis. Overall, the results show that PEM and MRI had similar sensitivities of 92.8% in depiction of index cancerous lesions. Similar to the Berg's study, MRI was more sensitive and less specific than PEM in detecting additional unsuspected ipsilateral lesions but, the difference was statistically insignificant. However, the authors did not discuss if they performed any power analysis to determine the appropriate sample size. The study did not examine whether PEM results alone influenced surgical treatment as all imaging results were available to the surgeons prior to surgery treatment.

Articles: The literature search revealed around two hundred articles on PET exams for the breast. Many were review articles, technical reports, or studies on the diagnostic accuracy of FDG-PET rather than PEM which is the focus of the review. There were a limited number of studies that compared the accuracy of PEM with mammography or MRI, and most were conducted by one PEM working group. The following studies were selected for critical appraisal: Berg WA, Weinberg IN, Narayanan D, et al. High resolution fluorodeoxyglucose positron emission tomography with compression ("positron emission mammography") is highly accurate in depicting primary breast cancer. *Breast J*. 2006;12:309-323. See Evidence Table. Berg WA, Madsen KS, Schilling K, et al. Breast cancer: comparative effectiveness of positron emission mammography and MR imaging in presurgical planning for the ipsilateral breast. *Radiology.* 2011;25:59-72. See Evidence Table. Schilling K, Narayanan D, Kalinyak JE, et al. Positron emission mammography in breast cancer: presurgical planning f comparison with magnetic resonance imaging. *Eur J Nucl Med Mol Imaging* 2011;25:23-36. See Evidence Table.

The use of Positron Emission Mammography (PEM) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

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	06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Perfusion Computed Tomography (PCT) in Patients with Acute Stroke

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Computed Tomography Cerebral Perfusion Analysis (CTP) (L38700)
Local Coverage Article	Billing and Coding: Computed Tomography Cerebral Perfusion Analysis (CTP) (A58225)

For Non-Medicare Members

Medical necessity review no longer required.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Acute stroke is the third leading cause of death and the third most costly adult disease in the United States. Ischemic stroke is the more common type, and hemorrhagic stroke the more serious. Patients with acute ischemic stroke, who have intracranial arterial obstruction, have poorer prognosis and higher probability of deteriorating at 24 hours. When a cerebral artery is occluded, a core of the brain tissues dies rapidly. Surrounding this infarct core is an area of brain tissue that is hypoperfused but does not die quickly due of collateral blood flow. This area is called the ischemic penumbra, and its fate depends on the rapid reperfusion of the ischemic brain. The presence and extent of the ischemic penumbra is time dependent and may vary among patients. 90-100% of those with supratentorial arterial occlusion show an ischemic penumbra in the first 3 hours of a stroke, but only 75-80% may still have penumbral tissue at 6 hours after a stroke onset. Thus, the rapidity of diagnosis, distinction between types of stroke, and determining the extent and duration of ischemia are all critical in selecting the treatment strategy (Wintermark 2005, Muir 2005, Brunser 2009).

The ischemic penumbra is potentially salvageable with the administration of thrombolytic agents, but irreversibly damaged tissue will not benefit from reperfusion and may be at a higher risk of hemorrhage after thrombolytic therapy. Currently intravenous tissue plasminogen activator (tPA) administered within 3 hours of symptom onset is the only FDA approved drug for acute stroke in North America. Clinical trials showed that it can significantly reduce the effects of stroke and reduce permanent disability when administered within a limited time period. Thrombolytic drugs however, can also cause serious bleeding in the brain which could be fatal, and thus it is crucial to determine which patient would likely benefit from or likely to be harmed by the treatment. This narrow time window for using thrombolytic therapy in patients with acute nonhemorrhagic stroke intensified the need for

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an accurate, rapid, and accessible neuro-imaging technique that is able to identify and quantify ischemic penumbra. MR perfusion, xenon CT, PET and SPECT have been used but are limited by their availability, cost and/or patient tolerance. Clinical assessment scales that predict arterial occlusion have also been developed but are not highly accurate and their use is restricted to the middle cerebral artery (Lev 2001, Hoeffner 2004, Brunser 2009).

Conventional noncontrast CT (NCCT) is the standard initial imaging modality used to evaluate patients with acute stroke symptoms. It is widely available, convenient, and has a high sensitivity for the detection of intracranial hemorrhage which represents an absolute contra-indication to thrombolytic therapy. The Alberta Stroke Program Early Computed Tomography Score (ASPECTS) was developed and validated in 1990 to quantify early ischemic changes on CT scans in the middle cerebral artery territory, before thrombolytic therapy. However, NCCT provides only anatomic and not physiologic information about the vessels. Researchers found that dynamic imaging after rapid injection of contrast material using CT or MRI allows assessing tissue hemodynamics from respective contrast curves, i.e. bolus tracking. MRI is currently the preferred imaging method for determining the core and penumbra tissue. It is the modality used in major clinical trials evaluating the use of tPA for stroke patients. However, MRI scanners may not be available or accessible in some hospitals and rapid imaging of acute stroke patients is of vital importance. CT scanners on the other hand are widely available in emergency rooms, and recent advances in CT and computer technology permit the calculation of contrast curves on a pixel-by-pixel basis providing high resolution perfusion CT (PCT) maps. Perfusion CT imaging has the potential of providing rapid assessment of the structural and functional status of cerebral vessels in patients who would have already undergone unenhanced head CT to exclude acute hemorrhage (Hoeffner 2004, Nabavi 2007).

PCT imaging, using standard nonionic iodinated contrasts can be performed as an adjunct to conventional CT imaging. It adds only a few minutes to the examination and does not require transferring the patient to another imaging device. PCT can be done with any spiral CT scanner and has the advantage of assessing both reversible and irreversible ischemia by generating parametric maps of cerebral blood volume (CBV), cerebral blood flow (CBF), and contrast mean transit time (MTT). The ultimate goal is to discriminate three types of tissues components: 1. The ischemic core that has the most severe ischemia and is the tissue at maximum risk of infarction, 2. Potentially salvageable tissue with mild to moderate ischemia, and 3. Tissue with normal hemodynamics. Unlike conventional CT which is normally assessed visually, perfusion imaging requires quantification of the enhancement in tissues and blood at certain time points following intravenous injection. By demonstrating a regional reduction in perfusion and prolongation of transit time, functional PCT can potentially make a positive diagnosis of acute cerebral ischemia and assess prognosis within the first few hours of stroke onset, when conventional CT images are typically normal. The perfusion maps can be generated in a short time at any workstation equipped by the appropriate software (Hoeffner 2004, Parsons 2005, Miles 2006, Nabavi 2007, Popiela 2008).

PCT however, has limited spatial coverage (20-48 mm thickness) and may not provide information on an ischemia located outside the scanning level. It also cannot detect small lacunae due to its limited spatial resolution. There is considerable variability in the protocols used for PCT scanning, perfusion post procession techniques, and in the threshold between scanners for CBV, CBF, and time to peak enhancement (TTP). Moreover, the reproducibility of PCT postprocessing has not been fully validated, the quantitative accuracy of the results is debated, and the quantitative analysis of the perfusion maps is still evolving, may be time consuming, and is less convenient in an emergency setting. It also has the disadvantage of exposure to ionizing radiation and use of iodinated contrast which may be associated with contrast-induced nephropathy in high risk patients (Wintermark 2005, 2008, Miles 2006, Kohrmann 2007).

The FDA has cleared several software packages (CT perfusion 4, syngo Neuro PBV, syngo perfusion CT and others) for post processing images acquired with CT imaging systems for patients with suspected stroke.

Medical Technology Assessment Committee (MTAC)

Perfusion computed tomography (PCT) for the Treatment of Acute Stroke

08/03/2009: MTAC REVIEW

Evidence Conclusion: Several small studies assessed the accuracy of PCT in identifying the site of occlusion and characterizing the infarct. All had their advantages and limitations; the majority was multicenter, used MRI or follow-up MRI, CTA or clinical condition as gold standards, and had blind assessment of results. However, they were mainly retrospective, did not assess the time of recanalization and /or combined the results of those who received and did not receive thrombolytic therapy, all of which are potential sources of bias and confounding.

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In a small prospective study, Murphy and colleagues (2006) investigated whether PCT can be used to differentiate between penumbra and infarcted tissue. They used noncontrast CT at 5-7 days as a gold standard and showed that the pair of CBV and CBF derived from PCT had a sensitivity and specificity of 97.0% and 97.2% respectively, in differentiating an infarct from a penumbral tissue. Tan and colleagues 2007, retrospectively compared different CT modalities and found that decreased cerebral blood volume (CBV) derived from PCT was more accurate than CT angiography (CTA) in predicting of the anatomic distribution of final infarct core (sensitivity 80.4%, specificity 96.8%), while CTA was more accurate in determining the site of occlusion (sensitivity 94.6%, specificity 100.00%).
Several other small studies including Schramm et al (2004, N=22, Schaeffer 2008, N=45, and Wintermark 2007, N=42) found that the PCT with or without and CTA correlate highly with MRI results in measuring the lesion volume in patients with acute stroke. In conclusion, the overall published evidence suggests that cerebral blood volume and cerebral blood flow values derived from a baseline PCT may have a potential use in differentiating an infarct from penumbral tissue. However, there are no large randomized trials that examined the use of perfusion CT for selection of patients for thrombolysis. All published randomized controlled trials to date used MRI for the selection of the therapeutic strategy based on the presence or absence of tissues at risk. The use of PCT in acute stroke patients needs to be to be investigated further in large RCTs to determine whether it could be used to guide treatment decisions and improve outcomes.
Articles: The search yielded almost three hundred articles on brain CT in acute stroke patients. Many were review articles, opinion pieces, or dealt with technical aspects of the scan.
The search results were screened for the studies on: 1. Accuracy of PCT in determining the site of vessel occlusion, infarct core, salvageable brain tissue, or collateral flow, and in predicting final infarct volume in patients with suspected acute stroke: The literature search identified around thirty prospective and retrospective studies that evaluated the accuracy of PCT in identifying the site of occlusion and characterizing the infarct. PCT with or without noncontrast CT (NCCT) was compared with MRI, CT angiography, or follow-up NCCT. All studies were small with population sizes ranging from 22 to 44, except for one retrospective study that included 132 patients and evaluated both the accuracy and prognostic value of PCT compared to other CT imaging modalities. The studies presented the results in sensitivity and specificity, or just correlated the findings with those of MRI. Few small studies with sample sizes ranging from 19 to 44 patients, evaluated the accuracy of PCT in predicting prognosis of ischemic stroke. Predicting prognosis was based on comparison with delayed perfusion MRI, follow-up CT, or monitoring the evolution of each patient's clinical condition. The majority of the studies were retrospective, used earlier generations of multiline CT scanners with limited spatial coverage, and no adjustments were made for the potential confounding factors. 2. Impact of PCT in management decisions and patient outcomes: The literature search did not reveal any randomized controlled trials that examined the impact of perfusion CT on the management of ischemic stroke patients and /or clinical outcomes. There was one small case-control study that investigated whether the lesion volume on PCT maps within 3 hours of onset of symptoms would predict final infarct volume, and the effect of intravenous tPA on affected brain tissue. The study however, had several limitations and used the 8-section multidetector scanner. The following three studies on the accuracy of PCT in characterizing the cerebral infarct were selected for critical appraisal: Murphy BD, Fox AJ, Lee DH, et al. Identification of penumbra and infarct in acute ischemic stroke using computed tomography perfusion-derived blood flow and blood volume measurements. Stroke 2006; 37:1771-1777. See Evidence Table. Tan JC, Dillon WP, Liu S, et al. Systematic comparison of perfusion-CT and CT-angiography in acute stroke patients. Ann Neuro. 2007; 61:533-543. See Evidence Table. Shramm P, Schellinger PD, Klotz E, et al. Comparison of perfusion computed tomography and computed tomography angiography source images with perfusion-weighted imaging and diffusion-weighted imaging in patients with acute stroke of less than 6 hours duration. Stroke 2004; 35:1652-1658. See Evidence Table.

The use of Perfusion computed tomography (PCT) for the treatment of acute stroke does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare & Non-Medicare-Medical necessity review no longer required

CPT® or HCPC Codes	Description
0042T	Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time

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Date Created	Date Reviewed	Date Last Revised
09/16/2009	Established annual review because of Medicare criteria 04/05/2011 [MDCRPC], 02/07/2012 [MDCRPC], 12/04/2012 [MDCRPC], 10/01/2013 [MPC], 08/05/2014 [MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	10/17/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/26/2015	Added CPT code
09/08/2015	Revised LCD L34886 Non-Covered Services.
04/26/2019	Per discussion with Kaiser Permanente neurology and Kaiser Permanente neuro-radiology, this imaging is considered medically necessary in the setting of an acute stroke to determine brain at risk for possible immediate intervention.
09/07/2021	Removed LCD L35008 and LCA A57642 and added LCD L38700 and LCA A58225 under Medicare section.
10/17/2022	Updated Medicare no longer requires review in applicable codes section as this procedure only done in and emergent setting.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Positron Emission Tomography (PET) Scan

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Positron Emission Tomography (PET) Scans (220.6) (General) *Effective January 1, 2022, the Centers for Medicare & Medicaid Services removed the umbrella national coverage determination (NCD) for Positron Emission Tomography (PET) Scans. In the absence of an NCD, coverage determinations for all oncologic and non-oncologic uses of PET that are not included in another NCD under section 220.6 will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act. All PET indications currently covered or non-covered under NCDs under section 220.6 remain unchanged and MACs shall not alter coverage for indications covered under NCDs.* ***Refer to the Noridian Local Coverage Article (A54668) listed below for coverage indications for specific radiopharmaceuticals**.* • PET for Perfusion of the Heart (220.6.1) • FDG PET for Myocardial Viability (220.6.8) • FDG PET for Refractory Seizures (220.6.9) • FDG PET for Dementia and Neurodegenerative Diseases (220.6.13) • Positron Emission Tomography (FDG) for Oncologic Conditions (220.6.17) • Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (220.6.19) *(not covered per Medicare NCD)* • Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease (220.6.20)
Local Coverage Determinations (LCD)	None
Local Coverage Article*	Positron Emission Tomography Scans Coverage (A54668) ***Documents coverage indications for PET scans and radiopharmaceuticals including but not limited to:** *A9587* Gallium GA-68 Dotatate (neuroendocrine tumors) *A9515* Choline C-11, diagnostic (prostate cancer) *A9588* Fluciclovine F-18 (Axumin PET - prostate) *A9593, A9594, A9496, A9800* Gallium GA-68 PSMA-11 (PSMA PET – a) *A9595* Piflufolastat F-18 (PSMA PET – prostate) A9602 Fluorodopa F-18 (Brain PET—Parkinsons)

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For Non-Medicare Members

No Oncologic Diagnosis Confirmed
In the absence of a confirmed oncological diagnosis, PET results may be needed to determine the optimal location to perform an invasive diagnostic procedure due to difficulty accessing potential biopsy sites because of anatomical complexity as described in the medical records.

Solitary Pulmonary Nodule (SPN) Solid or Part Solid	Indications
	1) Newly discovered, without known prior malignancy; and the following are met: a) A concurrent thoracic CT has been performed AND b) A single indeterminate or possibly malignant lesion more than 0.8 cm in diameter has been detected AND c) Not recommended for ground glass opacaities/nodules 2) The purpose of the scan is to determine likelihood of malignancy in order to plan management of care

Oncological Diagnosis Confirmed
For patients with a biopsy proven or confirmed oncologic diagnosis (typically biopsy proven), PET scans may be medically necessary for any of the listed diagnoses below when standard staging/restaging diagnostic and imaging studies are inconclusive AND further characterization is needed to make management decisions. The expected change in clinical management must be documented in the clinical records. The grid below contains the letters TNM. T is for tumor and the number associated describes the tumor. N is for lymph node involvement. M is for extent of metastasis.

Oncological Diagnosis	Indications
Anal	1) New diagnosis – consider PET scan for staging of T3 – T4, N0; or with any T, node positive
Breast Cancer	1) Stage I, II: PET scan is not recommended 2) Stage III A or B: PET scan is not recommended for operable stage III. May be helpful in non opearable stage III if equivocal findings on CT and bone scans 3) Stage IV: PET not routinely covered but may be indicated if conventional imaging is equivocal and results will change management 4) The following indications are not covered for PET scans a) Routine surveillance b) Initial diagnosis of breast cancer and the staging of axillary lymph nodes
Cervical	<u>Staging for Invasive Cervical Cancer as an Adjunct to Conventional Imaging:</u> An FDG PET scan is reasonable and necessary for the detection of metastases during the pre-treatment management phase (i.e., staging) in patients with newly diagnosed locally advanced cervical cancer with no extra-pelvic metastasis on conventional imaging tests, such as computed tomography (CT) or magnetic resonance imaging (MRI). Use of FDG PET as an adjunct may more accurately assist in the non-invasive detection of para-aortic, pelvic nodal involvement and other metastases in the pre-treatment phase of disease. The following conditions must be met: 1) If stage is less than or equal to IB1: PET not routinely recommended 2) If stage is IB2 or greater: CT, PET scan or MRI as clinically indicated
Colorectal Cancer	1) Initial staging Colon cancer appropriate for resection: Not routinely indicated and should not supplant contrast-enhanced CT. a) PET may be indicated for metastatic adeno carcinoma of the large bowel when there is potentially surgically curable metatstatic disease 2) Restaging a) When the post-operative carcinoembryonic antigen (CEA) or liver function tests (LFTs) remain elevated and other attempts at imaging are negative OR

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Oncological Diagnosis	Indications
	b) Evaluation of a potentially resectable metastatic lesion in order to confirm that it is resectable and to confirm absence of other sites of disease OR c) Differentiating local tumor recurrence from post-operative and/or post-radiation scarring 3) Surveillance: not recommended 4) Monitoring therapy progress is not indicated
Esophageal	For staging and restaging 1) If no evidence of metastatic disease on chest/abdominal CT and 2) Individual is a candidate for aggressive therapy
Gastric/GE Junction	For staging and restaging (not necessary for T1 patients) 1) If no evidence of metastatic disease on chest/abdominal CT and 2) Individual is a candidate for aggressive therapy
Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)	Kaiser Permanente endorses the recommendations for PET imaging using somatostatin receptor (SSR)-PET* for neuroendocrine tumors from the National Comprehensive Cancer Network® (NCCN) Guideline for Neuroendocrine and Adrenal Tumors. *(log-in required to access)* *This service is available at multiple Kaiser Permanente facilities. Please click to view Lutathera criteria
Head and Neck Cancers	1) Staging indicated for: a) Stage III-IV disease of oral cavity, oropharynx, glottic larynx and supraglottic larynx, hypopharynx, ethmoid sinus b) Nasopharynx, Paranasal sinus, and Maxillary sinus: Imaging optional for evaluation of distant metastases (i.e. chest, liver, bone) for stage III-IV disease. Naso-pharyngeal cancer may be appropriate for PET for stage II disease if lymph node positive. 2) Restaging (only for stage III – IV cancers) a) Post-treatment evaluation of cancers of head and neck (minimum 12 weeks after radiation completed). If the study is negative, repeat PET not indicated for surveillance. 3) Lip: No PET is indicated in the absence of advanced stage disease (stage III) 4) Salivary: No PET is indicated; CT & MRI as needed 5) Unknown primary in the head and neck (squamous cell carcinoma, adenocarcinoma, or anaplastic/undifferentiated epithelial tumor on FNA) when no tumor is evident on initial eval: Initial evaluation should consist of a flexible fiberoptic laryngoscopy as well of CT of the neck **For thyroid see below.**
Lung Cancer – Non-small cell	1) A positive PET scan finding can be caused by infection or inflammation, including absence of lung cancer with localized infection, presence of lung cancer with associated infection, and presence of lung cancer with related inflammation. A false negative PET scan can be caused by a small nodule, low cellular density, or low tumor activity for FDG. Serial PET scans are not recommended to follow response to therapy; conventional imaging is preferred. No need for bone scan if PET scan already done. 2) Initial staging: Indicated for stages I-III A or B when active treatment is planned. Not typically recommended for known stage IV. Documentation must show how results will alter treatment for stage IV treatment 3) Radiation planning in patients with significant atelectasis, IV contrast is contraindicated and when improved targeting is sought. (if meets criteria 1 above) See Solitary Pulmonary Nodule Above

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Oncological Diagnosis	Indications
Lung Cancer – Small Cell **Recommended clinical trials only**	1) Initial staging small cell lung cancer (SCLC) when it has been determined to be of limited-stage (i.e. limited to the ipsilateral hemithorax and regional lymph nodes) after standard staging evaluation AND patient is a potential surgical candidate or for a combined modality approach with radiation and chemotherapy 2) Restaging – not recommended for routine follow-up after initial therapy See Solitary Pulmonary Nodule Above
Hodgkin Disease Lymphoma	1) Initial staging a) Essential during initial work-up 2) Early/interim re-staging a) Prognostic value is seen with a PET after 2-4 cycles of standard dose chemotherapy, if change in treatment is anticipated 3) Restaging a) After completion of chemotherapy to assess treatment response and characterize residual mass at the end of treatment OR b) after radiation completion, typically at 3 months 4) Surveillance is not recommended due to risk of false positives 5) Pet Scan – field determination for radiation therapy planning
Melanoma	1) Stage I & II not for routine staging, only to evaluate specific signs or symptoms (CT, MRI also options) 2) Stage III or IV; recommended for baseline staging and/or to address specific signs and symptoms (CT, MRI also options)
Multiple Myeloma	**Effective until 06/01/2023** 1) Skeleteal survey with plain films is initial imaging of choice 2) Staging and restaging if standard imaging and lab tests cannot define extent of disease and results will change management **Effective 06/01/2023** 1) Whole-body imaging low-dose CT scan is preferred modality for patient initial workup for patients suspected of having MM, or Solitary Plasmacytoma. 2) FDG/PET CT is reserved for situations when initial whole-body low-dose CT or MRI is non diagnostic. 3) Whole-body imaging low dose CT is preferred for all Myeloma follow up.
Non-Hodgkin's Lymphoma	Low grade lymphoma: PET scan may be indicated for Stage I & II but not routinely for Stage III and IV unless management would be changed See Lymphoma Grade Table below Intermediate & High Grade Lymphoma: PET scan is indicated for restaging after completion of therapy (chemotherapy or radiation); not for surveillance See Lymphoma Grade Table below 1) Diffuse large B-cell lymphoma (intermediate) a) Initial staging is essential b) Restaging i) at completion of treatment (wait 8 weeks minimum) c) Early/interim restaging following 2-4 cycles of chemotherapy is controversial and should be done only if a planned change in management is documented. Biopsy of PET positive sites should be considered 2) AIDS-related B-cell lymphoma a) Initial staging is essential 3) Peripheral T-cell Lymphoma a) Initial staging is essential b) Interim restaging for all ALCL and ALK+ i) Repeat studies for all positive studies c) Restaging

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Oncological Diagnosis	Indications
	i) at completion of treatment ii) Repeat studies for all positive studies 4) Extranodal NK/T-cell lymphoma nasal type a) Initial staging is essential b) Post-radiation therapy the role remains uncertain 5) Pet Scan – field determination for radiation therapy planning
Occult Primary	1) Not routinely recommended. Documentation must clearly identify the clinical reason for such testing.
Ovarian	1) PET scan not routinely indicated for initial staging 2) Restaging: may be covered if conventional imaging (CT, MRI) give indeterminate results and PET will alter management 3) May be approved if there is a solitary lymph node that is a possible candidate for surgical resection
Prostate	1) Use is unproven and should be provided within a clinical trial setting
Prostate – Axumin PET	**Effective until June 01, 2023** **Covered for:** • Subsequent treatment strategy for individuals with prostate cancer who have a rising PSA (defined below) and have previously been treated with prostatectomy and/or radiation therapy. Both CT abdomen , CT pelvis, and bone scan must be negative for recurrence • Patient must be a candidate for local therapy (such as removal of prostate after prior XRT, or removal of a local recurrence , or focal radiation) If the patient has diffuse metastatic disease already diagnosed, this imaging is not needed. • Original clinical stage T1-T2, NX or NO and • Life expectancy > 10 years and • PSA now < 10ng/mL and • PSA ≥1 or <1 with rapid PSA doubling time (doubled in less than 6 months) **Not covered for:** • Initial treatment strategy for newly diagnosed prostate cancer • Surveillance of individuals with localized/advanced prostate cancer, who have completed definitive therapy or are receiving maintenance therapy and whose PSA is not rising. **Effective June 01, 2023** Axumin no longer recommended; please see PSMA PET criteria here
Prostate- PSMA PET	**Effective until June 01, 2023** ***PSMA PET currently being reviewed on a case-by-case basis based on medical necessity, until June 01, 2023:** Gallium GA-68 PSMA-11 (PSMA PET – prostate) A9593, A9594, A9596 Piflufolastat F-18 (PSMA PET – prostate) A9595 **Effective June 01, 2023** Please see PSMA PET criteria here
Soft Tissue Sarcoma	1) Not routinely recommended 2) Baseline staging, for cases when grade is uncertain or when conventional imaging has not conclusively evaluated the possibility of distant metastasis 3) Differentiation of suspected tumor from radiation or surgical fibrosis
Thyroid	1) Localization to plan treatment for papillary or follicular thyroid carcinoma with the following: a) Previously treated with thyroidectomy and radioiodine ablation AND b) Thyroid Globulin (TG-antibody) positive (stimulated or on suppression) greater than10 AND c) Negative structural imaging i.e. ultrasound and CT negative

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Oncological Diagnosis	Indications
	2) Initial staging OR follow-up for localization to monitor response to prior treatment (surgery, I131, radiation therapy, or tyrosine kinase inhibitor), for treatment planning or to predict prognosis for the following: a) Aggressive tumors confirmed by histology (Hurthle cell, poorly differentiated, anaplastic) OR b) Aggressive behavior i.e. any tumor with confirmed metastasis showing progression on structural imaging or by rising TG level despite prior treatment
All other cancers not listed above	1) Evaluated on a case by case basis, in conjunction with consultants and national guidelines

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WHO Classification	"Working Formulation" from the N-HLPC Project
The Indolent Lymphomas **B Cell Neoplasms** • **Small lymphocytic lymphoma/B-cell chronic lymphocytic leukemia** • **Lymphoplasmacytic lymphoma** • **Plasma cell myeloma/plasmacytoma** • **Hairy Cell leukemia** • **Follicular lymphoma (grade I and II)** • **Marginal zone B-cell lymphoma** • **Mantle cell lymphoma** **T Cell Neoplasms** • **T-cell large granular lymphocyte leukemia (LGL disease)** • **Mycosis fungoides** • **T-cell prolymphocytic leukemia** • **T-cell large granular lymphocyte leukemia** **Natural Killer cell neoplasm** • **Natural killer cell large granular lymphocyte leukemia**	**Low Grade** A. Malignant lymphoma Small lymphocytic consistent with CLL plasmacytoid B. Malignant Lymphoma, follicular Predominantly small cleaved cell C. Malignant lymphoma, follicular Mixed, small cleaved and large cell
The Aggressive Lymphomas **B Cell neoplasms** • **Follicular lymphoma (grade III)** • **Diffuse large B-cell lymphoma** • **Mantle cell lymphoma** **T cell neoplasm** • **Peripheral T-cell lymphoma** • **Anaplastic large cell lymphoma, T/null cell**	**Intermediate Grade** D. Malignant Lymphoma, follicular Predominantly large cell E. Malignant lymphoma, diffuse Small cleaved cell F. Malignant lymphoma, diffuse Mixed, small and large cell G. Malignant lymphoma, diffuse Large cell cleaved cell non-cleaved cell
The Highly Aggressive Lymphomas **B cell neoplasms** • **Burkitt's lymphoma** • **Precursor B lymphoblastic leukemia/lymphoma**	**High Grade** H. Malignant Lymphoma Large cell, immunoblastic I. Malignant lymphoma Lymphoblastic J. Malignant lymphoma Small non-cleaved cell Burkitt's Non-Burkitt's

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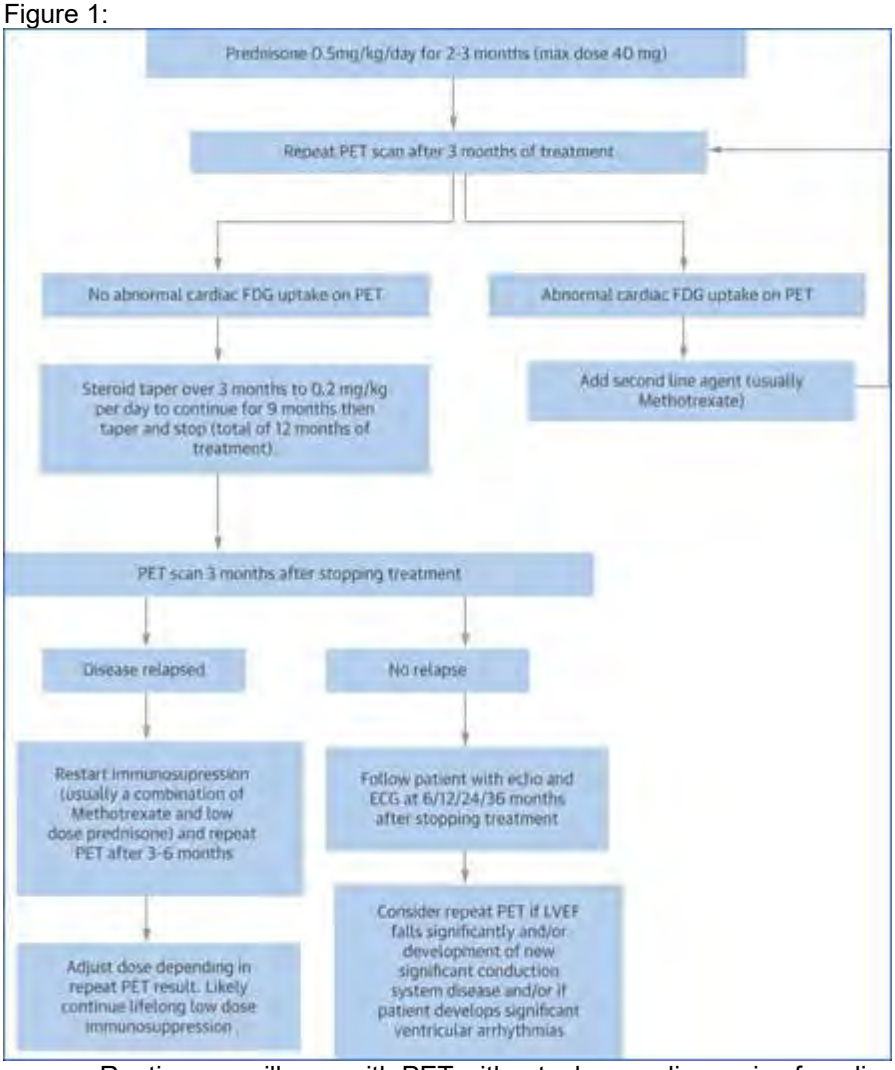
Non-oncological conditions	Indications
Heart For myocardial Viability Using Fluorodeoxy-D-glucose (FDG)	1. Determine myocardial viability prior to revascularization for patients who are potential candidates for CABG or stent if alternate diagnostic testing are not suitable or non-diagnostic a. SPECT is inconclusive or contraindicated due to BMI greater than 40 **AND** b. dobutamine stress echocardiogram is inconclusive or contraindicated **AND** c. cardiac MRI is contraindicated or non-diagnostic 2. Sarcoidosis with suspected/known cardiac involvement a. For initial diagnosis to evaluate active cardiac sarcoidosis a. if MRI cannot be performed b. if MRI is non-diagnostic or inconclusive, and high clinical suspicion for cardiac sarcoidosis remains c. if MRI is positive for cardiac sarcoidosis, a subsequent PET can be done for assessment of active myocardial inflammation b. Repeat PET study as per the algorithm below (Figure 1: Birnie, D. H., Nery, P. B., Ha, A. C., & Beanlands, R. S. B. (2016, July 26). Cardiac Sarcoidosis. Retrieved March 20, 2020, from http://www.onlinejacc.org/content/68/4/411 Figure 1:  c. Routine surveillance with PET without a known diagnosis of cardiac sarcoidosis is not medically indicated. Serial evaluation while on

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Non-oncological conditions	Indications
	treatment for cardiac sarcoidosis should not be more frequent than 3 months. If there is a request in a shorter time frame, Kaiser Permanente Medical Director review is required.
Perfusion of the Heart Using Ammonia N-13 or Using Rubidium 82	1) Following inconclusive SPECT prior to revascularization (other diagnostic tests or alternative test are contraindicated or not suitable).
Epilepsy refractory Seizures	1) pre-surgical evaluation of refractory seizures

Other forms of PET Scans	Indications
^{18}F-florbetapir (Amyvid) PET for Alzheimer's Disease **Flortaucipir F 18 injection PET for Alzheimer's Disease** **FDG Alzheimer's Disease and Dementia** **C-11 Acetate PET for Diagnosing Primary and Metastatic Prostate Cancer** **^{18}F Fluoro-Estradiol PET (FES-PET) to Measure Estrogen Receptor Expression - Breast Cancer** **^{18}F-NaF PET for the Detection of Bone Metastases** **Fluorodopa F-18 injection PET for Parkinsonian syndrome**	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or will provide better long term outcomes than current standard services/therapies.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

Positron Emission Mammography (PEM) (Click here for link)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

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Positron Emission Tomography has been studied over the past few years at the University of Washington as well as other academic centers. The efficacy of this scan is still being evaluated. Because medical staff members have asked to have this study covered for cancer detection, a criteria set for medical necessity has been developed which involves review by the Medical Director of the radiology department and maintenance of a request log with determination outcomes.

Positron emission tomography (PET) also known as positron emission transverse tomography (PETT), or positron emission coincident imaging (PECI), is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images by detecting radioactivity from a radioactive tracer substance (radiopharmaceutical) that is injected into the patient.

Positron Emission Tomograghy (PET) is a non-invasive nuclear medicine scanning technique that provides unique diagnostic information that cannot be obtained by other imaging modalities. While CT and MRI provide detailed images of the patient's anatomy; PET scanning reveals vital information concerning cellular function. This functional information can be critical in the evaluation of a variety of common and serious diseases. PET has shown utility in the management of a wide range of malignancies including lung cancer, colon cancer, lymphoma and melanoma. PET scanning also plays an important role in the evaluation of certain neurologic and cardiac diseases and the applications of this unique imaging modality continue to expand.

Recent developments in the field of PET scanning are certain to lead to a rapid expansion in the utilization of this powerful technique. There have been improvements in the resolution of the cameras allowing for higher diagnostic yield. Reimbursement issues are being worked out and HCFA has approved payment for several indications in the area of oncology. Additional indications may be approved in the near future. The problems surrounding the delivery of the radioisotopes are also being solved. This is particularly true for the Puget Sound area where a production facility (cyclotron) has recently been built in Kent.

Several careful studies have shown that there is a cost benefit associated with PET. In many cases PET will reveal findings not identified by CT or MRI, resulting in a more appropriate and timely diagnostic evaluation. Costs for unnecessary procedures are avoided. This results in an overall cost saving, despite the initial cost of performing the PET study.

Interest in PET scanning continues to grow rapidly in both the national and local medical community. Several local hospitals already have PET capability and the number of facilities offering this important diagnostic capability is certain to expand quickly. Many facilities are beginning their PET program by utilizing a mobile service. There are a number of mobile PET companies that are already providing or will soon be providing service to our area. This approach would allow for a minimal initial investment with low risk and could provide the opportunity to provide PET scanning at a number of different GH facilities on a rotating basis. In the future, depending on patient volume, consideration may be given to installing a permanent facility.

Evidence and Source Doucments

Alzheimer's Disease and Dementia
Breast Cancer, Staging and Re-Staging
Cervical Cancer, Staging and Re-Staging
Colorectal Cancer, Staging and Re-Staging
Esophageal Cancer, Diagnosis, Staging and Re-Staging
^{18}F Fluoro-Estradiol to Measure Estrogen Receptor Expression in Advanced Breast Cancer
Head and Neck Cancer, Diagnosis, Staging and Re-Staging
Melanoma, Staging and Re-Staging
Prostate Cancer, C-11 Acetate for Diagnosing Primary and Metastatic
Refractory Seizures, Pre-Surgical Evaluation
^{18} F-NaF PET for the Detection of Bone Metastases
18 F-florbetapir (Amyvid) PET for Alzheimer's disease
Axumin Injection

Medical Technology Assessment Committee (MTAC)

Alzheimer's Disease and Dementia

BACKGROUND

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Dementia is a general decline in multiple cognitive abilities including language, memory, and logical thinking. It is a common disorder in the elderly, and has many potential causes. Alzheimer's disease (AD), a degenerative neurological condition, is the most common form of dementia in the elderly and accounts for approximately two thirds the cases in the USA. Other causes of dementia include vascular dementia, dementia with Lewy bodies, dementia due to Parkinson's disease, frontotemporal dementia and others. These have to be considered in the differential diagnosis and ruled out before a diagnosis of AD is made. Alzheimer's disease is mainly characterized by progressive memory impairment and other cognitive dysfunctions that can interfere with the patient's normal daily activities and social life. Its onset is gradual and involves continuing cognitive decline. The milder forms are classified as "possible" and the more advanced forms as "probable" AD. The standard evaluation of dementia and potential AD is extensive and include medical and psychiatric history, physical examination, neuropsychologic mental status testing, lab tests and structural imaging. MRI and CT scans are used to detect structural changes late in the disease, and in ruling out tumors or other abnormalities in the brain that may cause dementia symptoms. Early and accurate diagnosis of dementia has become of greater concern lately because of the availability of more effective drug therapies to treat the symptoms of the disease. These medications would have a greater impact when used in the earlier stages of the disease (Silverman 1999). The most widely used diagnostic criteria for dementia in North America are based on definitions in the National Institute of Neurological and Communicative Disorders and Stroke-Alzheimer's Disease and related Disorders Association (NINCDS-ADRDA) Work Group. Diagnostic criteria for AD have also been grouped by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). The clinical evaluation based on these criteria is relatively accurate in ruling out dementia due to causes other than AD, and in identifying probable AD when the level of dementia is moderate to severe. The clinical criteria that define AD are not the ideal gold standard because the clinical diagnosis does not always conform with the pathological diagnosis. The perfect gold standard for the definitive diagnosis of AD or other specific forms of dementia is the histopathological examination of brain tissue, which is very rarely done during the patient's lifetime. Specific histopathologic findings of AD include gliosis, plaques, tangle formation, and neuronal loss (Hoffman 2000). Numerous studies have found that Alzheimer's disease and other neurodegenerative diseases could produce significant alterations in brain metabolism. AD was found to be associated with focal reduction of the cerebral metabolic rate of glucose (CMR-G1c) mainly in the temperoparietal, and frontolateral regions of the brain. Bilateral temperoparietal hypometabolism were found to be the characteristic patterns seen in AD but are not specific to it. Gamma camera imaging and single photon emission computed tomography (SPECT) have been used to measure the cerebral blood flow in the brain. However, they may not be very effective in identifying localized metabolic defects. Positron emission tomography (PET) is another technique proposed as a means for the diagnosis of dementia. PET is a functional nuclear imaging modality that uses biochemical rather than structural information to produce images. It involves using positron-emitting radioisotopes to generate radioactivity. The levels of radioactivity originating from a given point are recorded using certain camera-like devices. Different radiopharmaceuticals can be use in PET imaging. The most commonly used in brain imaging is ^{18}F-fluorodeoxyglucose (FDG) which has the ability to compete with glucose for absorption and metabolism in a variety of cell types, including neurons. In AD and some other forms of dementias the ability of the cells to take up glucose and FDG is impaired. Theoretically, FDG PET may help in the early diagnosis of AD and other forms of dementia by highlighting these regions of decreased FDG uptake before any structural damage can be detected by MRI or CT scans. FDG PET is usually done under resting conditions, but can be also performed under activation conditions to study the extent of neuronal stimulation. Brain PET scans can be interpreted by visual, quantitative and semi quantitative methods. The visual method, the most commonly used, greatly depends on the observer's experience, and lacks a clear cutoff between normal and pathological findings. PET scanners are approved by the Food and Drug Administration (FDA) for general use. The FDA does not approve imaging devices as PET scanners for specific indications. FDG PET is FDA approved for evaluating seizures, and was determined to be safe and effective in detecting malignancy. However, to date no PET radiotracers have been approved by the FDA for evaluating AD or other forms of dementia.

04/09/2003: MTAC REVIEW
Alzheimer's Disease and Dementia
Evidence Conclusion: There is insufficient evidence to allow us to draw conclusions about the value of PET in the diagnosis of AD and non-AD dementias, or in the assessment of treatment response. There was also no evidence on the impact of PET on the disease management and clinical outcome for patients with AD. The review focused on the use of FDG Pet in the diagnosis of Alzheimer's disease. It also focused on studies with histopathological confirmation, which provides a definitive diagnosis of AD because many forms of dementia have overlapping clinical presentations. The two studies reviewed had this advantage of histopathologic confirmation, but each had some validity threats that limit generalization of their results. Both studies were conducted among selected groups of patients who do not generally represent those who undergo dementia evaluation. In addition, neither study evaluated the impact of PET scanning on the disease management or the health outcome of the
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patients. Among the other limitations of the studies, is the small sample size in Hoffman's study, and the inclusion of two different cohorts with different protocols in Silverman's study. In these studies, Hoffman et al reported that FDG PET scans had a sensitivity of 92.9% and 87.5% in diagnosing AD alone, or with concurrent non AD dementias, and a specificity of only 62.2% and 66.7% respectively. Silverman reported a similar sensitivity of 93.8%, but a higher specificity of 73.2% for patient with neuropathologic confirmation of their AD diagnosis.
In conclusion, the available studies do not provide sufficient evidence to support the addition of PET to the standard clinical evaluation of patients with Alzheimer's disease/dementia, and further prospective studies are needed to establish its diagnostic and prognostic values. An ideal study would include a large representative sample of patients, who would be followed up from the development of symptoms until death when histopathologic confirmation can be made. Ideally also the patients would be randomly assigned to different management groups to assess the value of PET scanning on the outcome of the disease.
Articles: *Diagnosis of Alzheimer's disease dementias:* The search revealed 24 studies. All were prospective with the exception of 2 studies. The inclusion/exclusion criteria were not specific in all of the studies, and the blinding of PET interpreters was not always discussed. In 22 of these studies clinical evaluation was the gold standard, and in only 2 studies FDG PET performance was compared to histopathological findings. The use of clinical criteria for the diagnosis of AD does not give an accurate assessment of sensitivity and specificity of PET, and the true accuracy of the test needs histopathologic confirmation. The following two studies with pathological confirmation were selected for critical appraisal: Hoffman JM, Welsh-Bohmer KA, Hanson M, et al. FDG PET in patients with pathologically verified dementia. *J Nucl Med* 2000;41:1920-1928. See Evidence Table. Silverman DH, Small GW, Chang CY, et al. Positron Emission Tomography in Evaluation of Dementia. *JAMA* 2001;286:2120-2127. See Evidence Table. *Diagnosis of non- Alzheimer's disease dementias:* The search revealed 7 studies on the diagnosis of vascular dementia, dementia with Lewy bodies, or frontotemporal dementia using FDG PET. All studies had very small sample sizes (7 to 21 patients), and various methodological issues including nonblinding of PET interpreters, nonspecific inclusion/exclusion criteria, and lack of histological confirmation of the diagnosis. None was selected for critical appraisal. *Assessment of AD treatment response:* The search revealed 5 studies evaluating the role of FDG PET in assessing the treatment response. All had very small sample sizes (10 to 30 patients), and various methodological issues including nonblinding of PET interpreters, nonspecific inclusion/exclusion criteria, and lack of histological confirmation of the diagnosis. Two of these studies were conducted to evaluate the effect of passive audiovisual stimulation on the cerebral metabolic response, and another to study the effect of a therapeutic agent (propentofylline) in enhancing the metabolic response to auditory memory stimulation. None of theses studies was selected for critical appraisal.

The use of FDG PET in the evaluation of Alzheimer's Disease or Dementia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/20/2010: MTAC REVIEW
Alzheimer's Disease and Dementia
Evidence Conclusion: The first retrospective cohort study included 45 patients with dementia and assessed whether the addition of FDG-PET to clinical history and examination improves accuracy in distinguishing frontotemporal dementia (FTD) and Alzheimer's disease (AD). Findings from this study suggest that the addition of FDG-PET to clinical diagnosis improves diagnostic accuracy, sensitivity, and specificity in distinguishing FTD from AD. However, because of the characteristics of this analysis (results were reviewed by six experts who were aware that the entire population had dementia) the result of this study may not be applicable to clinical practice. Additionally, the effect on disease management and health outcomes cannot be determined from this study (Foster 2007).

Diagnostic accuracy, sensitivity, and specificity

	Clinical scenario	Clinical scenario + FDG-PET
	Mean (95% CI)	
Accuracy	78.8% (73-87)	89.2% (87-91)
Alzheimer's disease		
Sensitivity	86% (74-100)	97.6% (94-100)
Specificity	63% (36-79)	73.2% (57-82)

The second retrospective cohort study included 44 patients with and without dementia and evaluated the potential ability of both clinical and imaging diagnoses to detect AD. The results of this study suggest that the addition of FDG-PET to the initial clinical diagnosis of AD increased the sensitivity and specificity of the diagnosis; however, it is unknown whether these results will translate into clinical practice as two reviews rated each PET scan and the diagnosis of AD was determined at a multidisciplinary conference after review of all clinical data. Additionally,

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confidence intervals were not reported and there was a delay between initial examination and PET examination. PET imaging was performed an average of 1.3 years after initial examination (Jagust 2007).

Sensitivity and specificity

	Initial	Initial + PET
Sensitivity	76%	84%
Specificity	58%	74%

Conclusion:
There is insufficient information to determine whether the addition of FDG-PET to clinical diagnosis will lead to a more accurate diagnosis of AD.
Articles: Several articles were identified that evaluated whether the addition of a FDG-PET scan to clinical diagnosis would lead to a more accurate diagnosis of AD. The majority of these studies compared the addition of FDG-PET to a clinical diagnosis, which may be inaccurate and therefore not an ideal gold standard. Two small retrospective cohort studies that compared the addition of FDG-PET to a clinical diagnosis to a postmortem pathologic diagnosis of AD were selected for review. The following studies were critically appraised:
Foster NL, Heidebrink JL, Clark CM, et al. FDG-PET improves accuracy in distinguishing frontaltemporal dementia and Alzheimer's disease. *Brain 2007;* 130:2616-2635. See Evidence Table. Jagust W, Reed B, Mungas D, et al. What does fluorodeoxyglucose PET imaging add to a clinical diagnosis of dementia? *Neurology 2007;* 69:871-877. See Evidence Table

The use of FDG PET in the evaluation of Alzheimer's Disease or Dementia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Breast Cancer: Diagnosis, Staging and Restaging
BACKGROUND
Positron emission tomography (PET) with ^{18}F-fluorodeoxyglucose (FDG) has the potential for demonstrating tumor metabolic activity before structural changes can be shown by other methods such as computed tomographic (CT) imaging. FDG is a biological tracer that allows the evaluation of glucose metabolism. Tumor cells have increased glucose metabolism compared to benign cells and PET imaging with FDG takes advantage of this metabolic difference. Elevated uptake of FDG has been shown in several types of malignant primary tumors. FDG PET is potentially useful for diagnosis, staging and restaging of breast cancer. Diagnosis: While mammography remains the main imaging technique for screening breast lesions, it may be nondiagnostic in women with dense breasts and fibrocystic disease. Staging: Detection of tumor-involved lymph nodes is important. If PET can accurately detect axillary node involvement, patients may be able to avoid surgical morbidity from axillary dissection. Restaging: Another potential use of PET is to detect metastatic breast cancer outside of the breast and axillary nodal basins. This can help identify patients who are most likely to benefit from chemotherapy or radiation therapy. Monitoring response to chemotherapy: The response to chemotherapy could be monitored by PET because FDG uptake may decrease more in tumors that respond to chemotherapy than those that do not respond (Hoh & Schiepers, 1999).

06/07/2001: MTAC REVIEW
Breast Cancer: Diagnosis, Staging and Restaging
Evidence Conclusion: Diagnosis - The one study reviewed, Avril, found that FDG PET was insufficiently sensitive and specific at diagnosing breast tumors. Using the more conservative image interpretation, the negative predictive value was only 61%. This was a reasonably well-done study with a sample size of 144. Staging (staging of axilla) - The three studies had sensitivities varying from 79-90% and specificities varying from 91-97%. FDG PET seemed to perform better than clinical examination. False-negative results do occur with FDG PET. Restaging - The one study reviewed (Moon) suggests that FDG PET may not have sufficiently high sensitivity and specificity to forgo biopsy. This was a reasonably well-done study with n=57 patients. Replication of this study and comparisons with other diagnostic tests would provide stronger evidence about whether or not FDG PET and other non-invasive procedures can be used to restage breast cancer. Monitoring response to chemotherapy - The Smith study, which had a small sample size, found that primary breast cancers that improved clinically had a greater reduction in the rate of FDG uptake after one pulse of chemotherapy than cancers that did not respond to chemotherapy. As the authors conclude, these findings need to be replicated in larger studies with strong methodologies. In addition, more work needs to be done on determining the appropriate amount in decrease of FDG update to indicate a clinical response to chemotherapy.

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Articles: The search yielded 120 articles. Articles that were opinion pieces, basic science, dealt with technical aspects of the FDG PET procedure or had very small numbers of patients (i.e. <30) were excluded. Articles on diagnosis, staging and restaging were considered separately. There was one empirical study on the use of FDG PET for initial diagnosis of breast cancer. Four articles were identified on the use of PET for staging of the axilla. One of these did not have well described methodology and results; a summary evidence table was created for the other three articles which were similar methodologically. One article focused on the use of FDG PET for restaging breast cancer (detecting recurrent or metastatic disease). There were two articles that addressed the use of FDG PET for monitoring patients' response to chemotherapy. The study with the stronger methodology was reviewed. Evidence tables were created for: Diagnosis: Avril N, Rose M, Schelling J, Dose W, Kuhn S, Weber W. et al. Breast imaging with Positron Emission Tomography and fluorine-18 fluorodeoxyglucose: Use and limitations. J Clin Oncol 2000; 18: 3495-3502. See Evidence Table. Staging: Smith IC, Ogston KN, Whitford P, Smith FW, Sharp P, Norton M et al. Staging of the axilla in breast cancer: accurate in vivo assessment using positron emission tomography with 2-(fluorine-18)-fluoro-2-deoxy-d-glucose. Ann Surg 1998; 228: 220-227. See Evidence Table. Avril N, Dose J, Janicke F, Ziegler S, Romer W, Weber W et al. Assessment of axillary lymph node involvement in breast cancer patients with positron emission tomography using radiolabeled 2-(fluorine-18)-fluoro-2-deoxy-D-glucose. J Natl Cancer Inst 1996; 88: 1204-9. See Evidence Table. Crippa F, Agresti R, Seregni E, Greco M, Pascali C, Bogni A et al. Prospective staging of fluorine-18-FDG PET in presurgical staging of the axilla in breast cancer. J Nucl Med 1998; 39: 4-8. See Evidence Table. Restaging: Moon DS, Maddahi J, Silverman DHS, Glapsy JA, Phelps ME, Hoh CK. Accuracy of whole-body fluorine-18-FDG PET for the detection of recurrent or metastatic breast carcinoma. J Nucl Med 1998; 39: 431-435. See Evidence Table. Monitoring response to chemotherapy: Smith IC, Welch AE, Hutcheon AW, Miller ID, Payne S, Chilcott F et al. Positron emission tomography using 18-F-Fluorodeoxy-D-glucose to predict the pathologic response of breast cancer to primary chemotherapy. J Clin Oncol 2000; 18: 1676-1688. See Evidence Table

FDG PET for diagnosis, staging and restaging breast cancer did not pass the *Kaiser Permanente Medical Technology Assessment Diagnostic Test Evaluation Criteria.*

Cervical Cancer, Staging and Re-Staging

BACKGROUND

Cervical cancer is the second most frequently diagnosed gynecological malignancy in women worldwide (Chung et al., 2006). An analysis by the Centers for Disease Control and Prevention (Saraiya et al., 2007) identified about 60,000 cases of incident cervical cancer in the United States between 1998 and 2002. Rates were substantially higher among African-American and Hispanic women than other groups. If detected early, there is a high rate of treatment success with initial cervical cancer. However, the prognosis for women with recurrent cervical cancer is poor. There are limited treatment options, and treatment is often of a palliative nature (Dreyer et al., 2005). There is no generally accepted surveillance approach to detect recurrence in women with a history of cervical cancer. 80-90% of patients with recurrence will have signs or symptoms of disease, leading to investigations to confirm the diagnosis. Biopsy is routinely performed in symptomatic patients to confirm diagnosis. CT and MRI scanning, anatomic imaging techniques, are commonly used for cervical cancer imaging. In particular, CT-scan-directed biopsy is believed to be useful for obtaining histological confirmation of recurrence. There are concerns, however, that these techniques may result in false-positives due to the inability to distinguish between tumor masses and masses of necrotic or scar tissue, and false-negatives due to the inability to identify small tumors (Dreyer et al., 2005; Havilesky et al., 2005).Positron emission tomography (PET) with 18F-fluorodeoxyglucose (FDG) is proposed as an alternative to CT and MRI to confirm cervical cancer recurrence in symptomatic patients. In addition, it is proposed as a method for early detection of cervical cancer recurrence in asymptomatic women. Unlike CT and MRI, PET is a functional imaging method and examines cellular function. PET is commonly used with the biological tracer FDG, a glucose analog, which allows the evaluation of glucose metabolism. This is useful for detecting cancer since FDG is preferentially taken up by and retained within malignant cells. PET has shown utility in the management of a wide range of malignancies including lung cancer, colon cancer, lymphoma and melanoma.

08/04/2007: MTAC REVIEW

Cervical Cancer, Staging and Re-Staging

Evidence Conclusion: Diagnostic accuracy - The best available evidence on diagnostic accuracy of PET for cervical cancer recurrence is from a meta-analysis of observational studies (Havrilesky et al., 2005). To be included in the meta-analysis, diagnostic accuracy studies needed to include a reference standard (histology or clinical follow-up) for all participants. The Havrilesky analysis is limited, however, because all of the available studies were observational, retrospective and with small sample sizes (most had fewer than 40 patients). A pooled analysis of 3 studies in patients with a clinical suspicion of recurrence found a pooled sensitivity for PET of 0.96 (0.87-0.99) and specificity of 0.81 (0.58-0.94). A pooled analysis of 2 studies in patients without a clinical

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suspicion of recurrence found a sensitivity of 0.92 (0.77-0.98) and specificity of 0.74 (0.69-0.90). There is insufficient evidence on the diagnostic accuracy of PET compared to CT or MRI. No studies were identified that compared the accuracy of these tests in women with a clinical suspicion of cervical cancer recurrence. Diagnostic impact - Three small studies addressed the diagnostic impact of PET (The Lai and Belhocine studies were discussed in the Havrilesky meta-analysis). The Lai and Yen studies were both conducted among women with biopsy-documented recurrent cervical cancer. The Belhocine study included women with a clinical suspicion of recurrence as well as a small number of women who were undergoing routine post-treatment surveillance. Lai et al. (2004) reported that 22 out of 40 patients with known cervical cancer recurrence had their treatment changed after PET imaging, 15 changed from curative to palliative care. In the Yen et al. (2005) study, 36 out of 55 patients had their treatment plans modified after PET, 9 had a change in curative therapy and 27 switched to palliative therapy. Belhocine et al. (2002) reported that PET findings "induced a treatment" in 24 of the 25 patients with confirmed recurrence, and that PET was "particularly contributive" to the treatment plans of the 13 patients with an equivocal or false-negative result in the routine protocol. The studies on diagnostic impact were all limited by small sample sizes, particularly for sub-group analysis. Moreover, none of the studies provided detailed descriptions of treatment decisions based on CT or MRI versus treatment decisions based on PET. In addition, in the Yen and Lai studies, PET images were fused with CT/MRI results for patients with positive findings, so decisions were based on the combination imaging, not PET alone. Therapeutic impact - There is insufficient evidence on therapeutic impact. None of the studies reported health outcomes in patients managed by PET to those managed without PET. The Lai study included a historical control group; none of the other studies identified had comparison groups. Compared to historical controls, the 15 patients who had undergone surgery for their initial cervical cancer had a better 2-year survival rate. There was no significant difference in survival in the 25 patients who received radiation for their initial cervical cancer compared to historical controls.
Articles: There was a meta-analysis of observational studies on the use of FDG-PET for managing cervical cancer (Havrilesky et al., 2005). The authors systematically searched the literature through April, 2003. The Havrilesky analysis was critically appraised, as well as two studies included in the meta-analysis that reported on changes in treatment plan after PET scans (Belhocine et al., 2002 and Lai et al., 2004). Two studies published after the Havrilesky meta-analysis were considered for review. One study (Chung et al., 2006) was ultimately excluded because did not systematically select patients for scanning or evaluate the impact of PET findings on therapy. The other study (Yen et al., 2005) examined change in treatment following PET and was critically appraised. The studies that were critically appraised include:
Havrilesky LJ et al. FDG-PET for management of cervical and ovarian cancer. Gynecol Oncol 2005; 97: 183-191. See Evidence Table. Lai G-H, Huang K-G, See L-C et al. Restaging of recurrent cervical carcinoma with dual-phase 18F fluoro-2-deoxy-d-glucose positron emission tomography. Cancer 2004; 100: 544-552. See Evidence Table. Belhocine T, Thille A, Fridman V et al. Contribution of whole-body FDG PET imaging in the management of cervical cancer. Gynecol Oncol 2002; 87: 90-97. See Evidence Table. Yen T-C, See L-C, Change T-C et al. Defining the priority of using FDG-PET for recurrent cervical cancer. J of Nuclear Med 2005; 45: 1632-1639. See Evidence Table.

The use of FDG-PET in the diagnosis of cervical cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Colorectal Cancer, Staging and Re-Staging
BACKGROUND
Positron emission tomography (PET) with ^{18}F-fluorodeoxyglucose (FDG) has the potential for demonstrating tumor metabolic activity before structural changes can be shown by other methods such as computed tomographic (CT) imaging. FDG is a biological tracer that allows the evaluation of glucose metabolism. Tumor cells have increased glucose metabolism compared to benign cells and PET imaging with FDG takes advantage of this metabolic difference. Elevated uptake of FDG has been shown in several types of malignant primary tumors. On March 12, 2000, the FDA published a notice in the Federal Register that expanded approval of FDG for new indications. The use of FDG PET for the diagnosis, staging and restaging of colorectal cancer is one of the newly approved indications. In particular, FDG PET may be potentially useful for distinguishing local recurrences from postoperative scarring, for detecting hepatic and extrahepatic metastases prior to any surgery/therapy and for assessing recurrent colorectal cancer when there are indicators other than rising carcionoembryonic (CEA) levels. For these uses, a high negative predictive value (NPV) (the proportion of people who test negative who actually do not have the disease) is desired.

05/30/2001: MTAC REVIEW
Colorectal Cancer, Staging and Re-Staging
Evidence Conclusion: Diagnosing/ Primary staging: The evidence supporting the effectiveness FDG PET for primary staging of colorectal cancer in the absence of CT testing is weak. The strongest article (Abdel-Nabi et al.)
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was limited by the small sample size and the fact that assessors had access to CT information when they reviewed PET scans. Recurrence/Restaging: There is evidence to support the accuracy of FDG PET in identifying colorectal cancer recurrence and metastases. There were two reasonably well done comparison of diagnostic test studies (Staib, Imdahl), more recent than the meta-analysis. Study quality was defined as having a sample size >50 (ideally >100), prospective, blinded evaluation of FDG PET scans and use of an appropriate gold standard. Both studies found that PET performed well and was more accurate than CT. There is evidence from Staib that PET findings influence surgical decision-making (61% of patients in the study). The meta-analysis, which had weak methodology, found that there was a a change in management for 29% of patients based on PET findings. However, there is no published evidence on the impact of FDG PET for colorectal cancer on health outcomes (e.g. survival).
Articles: The search yielded 63 articles. Articles on primary staging and diagnosis of colorectal cancer and colorectal cancer recurrence were examined separately. There were two articles. There were 7 empirical studies examining primary staging/diagnosis of colorectal cancer and 17 empirical studies examining staging of colorectal cancer recurrences. Most of the studies were case series on FDG PET findings or a comparison of diagnostic tests and had small sample sizes. There was 1 meta-analysis of colorectal cancer recurrence. The rest of the articles were reviews or opinion pieces, assessed non-clinical outcomes or concerned technical aspects of FDG PET usage. The meta-analysis and the case series studies with the strongest methodology and the largest sample sizes were evaluated in detail. Evidence tables were created for the following articles: Diagnosis/ Primary staging:
Abdel-Nabi H, Doerr RJ, Lamonica DM, Cronin VR, Galantowicz PJ, Carbone GM, Spaulding MB. Staging of primary colorectal carcinomas with fluorine-18 fluorodeoxyglucose whole-body PET: Correlation with histopathologic and CT findings. Radiology 1998; 206: 755-760. See Evidence Table . Recurrence/ Restaging: Huebner RH, Park KC, Shephard JE, Schwimmer J, Czernin J, Phelps ME, Gambhir SS. A meta-analysis of the literature for whole-body FDG PET detection of recurrent colorectal cancer. J Nucl Med 2000; 41: 1177-1189. See Evidence Table . Recurrence/ Restaging: Huebner RH, Park KC, Shephard JE, Schwimmer J, Czernin J, Phelps ME, Gambhir SS. A meta-analysis of the literature for whole-body FDG PET detection of recurrent colorectal cancer. J Nucl Med 2000; 41: 1177-1189. See Evidence Table . Imdahl A, Reinhardt MJ, Nitzsche EU, Mix M, Dingeldey A, Einert A. et al. Impact of 18F-FDG-positron emission tomography for decision making in colorectal cancer recurrences. Langenbeck's Arch Surg 2000; 385: 129-134. See Evidence Table . Staib L, Schirrmeister H, Reske SN, Beger, HG. Is 18F-fluorodeoxyglucose positron emission tomography in recurrent colon cancer a contribution to surgical decision making? Am J Surg 2000; 180: 1-5. See Evidence Table .

The use of FDG PET as a diagnostic tool for Colon cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Esophageal Cancer, Diagnosis, Staging and Re-Staging
BACKGROUND
2 fluoro-2-deoxy-D-glucose (FDG) freely enters glycogen pathways; however, it gets trapped in these cycles, and significant intracellular accumulation occurs in cells with active glucose metabolism. Degeneration of this radioactive material can be detected by PET. Malignant tumor cells have increased glucose metabolism compared to benign cells. This increased glycolytic activity can be used to detect early-stage disease before any structural abnormality is evident. It can also help exclude the presence of malignant disease in an anatomically altered structure. Esophageal cancer is associated with unfavorable prognosis, and thus accurate determination of the tumor size, extent of local invasion, lymph node involvement, and distant metastases, provides valuable information for prognosis, assessment, and treatment selection. The standard noninvasive staging modalities are CT of the chest and abdomen for evaluating the local tumor extent, and detecting distant metastases, and endoscopic esophageal ultrasound (EUS) for the evaluation of tumor depth and locoregional LN staging in non-obstructing esophageal cancer. However, these techniques entirely depend on structural characteristics for diagnosis. This may cause limitations in diagnostic specificity (false positive findings in enlarged inflammatory LN) and sensitivity (false negative findings in non enlarged invaded LN). FDG PET has been reported to accumulate in 92% to 100% of esophageal cancers and is potentially useful for diagnosis, staging, and restaging.

05/30/2001: MTAC REVIEW
Esophageal Cancer, Diagnosis, Staging and Re-Staging
Evidence Conclusion: Apparently, three of these studies, two on staging (Flamen and Lerut) and one on restaging (Flamen) of esophageal cancer were made by the same group, and published in different medical journals. These were reasonably well done studies, yet not without biases. The Luketich study had several threats to its validity. Diagnosing and staging: These studies showed that FDG PET is not an appropriate first line diagnostic procedure in the detection of esophageal cancer. It also did not solve the problem of accurate clinical
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staging. There was no relationship between the primary tumor standardized uptake value (SUV) and the depth of the tumor invasion (T classification). FDG PET, could not define the esophageal wall, or paraesophageal tissue, and was not helpful in detecting local invasion by the primary tumor. It over staged when it did not distinguish inflammatory from neoplastic nodes, and under-staged when it could not identify minimally involved nodes, or tumors. It also did not discriminate the primary tumor from peritumoral lymph nodes. However, FDG PET was more sensitive than CT scan in detecting distant nodes and occult organ metastases. It also had a higher specificity than CT and EUS combined, in detecting distant nodal metastases. It was recommended by Flamen et al, in their two studies, that the positive findings on a FDG PET scan must be interpreted cautiously and verified histologically or radiologically, before a patient is considered as having unresectable disease and denied a curative treatment. Restaging: There was only one study found that focussed on the utility of FDG PET for the diagnosis and staging of recurrent esophageal cancer. The Flamen study showed that FDG PET was highly sensitive in staging symptomatic recurrent esophageal cancer. However, its higher sensitivity was statistically insignificant compared to the other conventional diagnostic procedures. Moreover, the false positive uptake at inflammatory lesions offered a major problem. More studies are recommended to study the potential benefit of PET on earlier diagnosis of recurrent disease. Change in patient management: In two of these studies, Luketich (staging) and Flamen (re-staging), patient management was changed in 15% and 11% of cases respectively. The effect of changing the treatment course on the patient survival and quality of life was not studied.
Articles: The search yielded 22 articles. Articles on diagnosis and primary staging of esophageal cancer and cancer recurrence were examined separately. There were six empirical studies on diagnosis and primary staging of esophageal cancer, and only one study on esophageal cancer recurrence. Most of the articles were case series on FDG PET findings or a comparison of diagnostic tests and had small sample sizes. Some were reviews or opinion pieces. There was no meta-analysis done. The studies with the strongest methodology and larger sample sizes were evaluated in detail. Three of the stronger studies, Flamen (J Clin Oncol), Flamen (J Thorac Cardiovasc Surg), and Lerut, were made by the same group. The Luketich study, that had several threats to its validity, was included to add a different view. Evidence tables were created for the following studies:
Staging: Flamen P, Lerut A, Van Cutsem E, De Wever W, Peeters M, et al. Utility of Positron Emission Tomography for the Staging of Patients with Potentially Operable Esophageal Carcinoma. J Clin Oncol 2000; 18:3202-3210. See Evidence Table . Luketich JD, Friedman DM, Wiegel TL, Meehan MA, Et al. Evaluation of Distant Metastases in Esophageal Cancer: 100 Consecutive Positron Emission Tomography Scans. Ann Thorac Surg 1999; 68: 1133-7. See Evidence Table . Lerut T, Flamen P, Ectors N, Van Cutsem E, Peeters M, et al. Histopathologic Validation of Lymph Node Staging with FDG-PET Scan in Cancer of the Esophagus and Gastroesophageal Junction. A Prospective Study Based on Primary Surgery with Extensive Lymphadenectomy. Annals of Surgery 2000; 232(6): 743-752. See Evidence Table . Restaging: Flamen P, Lerut A, Van Cutsem E, Cambier JP, Et al. The Utility of Positron Emission Tomography for the Diagnosis and Staging of Recurrent Esophageal Cancer. J Thorac Cardiovasc Surg 2000; 120: 1085-92. See Evidence Table.

The use of FDG PET As a diagnostic tool for Esophogeal Cancer failed criterion 1 of the diagnostic modality evidence criteria for evaluating efficacy of the evidence for re-staging and passed all criteria for diagnosis.

18F Fluoro-Estradiol to Measure Estrogen Receptor Expression in Advanced Breast Cancer
BACKGROUND
Estrogens are involved in the growth and development of both normal and cancerous breast tissues. The activity of estrogens in breast tissue is mediated by ligand-dependent transcription factors called estrogen receptors (ER). ER expression is generally categorized as ER-positive (ER+) and ER-negative (ER-). ER+ means that a significant number of cancer cells have receptors, generally 5-10% of cells. About 70% of invasive breast cancers are ER-positive. Higher ER expression has been found to be associated with an increased likelihood of response to endocrine therapy. (Murphy & Watson, 2006; Linden et al., 2006). Measurement of ER expression by biopsy at the time of primary diagnosis of breast cancer is standard care. However, it may be difficult to accurately measure ER expression in metastatic breast cancer because ER expression can be heterogeneous. That is, cells at one site may be ER+, while other sites may be ER-. In addition, ER expression may change over time. Recurrent breast cancer may have low ER expression even when the original primary tumor is ER+ (Murphy & Watson, 2006; Linden et al., 2006). 18F Fluoro-Estradiol PET (FES-PET) is proposed as an alternative to biopsy to assess ER expression in metastatic breast cancer. FES-PET for advanced breast cancer has not been previously reviewed by MTAC.

12/04/2006: MTAC REVIEW
18F Fluoro-Estradiol to Measure Estrogen Receptor Expression in Advanced Breast Cancer
Evidence Conclusion: The evidence on accuracy of FES-PET for assessing ER expression in breast cancer tumors is insufficient due to the availability of only one small study on this topic. Mortimer et al., (1996) compared biopsy and FES-PET findings in 41 breast cancer patients. Out of 21 patients identified on biopsy to be ER+,
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FES-PET identified 16 (sensitivity=76%). All 20 patients identified on biopsy as ER- were also negative according to FES-PET (specificity=100%). In addition to the limited quantity of evidence, biopsy is an imperfect gold standard so when there is discordance between biopsy and FES-PET findings, it is not possible to conclusively determine which method identified the "true" ER status. There are preliminary data from another small study with 47 patients (Linden et al., 2006). This study found that quantitative but not qualitative analysis of FES-PET significantly predicted response to hormonal therapy among patients with ER+ breast tumors confirmed by immunochemical analysis. The Linden study was not designed to evaluate the diagnostic accuracy of FES-PET.
Articles: The ideal study would evaluate the ability of FES-PET to identify ER-positive tumors using biopsy as the best available gold standard. One study (Mortimer et al., 1996) was identified that included both FES-PET imaging and biopsy of breast cancer tumors, although the primary purpose of the study was to correlate ER status with response to systemic therapy, not diagnostic accuracy. One other study was identified (Linden et al., 2006) that evaluated the ability of FES-PET to predict response to hormonal therapy in patients with breast cancer; the second study was restricted to patients with tumors already known to be ER-positive. These two studies were critically appraised: Mortimer JE, Dehdashti F, Siegel BA et al. Positron emission tomography with (FDG and FES) in breast cancer: correlation with estrogen receptor status and response to systemic therapy. Clin Cancer Res 1996; 2: 933-939. See Evidence Table. Linden HM, Stekhova SA, Link JM et al. Quantitative fluoroestradiol positron emission tomography imaging predicts response to endocrine treatment in breast cancer. J Clin Oncol 2006; 24: 2793-2799. See Evidence Table.

The use of ^{18}F Fluoro-Estradiol PET (FES-PET) in the treatment of advanced breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Head and Neck Cancer, Diagnosis, Staging and Re-Staging

BACKGROUND
Positron emission tomography (PET) with ^{18}F-fluorodeoxyglucose (FDG) has the potential for demonstrating tumor metabolic activity before structural changes can be shown by other methods such as computed tomographic (CT) imaging. FDG is a biological tracer that allows the evaluation of glucose metabolism. Tumor cells have increased glucose metabolism compared to benign cells and PET imaging with FDG takes advantage of this metabolic differences. Elevated uptake of FDG has been shown in several types of malignant primary tumors.

With head and neck cancer, FDG PET can be used to identify lymph node involvement to stage newly diagnosed patients. Lymph node status is the principal prognostic factor affecting the survival of head and neck cancer patients. Another possible application of FDG PET in initial stating is identification of unknown sites of primary cancer in patients who present with cervical nodal disease. An unknown primary cancer site occurs for only 1-5% of patients (Chisin & Macapinlac), but this group is presents special challenges in diagnosis and treatment. FDG PET could also be used to identify disease post-treatment residual disease or disease recurrence. Recurrent head and neck cancer is difficult to diagnose with conventional imaging techniques or clinical examination because of the anatomic changes, inflammation and scarring caused by surgery and radiotherapy.

05/30/2001: MTAC REVIEW
Head and Neck Cancer, Diagnosis, Staging and Re-Staging
Evidence Conclusion: Diagnosing and staging (including identifying lymph node metastases): There were two reasonably well-done prospective studies with sample sizes > 50 comparing FDG PET with other diagnostic modalities. Both showed FDG PET to have superior performance (higher sensitivity and specificity). Positive predictive value of FDG PET and CT varied considerably in the two studies. This provides some evidence about the effectiveness of FDG PET, although the variation in estimates across studies is concerning. Neither of the studies specifically discussed the ways in which FDG PET findings affect patient management. Restaging: Studies were not as strong methodologically as those for staging (e.g. had inconsistent use of a "gold standard"). In the Lapela study, FDG PET did not clearly perform better than CT (in one classification system, FDG PET had higher sensitivity and somewhat lower specificity; in the other classification system, FDG PET performed slightly better, statistical difference in performance is unknown). In the Lonneux study, FDG PET clearly performed better than CT plus MRI, but specificity was low. The available evidence does not permit clear conclusions about the effectiveness of FDG PET at detecting recurrence of head and neck cancer.
Articles: The search for the period 1997 through February 2001 yielded 83 articles. Articles that were opinion or discussion pieces or addressed technical aspects of FDG PET were excluded. There were 4 prospective comparisons of diagnostic test studies with sample sizes for diagnosis/staging and 1 for restaging. Evidence tables were created for the two staging articles with n>50 and with the strongest methodologies. An evidence table was created for the prospective restaging article and for a study of restaging where n=44 but that presented data on the impact of FDG PET on patient management. There are evidence tables for the following studies:
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Adams S, Baum RP, Stuckensen T, Bitter K, Hor G. Prospective comparison of 18F-FDG PET with conventional imaging modalities (CT, MRI, US) in lymph node staging of head and neck cancer. Eur J Nucl Med 1998; 25: 1255-1260. See Evidence Table . Stokkel MPM, ten Broek F-W, Hordjik G-J, Kooke R, van Rijk PP. Preoperative evaluation of patients with primary head and neck cancer using dual-head 18-fluorodeoxyglucose positron emission tomography. Ann Surg 2000; 231: 229-234. See Evidence Table . Lapela M, Eigtved A, Jyrkkio S, Grenman R, Kurki T, Lindholm P. et al. Experience in qualitative and quantitative FDG PET in follow-up of patients with suspected recurrence from head and neck cancer. Eur J Cancer 2000; 36: 858-67. See Evidence Table . Lonneux M, Lawson G, Ide C, Bausart R, Remacle M, Pauwels S. Positron emission tomography with fluorodeoxyglucose for suspected head and neck tumor recurrence in the symptomatic patient. Laryngoscope 2000; 110: 1493-97. See Evidence Table .

The use of FDG PET As a diagnostic tool for head and neck cancers failed criterion 4 of the diagnostic modality evidence criteria for evaluating efficacy of the evidence.

Melanoma, Staging and Re-Staging

BACKGROUND

Positron emission tomography (PET) with ^{18}F-fluorodeoxyglucose (FDG) has the potential for demonstrating tumor metabolic activity before structural changes can be shown by other methods such as computed tomographic (CT) imaging. FDG is a biological tracer that allows the evaluation of glucose metabolism. Tumor cells have increased glucose metabolism compared to benign cells and PET imaging with FDG takes advantage of this metabolic differences. Elevated uptake of FDG has been shown in several types of malignant primary tumors. A potential benefit of FDG PET for patient outcome is the ability to improve the selection of patients for surgery and other treatments. On March 12, 2000, the FDA published a notice in the Federal Register that expanded approval of FDG for new indications. One new indication was the use of FDG PET for the diagnosis, staging and restaging of melanoma. FDG PET is not covered for regional lymph node evaluation.

05/30/2001: MTAC REVIEW

Melanoma, Staging and Re-Staging

Evidence Conclusion: The evidence concerning the effectiveness of FDG PET for diagnosing, staging and restaging melanoma is inconclusive. The three best studies identified that examined the efficacy of FDG PET (excluding Wagner which looked only at regional lymph node basins) varied in their findings on sensitivity and specificity:

PET (By lesion) Sensitivity Specificity
Schwimmer* 92 87
Tyler (restaging) 87 43
Rinne (staging) 100 94
Rinne (restaging) 92 94
*Unclear whether staging and/or restaging

In particular, Tyler found substantially lower specificity than the other studies. The Tyler study included patients with advanced melanoma (Stage III) whereas the Rinne study had at least some patients with less advanced disease. Possibly, effectiveness varies by stage of disease but this is not clear from the available evidence. Only the Rinne study compared FDG PET results with conventional imaging and found that PET had superior sensitivity and specificity. However, conventional diagnostics may not have been consistently performed. No study directly compared PET and CT. In addition, the Wagner study found that sentinel node biopsy was more effective than PET for regional lymph node metastases. FDG PET may be useful for some aspects of melanoma staging and not others. There is a deficiency of evidence on long-term patient outcome following FDG PET for melanoma and on any possible adverse effects.

Articles: The search yielded 37 articles. Many of the studies included mixed groups of patients (primary and recurrent melanoma). There was one meta-analysis and several case series or cross-sectional analyses of FDG PET. The rest of the articles were reviews or opinion pieces, assessed non-clinical outcomes or concerned technical aspects of FDG PET usage. Evidence tables were created for the meta-analysis (staging vs. restaging unclear) and the three evaluations of FDG PET with the strongest methodologies. These articles are: Restaging: Tyler DS, Onaitis M, Kherani A, Hata A, Nicholson E, Keogan M et al. Positron emission tomography scanning in malignant melanoma. Cancer 2000; 89: 1019-25. See Evidence Table . Staging and restaging: Rinne D, Baum RP, Hor G, Kaufmann R. Primary staging and follow-up of high risk melanoma patients with whole-body 18f-fluorodeoxyglucose positron emission tomography. Cancer 1998; 82: 1664-71 See Evidence Table . Wagner JD, Schuwecker D, Davidson D, Coleman JJ, Saxman S, Hutchins G, Love C, Hayes JT. Prospective study of fluorodeoxyglucose positron emission tomography imaging of lymph node basins in melanoma patients undergoing sentinel node biopsy. J Clin Oncol 1999; 17: 1508-15 See Evidence Table . Staging/restaging not specified: Schwimmer J, Essner R, Patel A, Jahan A, Shephard JE, Park K et al. A review of the literature for

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whole-body FDG PET in the management of patients with melanoma. Q J Nucl Med 2000; 44: 153-67 See Evidence Table .

The use of FDG PET As a diagnostic tool for Melanoma permits conclusions about the accuracy for diagnosing distant metastases. This excluded accuracy for diagnosing local disease and regional lymph node metastases.

Prostate Cancer, C-11 Acetate for Diagnosing Primary and Metastatic

BACKGROUND

Positron emission tomography (PET) with ^{18}F-fluorodeoxyglucose (FDG) is used to identify tumors by their increased rates of glucose metabolism compared to benign cells. Prostate tumors grow slowly and have lower rates of glucose metabolism than other types of tumors. Thus, FDG PET is less useful for the diagnosis and monitoring of prostate cancers than for other cancers such as such as colorectal and head and neck cancer. Carbon-11 (C-11) acetate has been proposed as a more promising tracer for prostate tumor cells. C-11 has a short half-life, only about 20 minutes and the application of C-11 acetate PET is limited to sites that have an on-site medical cyclotron for radiotracer production.

02/13/2003: MTAC REVIEW

Prostate Cancer, C-11 Acetate for Diagnosing Primary and Metastatic

Evidence Conclusion: There is insufficient evidence to determine the ability of C-11 acetate PET to accurately diagnose or monitor prostate cancer. Only one study was identified that compared C-11 acetate PET to a gold standard (Kotzerke et al., 2002) and this study had too small a sample size for meaningful statistical analysis.

Articles: The search yielded 11 articles. All of the empirical studies had small sample sizes (fewer than 50 patients). One study (Kotzerke) compared C-11 acetate PET to a gold standard (transrectal ultrasound and biopsy). However, this study had only 31 patients and the authors did not calculate sensitivity and specificity or do any other statistical analysis due to the small number of patients evaluated. This study was not critically appraised because of its small sample size and lack of statistical analysis.

The use of C-11 Acetate PET in the evaluation of Primary and Metastatic Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Refractory Seizures, Pre-Surgical Evaluation

BACKGROUND

Positron emission tomography (PET) with ^{18}F-fluorodeoxyglucose (FDG) has the potential for identifying areas of seizure focus (epileptogenic region). FDG is a biological tracer that allows the evaluation of glucose metabolism and areas of seizure focus have decreased glucose metabolism (hypometabolism). For patients whose seizures are uncontrolled by medication, surgery may eliminate seizures or make them easier to control. Most patients who are surgical candidates have complex partial seizures of temporal lobe origin. The most common surgical procedure performed is an anterior temporal lobectomy which consists of resection of the lateral temporal neocortex and the mesiobasal temporal cortex. Invasive recording techniques are the most accurate way to localize the epileptogenic region but noninvasive tests are preferred. Possible noninvasive tests are surface EEG, MRI, ictal single photon emission computed tomography (SPECT) and FDG PET.

05/30/2001: MTAC REVIEW

Refractory Seizures, Pre-Surgical Evaluation

Evidence Conclusion: The studies evaluating FDG-PET for the presurgical evaluation of seizures tended to be small and have methodological flaws. Studies suggest that FDG-PET may be useful for presurgical evaluation, but larger, better-done studies need to be done.

Articles: The search yielded 101 studies. Articles that were opinion or discussion pieces, addressed technical aspects of FDG PET, only included children or did not address presurgical evaluation of seizures were excluded. Nine case series/evaluation of diagnostic test studies remained. Two were by the same research group. None of the studies had sample sizes > 50. The two studies with the strongest methodology were reviewed. Strong methodology was defined as including as many of the following elements as possible: prospective, relatively large sample size, comparative studies, quantified PET results, blinded interpretation of FDG PET, consecutive patients. Only one study (Theodore) was prospective, quantified PET results and included > 30 patients. Evidence tables were created for: Theodore WH, Sato S, Kufta CV, Gaillard WD, Kelly K. FDG-positron emission tomography and invasive EEG: Seizure focus detection and surgical outcome. Epilepsia 1997; 38: 81-86. (The more recent Theodore study). See Evidence Table . Knowlton RC, Lazer KD, Ende G, Hawkins RA, Wong STC, Matson GB et al. Presurgical multimodality neuroimaging in electroencephalographic lateralized temporal lobe epilepsy. Ann Neurol 1997; 42: 829-37. See Evidence Table .

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The use of FDG PET As a diagnostic tool for Refractory Seizures failed criterion 2 of the diagnostic modality evidence criteria for evaluating efficacy of the evidence for pre-surgical evaluation.

18 F-NaF PET for the Detection of Bone Metastases

BACKGROUND

Bone metastases occur in 50% of oncologic patients, and in up to 70% of patients with breast and prostate cancer. These may result in significant morbidity including pain, pathological fractures, spinal cord compression, bone marrow suppression, and hypercalcemia. In the initial phase, metastatic lesions in the bone infiltrate the bone marrow disturbing the balance and enhancing osteolytic or osteoblastic processes. Fast-developing and aggressive metastases are usually lytic while the slow developing lesions are typically accompanied by osteoblastic processes. Prostate cancer predominantly demonstrates osteoblastic metastases, lung cancer predominantly demonstrates osteolytic metastases, and breast cancer often demonstrates osteolytic or mixed osteolytic and osteoblastic metastases (Cook 2010, Qu 2011, Tarnawska-Pierscinska 2011). Evaluation of metastatic bone lesions is crucial for determining the therapeutic plan and improving patient prognosis. Radionuclide whole-body bone scintigraphy (BS) using technetium-99m-labelled radiopharmaceuticals, such as methylene disphosphonate (99mTc MDP) tracers has been the standard modality used for the evaluation of skeletal malignancy for decades. It is widely available and has the ability of evaluating the entire skeleton within a reasonable amount of time, and at a relatively low cost. BS provides information on the presence, location, extent, and response to therapy of bone metastases. However, it identifies an increased turnover state associated with osteoblastic activity rather than proliferation of tumor cells, and therefore may be less sensitive in detecting early metastases, metastatic tumors that are small in size or confined to the bone marrow, osteolytic lesions, or lesions with minimal or no osteoblastic activity. Lytic lesions are visible by scintigraphy studies as “cold” areas that are difficult to interpret. BS may also lead to false positive findings in cases of osteoarthritis, healing fractures, and inflammation (Yen 2010, Cheng 2011, Chang 2012, Tarnawska-Pierscinska 2011). More recent improvements and developments of other non-invasive methods are increasingly being used for detecting bone metastases. These include multidetector computed tomography (CT), magnetic resonance imaging (MRI), SPECT/CT, and positron emission tomography (PET) with or without computed tomography (PET/CT). Each modality has its advantages and limitations, as well as imaging capability which could be morphologic, functional, or a combination of both. MRI and CT are anatomic imaging modalities that analyze tumor tissue based on their morphologic appearance; while 99mTc MDP bone scintigraphy and PET are functioning imaging modalities. Bone scintigraphy identifies bone metastasis by detecting the osteoblastic response to bone destruction by tumor cells and the accompanying increase in blood flow. 18F-FDG PET identifies viable tumors based on the higher glycoloytic rates in the neoplasm than in normal tissue, and 18F- labeled sodium fluoride (18 F-NaF), a radiotracer used with PET bone scans, has a skeletal uptake mechanism similar to that of 99mTc, but clears from circulation faster as it does not bind to plasma proteins. 18 F-NaF relies on the exchange of hydroxyl ions in the in the hydroxyapatite crystal and is an indicator of bone metabolic activity. The increased uptake of the tracer in malignant bone lesions reflects the increase in regional blood flow and bone turnover characterizing these lesions. 18 F-NaF PET scans may identify lytic bone metastases that may not be detected by 99mTc scintigraphy. The accumulation of fluoride however, is not tumor specific and it may be difficult to differentiate metastases from benign bone lesions such as degenerative diseases (Hetzel 2003, Evan-Sapir 2006, Cook 2010, Liu 2011, Tarnawska-Pierscinska 2012).18 F-NaF, introduced in the early 1960s, was the first radiopharmaceutical agent used for imaging bone lesions. It was initially used as a planar scintigraphy tracer and has the advantage of high and rapid bone uptake and very rapid blood clearance. It was abandoned however, with the introduction of 99mTc in the 1970s, because the relatively high energy of the annihilation photons produced by the decay of 18F required the use of special scanners. More recently, 18 F-NaF for bone imaging re-emerged with the introduction of PET and the availability of electronic generators that may allow its use. The interest in 18 F-NaF was also increased due to the worldwide shortages of 99mTc-MDP (Grant 2008, Chua 2009, Cook 2009, Yen 2010).

18 F-NaF was cleared by the Food and Drug Administration (FDA) for clinical use in 1972. The approval was then withdrawn, and it is unclear whether it was-re-approved.

10/15/2012: MTAC REVIEW

18 F-NaF PET for the Detection of Bone Metastases

Evidence Conclusion: There is limited published evidence on the use of ^{18}F-NaF PET for the detection of bone metastases. The majority of published studies were on the use of ^{18}F-FDG PET and ^{18}F-FDG PET/CT. The studies that evaluated ^{18} F-NaF PET were small in size, more than half were retrospective in design, and the specific diagnosis was not reported in some and was a variety of carcinomas in others. ^{18}F-NaF PET with or without CT was mainly compared with bone scintigraphy or FDG PET. No direct comparisons were made vs. MRI. In addition histopathological confirmation as a gold standard was performed in a small number of these studies and not for all participants in the studies. Tateishi and colleagues’ meta-analysis as well as Lagaru et al’s study

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show that ^{18}F-NaF PET or ^{18}F-NaF PET/CT, may be more sensitive, but with similar specificity to bone scintigraphy and ^{18}F-FDG PET in the detection of bone metastases. Patients included in the studies had a variety of carcinomas which may affect the accuracy of the imaging modalities used. Safety and effect of the using ^{18}F-NaF PET on patient management were not evaluated. The results of the published studies to date should be interpreted with caution. Larger prospective studies among cohorts of patients with specific malignancies are needed to determine whether 18F-NaF PET is safe, improves the detection rate of bone metastases, and has a positive impact on patient management. A randomized prospective multicenter study of almost 500 patients is conducted by the Academy of Molecular Imaging (AMI) is underway in the US to compare ^{18} F-NaF PET with ^{99m}Tc.

Articles: There literature search revealed one meta-analysis and a limited number of small studies that evaluated ^{18} F-NaF PET and compared its performance to one or more other diagnostic modalities used for the detection of bone metastases in patients with lung cancer, breast cancer, prostate cancer, and/or hepatocellular carcinoma. The meta-analysis and a more recent study with generally valid methodology were selected for critical appraisal. Tateishi U, Morita S, Taquri M, et al. A meta-analysis of ^{18}F-Fluoride positron emission tomography for assessment of metastatic bone tumor. Ann Nucl Med 2010.24:523-531. See Evidence Table . Lagaru A, Mittra E, Dick DW, et al. Prospective evaluation of ^{99m}Tc MDP scintigraphy, ^{18}F NaF PET/CT, and ^{18}F FDG PET/CT for detection of skeletal metastases. Mol Imaging Biol. 2012;14:252-259. See Evidence Table.

The use of ^{18}F-FDG PET and ^{18}F-FDG PET/CT for bone metastases does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Axumin Injection for PET Scans

BACKGROUND

Prostate cancer is the second most frequently diagnosed cancer across the globe (Wolff et al., 2015). A 2008-2010 data estimated that 15% of men in the United States will be diagnosed with prostate cancer at some point in their lives (Wolff et al., 2015). However, the mortality rate is low because it is a slow growing cancer.

Treatment is based on a number of factors including tumor stage, prostate specific antigen (PSA) value, Gleason score (GS), patient's age, concomitant diseases, life expectancy and patient's preference (Warmuth, Johansson, & Mad, 2010). A wide range of options are available for prostate cancer and these include active surveillance, watchful waiting, radical prostatectomy, hormone therapy, radiotherapy, external beam radiotherapy (EBRT), brachytherapy and chemotherapy (Wolff et al., 2015).

Iimportant proportion (20 to 50%) of men treated for prostate cancer will experience recurrence (Bruce, Lang, McNeel, & Liu, 2012; Roehl, Han, Ramos, Antenor, & Catalona, 2004; Simmons, Stephenson, & Klein, 2007). Of those with recurrent prostate cancer, a high proportion (25%) will develop metastatic disease with morbidity and mortality (Boorjian et al., 2011; James et al., 2015). Given the impact of recurrence, and for better treatment, it is crucial to determine the sites of the recurrence. Diagnostic tests include MRI, bone scintigraphy, CT. However, the accuracy of these standard imaging tests is low (diagnostic yield of 11%) (Choueiri, Dreicer, Paciorek, Carroll, & Konety, 2008). Therefore, tests with better diagnostic yield are necessary. Positron emission tomography (PET) with fluciclovine radiotracer has been the center of attention.

PET is a molecular imaging technique using tumor biology to improve detection of prostate cancer (Parent & Schuster, 2018). PET with tracers visualize receptor profile of tumor cells. Axumin or fluciclovine or Anti-1-amino-3-18F-flurocyclobutane-1-carboxylic acid (18F-fluciclovine) is an amino acid PET radiotracer. The characteristics of the tumor-imaging of this radiotracer is similar to the increased amino acid transport found in prostate cancer (Parent & Schuster, 2018). It visualizes the increased amino acid transport associated with tumor cells compared to normal tissues.

One of the benefits of Axumin PET/CT is helping to select optimal treatment strategy (i.e., salvage surgery vs. XRT vs. systemic therapy, depending on site(s)/extent of disease involvement). This can help with resource utilization and patient morbidity: e.g., bypassing futile surgery or local XRT if PET (which is generally more sensitive) identifies more extensive and/or distant disease than CT/MR identify; alternatively, using focal XRT or SABR and avoiding systemic therapy if only isolated or oligometastatic disease.

01/14/2019: MTAC REVIEW

Evidence Conclusion:

Low evidence demonstrates that:

- The clinical performance of PET with fluciclovine tracer is high in men with suspicion of prostate cancer recurrence after having treatment

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- Compared to standard imaging and other radiotracers (111In-capromab, 11 C-choline, and contrast-enhanced CT alone), the diagnostic performance of PET with fluciclovine is high
- PET with fluciclovine tracer is clinically useful in defining target volume, and changing management plan
- No acute toxicity was reported. Longer term studies are warranted

Articles:

PubMed was searched through September 4, 2018 with the search terms (Axumin OR fluciclovine) AND PET AND prostate cancer. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications.The search yielded several articles but six met the inclusion criteria and framework. The articles can be found in evidence tables 1 & 2. See Evidence Table.

The use of Axumin Injection for PET Scan does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

18 F-florbetapir (Amyvid) PET for Alzheimer's disease

BACKGROUND

Alzheimer's disease (AD) is the most common cause of dementia in the elderly people. It is an age- dependent neurodegenerative disease characterized by progressive cognitive impairment, behavior disturbance, and irreversible memory loss. It is estimated that approximately 5 million people aged 65 years or older in the US are diagnosed with AD. The number continues to increase and is estimated to reach 6.7 million by 2025. The etiology of AD has not been established and there is no proven treatment to prevent or slow the progression the disease. It is however, necessary to examine the accuracy of the currently used diagnostic methods as these are critically important for AD research and prevention and treatment studies. Traditionally diagnosis of dementia in North America is based on clinical criteria defined by the National Institute of Neurological and Communicative Disorders and Stroke and Alzheimer's disease and related Disorders Association (NINCDS-ADRDA) Work Group in 1984. In 2011, the National Institute of aging (NIA) and the Alzheimer's Association recommended broadening and refining the 1984 criteria by proposing some changes in the classification criteria of AD, and incorporating biomarkers into the AD criteria. By most diagnostic criteria currently in use, AD is a diagnosis of exclusion based on evidence of chronic progressive cognitive and functional decline of insidious onset in middle aged and elderly patients with no other identifiable alternative explanation such as major, stroke, brain tumor, or systemic disease. Definitive diagnosis of AD depends on the histological examination of brain tissue, which is contraindicated for AD during the patient's lifetime due to the high risk/benefit ratio. While the clinical criteria for diagnosing AD have not changed substantially since they were introduced in 1984, the neuropathological diagnostic criteria have been changed several times in the past three decades. A recent analysis of clinical and neurologic data collected by the National Alzheimer's Coordinating Center from 2005-2010, showed that the sensitivity for AD diagnosis ranged from 70.9-87.3% and the specificity ranged from 44.3-70.8% depending on clinical criteria used. It was also found that as many as 20% of patients diagnosed with AD do not have AD pathology at autopsy (Jack 2011, Beach 2012, Kingwell 2012, Grundman 2013, Newberg 2012). The pathological process of AD is still unclear, but the most widely accepted theory is the amyloid cascade hypothesis, which explains that the accumulation and aggregation of amyloid -ß protein in the brain triggers a pathologic cascade ultimately leading to neuronal degeneration and dementia. Autopsy studies showing extracellular accumulation of amyloid plaques and intracellular neurofibrillary tangles support this hypothesis. On the other hand, some investigators postulate that the amyloid-ß aggregates are protective, and that the soluble oligomers and not the aggregates are toxic. Another argument against the amyloid-ß theory is the failure of a drug that reduces the amyloid -ß from the brain to improve cognition in patients with AD. Despite the disagreement about the role that the amyloid-ß protein plays in AD, the currently accepted pathologic definitions of AD require the presence of abnormal levels of amyloid-ß deposits throughout the cerebral cortex of the patient. Some argue that fibrillary plaques containing amyloid-ß may be necessary but insufficient for the diagnosis of AD. Amyloid plaques are also seen in other diseases such dementia with Lewy bodies, vascular dementia, and spongiform encephalopathy. They can also be detected in cognitively normal older adults, and according to researchers, individuals' brains may differ in their ability to tolerate amyloid aggregates based on genetic factors, lifestyle choices, environmental factors, and neuropathological comorbidities, all of which may alter the threshold for the onset of cognitive impairment associated with ß-amyloid aggregation (Okamura 2010, Clark 2011, Lister-James 2011, Herholz 2012, Newberg 2012). Lately, *in vivo* amyloid imaging techniques have received a lot of attention for their potential pre-symptomatic detection of amyloid -ß pathology. It is believed that *In vivo* imaging agents that are specific and sensitive for detecting amyloid plaques would be very useful for the molecular diagnosis of AD. Investigators suggest that a test which can rule out the presence of pathologically significant levels of amyloid-ß plaque in the brain, can rule out a diagnosis of AD even in patients with signs and symptoms consistent with the common forms of dementia. In contrast, the test that indicates abnormal levels of amyloid-ß in the brain, may add confidence to the clinical diagnosis of AD, but does not provide a definite diagnosis of AD. On this basis, a number of ß-sheet-

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biding radiotracers have been developed for PET. The most widely used agent is the ^{11}C-labeled Pittsburgh compound B (^{11}C-PIB). However, the short half- life (20 minutes) of the radioisotope ^{11}C limits the utility of the compound in the clinical setting as a tool for diagnosis and therapeutic evaluation of AD (Okamura 2010, Wong 2010, Lister-James 2011, Newberg 2012). More recently Avid Radiopharmaceuticals have developed an ^{18}F-labeled amyloid- ß PET tracer for the potential detection of AD. The ^{18} F-florbetapir is an amyloid- ß avid imaging agent selected from four styryl- pyridine derivatives due to its high affinity and specific binding for amyloid, fast uptake, and fast washout kinetics in the brain. ^{18}F-florbetapir is a radioactive agent with a half-life of 110 minutes that is given before positron emission tomography (PET) imaging of the brain. According to the manufacturer, ^{18} F-florbetapir crosses the blood brain barrier and binds to amyloid aggregates in the brain. A PET scanner can detect the signal emitted by the drug's radioactive fluorine and the resultant image will show the density of amyloid-ß neuritic plaques in the brain. The PET-tracer ^{18} F- florbetapir does not measure tau proteins (proteins that stabilize microtubules), which some experts believe plays a crucial role in AD (Okamura 2010, Wong 2010, Lister-James 2011, Newberg 2012, Rosenberg 2013). The PET-tracer ^{18} F-florbetapir (Amyvid,[Avid Radiopharmaceuticals, a subsidiary of Eli Lilly &Co), received FDA approval in 2012 for imaging of the brain in subjects under evaluation for AD and other cases of cognitive impairment. The FDA approval announcement indicated that Amyvid is not a test for predicting the development of AD-associated dementia and is not for monitoring patient response to AD therapy, nor does it replace other diagnostic tests used for the evaluation of cognitive impairment. The labeling explicitly states that a positive scan does not establish a diagnosis of AD or other cognitive disorder.

10/21/2013: MTAC REVIEW
18 F-florbetapir (Amyvid) PET for Alzheimer's disease
Evidence Conclusion: Analytic validity: Clark and colleagues (2011, 2012), evaluated the accuracy of the ^{18}F-florbetapir -PET scans among terminally ill patients who consented to undergo a postmortem biopsy. The mean age of the participants was 79.3 years, 48.6% had AD as their diagnosis, 8.6% had mild cognitive impairment, 17% had another dementing disorder, and 25.7% were cognitively normal. In the initial study (Clark et al, 2011) participants were followed-up until 35 individuals had died and underwent postmortem brain biopsy. Surviving individuals were followed for an additional 1 year after initial study or for up to 2 years after the florbetapir PET scan (Clark et al, 2012). The premortem scan was then compared to the postmortem brain autopsy findings. Each scan was interpreted with at least three nuclear medicine physicians who had undergone training on reading the florbetapir-PET scans. The results of the study showed a mean (among readers) sensitivity of florbetapir-PET scan of 87% and mean specificity of 95% with an overall mean accuracy of 90%. The authors performed a florbetapir -PET scan on a group of 74 healthy young individuals (mean age 26.7 years) to evaluate the specificity of the test. They assumed, and interpreted a negative scan in these patients as amyloid negative without comparing it to the gold standard. The study had the advantage of comparing ^{18}F-florbetapir-PET findings with the gold standard of histopathological findings. However, it also had a number of limitations, many of which were acknowledged by the investigators. These include but are not limited to:The accuracy of Florbetapir-PET was assessed in a nonrandom sample of terminally ill patients who were generally older and/or with poorer health conditions than those in the population that would typically be evaluated for AD in clinical practice. Mean time interval from of onset of symptoms of AD (among patients with the disorder) to enrollment was 9 years. This makes it hard to determine how early in the disease course, the amyloid plaques can be detected. Relatively small number of patients underwent postmortem brain biopsies. 22% of the autopsies were performed more than 12 months after the scan: according to the authors, "The relation between post-mortem pathological changes and actual changes in the brain at the time of PET scan might decrease with increasing scan-to autopsy interval (majority reading sensitivity of scan was 96% when autopsy was performed within 1 year from scan and 92% for that performed within 2 years). Both the imaging and histopathological results were distributed bimodally i.e. amyloid positive (moderate to frequent plaques) or negative (no or sparse plaques). There was no intermediate category (sparse to moderate). It is hard to determine whether measurable, but low levels of amyloid at pathology that are not associated with amyloid positive scan represent an early stage of the disease, variant of amyloid deposition, or normal aging. Each scan was interpreted with 3-5 nuclear medicine physicians who had underwent extensive training on reading the scan, which would not be the case outside of an investigational setting.
There were variations between the readers interpreting the scan especially with borderline amyloid levels leading to more false negative results. It is worth noting that the study was sponsored by Avid Radiopharmaceuticals, the developer of Amyvid, which was also involved in the collection, analysis, and interpretation of the data, as well as writing the report. Clinical validity - There is weak, insufficient published evidence to determine the usefulness of florbetapir-PET imaging in identifying individuals with mild cognitive impairment or cognitive symptoms who would progress to AD. Doraiswamy and colleagues (2012) investigated whether ^{18}F-florbetapir- PET scan can predict subsequent cognitive decline in older at-risk subjects. The study included 69 cognitively normal individuals at baseline, 51 with mild cognitive impairment (MCI), and 31 patients with AD. All underwent ^{18}F-florbetapir- PET scanning at baseline, and the images were interpreted by three readers as amyloid -ß (Aß) positive or Aß
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negative. The participants were followed-up for 18 months after which they were re-assessed for their cognitive status and function. The results showed that MCI patients who were amyloid positive had significantly greater decline in the majority of psychomotor tests vs. those who were amyloid negative. There was a small yet significantly higher conversion rate from MCI to AD among those who were amyloid positive versus amyloid negative patients. These results have to be interpreted with caution due to limitations of the study. It was relatively small, conducted in an investigational setting, had only 18 months of follow-up, the authors did not adjust for multiple comparisons, and the images were interpreted with three readers with some disagreement.
Clinical utility - Grundman and colleagues (2013) conducted a study to determine the impact of amyloid imaging with ^{18}F-florbetapir PET on the physicians' diagnostic thinking and intended management of 229 patients with progressive cognitive decline undergoing evaluation for suspected AD and diagnostic uncertainty. The treating physicians provided a provisional diagnosis, an estimate of their diagnostic confidence, and their plan for diagnostic evaluation and management both before and after receiving the results from amyloid imaging with ^{18}F-florbetapir. The scan was amyloid positive in 133 patients and amyloid negative for 116 patients. No histopathological confirmations were done.The results of the analysis shows that after receiving the results of the florbetapir scan, diagnosis changed in 125/229 (54.6%) patients. Intended medication management of AD increased by 17.7% for patients with positive scans and decreased by 23.3% among those with negative scans. Among subjects who had not yet undergone a completed work up, planned brain structural imaging decreased by 24.4% and planned neuropsychological testing decreased by 32.8%. The analysis also showed that 55% of the subjects were classified with an indeterminate diagnosis after a negative scan rather than a non-AD diagnosis which may reflect lack of confidence in the scan results.The study had the advantage of investigating the clinical utility of ^{18}F-florbetapir PET scan. However, the physicians were asked whether they would change their management plan, rather than observing the actual patient management over time. The study included patients with progressive cognitive decline and diagnostic uncertainty, and was conducted in a clinical trial setting by memory disorder experts experienced in the diagnosis and treatment of AD, and the scans were over-read by expert nuclear medicine specialists, thus the results may not be generalizable to the overall population evaluated for cognitive complaints. The effect of ^{18}F-florbetapir PET scan on patient outcome has not been examined and to date, there is no proven therapy for Alzheimer's disease or for lowering and/or reversing amyloid aggregates.
Safety - The most common adverse reactions reported in these published clinical trials include headache (1.8%), musculoskeletal pain (0.8%), fatigue (0.6%), nausea (0.6%), anxiety (0.4%), back pain (0.4%), increased blood pressure (0.4%), claustrophobia (0.4%), feeling cold (0.4%), insomnia (0.4%), and neck pain (0.4%). In conclusion, there is insufficient evidence to determine whether the use of ^{18}F-florbetapir-PET can accurately predict the risk of AD, would have impact on patient management, or improve net health outcomes of patients at risk of AD. More prospective studies are needed to verify its accuracy and role in the diagnosis and management of the AD. Alzheimer's Disease Neuroimaging initiative 2 (ADNI2) is an ongoing large longitudinal multicenter study that may determine the relationships among clinical, imaging, genetic, and biochemical biomarker characteristics of the entire spectrum of Alzheimer's Disease (AD), as the pathology evolves from normal aging through very mild symptoms, to mild cognitive impairment (MCI).
Articles: The literature search revealed a large number of articles on amyloid-ß imaging with PET, but only a limited number of studies was related to the current review. There was one phase III trial and a small number of phases I and II studies on the use of 18F-florbetapir-PET in patients with mild cognitive impairment (MCI) or dementia due Alzheimer's disease. The search also identified one study on the prognostic utility of the scan, and another on the potential impact of the imaging on patient management. The phase III study (submitted to the FDA), the study on the prognostic utility the imaging, as well as the larger study on its impact on patient management were selected for critical review. Doraiswamy PM, Sperling RA, Coleman RE, et al. Amyloid-β assessed by florbetapir F 18 PET and 18-month cognitive decline: a multicenter study. Neurology.2012;79:1636-1644. See Evidence Table. Clark CM, Schneider JA, Bedell BJ, et al for the AV45-A07 Study Group. Use of florbetapir-PET for imaging beta-amyloid pathology. JAMA. 2011;305:275-283. See Evidence Table. Clark CM, Pontecorvo MJ, Beach TG, et al for the AV-45-A16 Study Group. Cerebral PET with florbetapir compared with neuropathology at autopsy for detection of neuritic amyloid-β plaques: a prospective cohort study. Lancet Neurol. 2012;11:669-678. Grundman M, Pontecorvo MJ, Salloway SP, et al for the 45-A17 Study Group. Potential impact of amyloid imaging on diagnosis and intended management in patients with progressive cognitive decline. Alzheimer Dis Assoc Disord. 2013;27:4-15. See Evidence Table.

The use of ^{18} F-florbetapir (Amyvid) PET for Alzheimer's disease does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT® Codes	Description
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study;
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
A9587	Gallium Ga-68, dotatate, diagnostic, 0.1 mCi
A9515	Choline C-11, diagnostic, per study dose up to 20 mCi
A9592	Copper Cu-64, dotatate, diagnostic, 1 mCi
A9593	Gallium Ga-68 PSMA-11, diagnostic, (UCSF), 1 mCi
A9594	Gallium Ga-68 PSMA-11, diagnostic, (UCLA), 1 mCi
A9595	Piflufolastat f-18, diagnostic, 1 mCi
A9596	Gallium Ga-68 gozetotide, diagnostic, (Illuccix), 1 mCi
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9598	Positron emission tomography radiopharmaceutical, diagnostic, for nontumor identification, not otherwise classified
A9601	Flortaucipir F 18 injection, diagnostic, 1 mCi
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 mCi
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 mCi

Non-Medicare Members:
Effective until June 1, 2023

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Axumin – PET

HCPCS Codes	Description
A9588	Fluciclovine F-18, diagnostic, 1 mCi

Effective June 1, 2023

Non-Medicare Members:
Axumin – PET is no longer recommended

HCPCS Codes	Description
A9588	Fluciclovine F-18, diagnostic, 1 mCi

Medicare – Considered not covered
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

HCPC Codes	Description
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
G0219	PET imaging whole body; melanoma for noncovered indications

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
12/1997	02/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 11/06/2012[MDCRPC],09/03/2013[MPC] ,12/03/2013[MPC],12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/18/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/05/2015	Added Medicare Link to NCD 210.3 for Colorectal Cancer Screening Test
01/03/2017	Added Coverage Article A54668
05/01/2018	MPC approved to adopt Axumin PET non-coverage criteria
10/02/2018	Updated guidelines for head and neck cancers
12/7/2018	Added clarification about Medicare Radiopharmaceuticals
02/05/2019	MPC approved to adopt coverage criteria for Axumin Injection for PET scan. Added to background MTAC review from 01/2019.
03/05/2019	Added indications for Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)
04/02/2019	MPC approved criteria for Axumin PET for prostate cancer
05/07/2019	MPC approved to adopt criteria for Cardiac PET
01/27/2020	Updated Site of Service for Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)
05/05/2020	MPC approved to adopt updates for cardiac sarcoidosis
06/01/2021	MPC approved to endorse the recommendations for PET imaging using somatostatin receptor (SSR)-PET for neuroendocrine tumors from the National Comprehensive Cancer Network® (NCCN) Guideline for Neuroendocrine and Adrenal Tumors. Also, removed reference to using Swedish as the site of service and added Kaiser Permanente locations. Requires 60-day notice, effective date 11/01/2021.
01/07/2022	Listed covered radiopharmaceuticals in Medicare section as per LCA A54668. Added Gallium GA-68 PSMA-11 and Piflufolastat F-18 (PSMA PET for prostate) as currently not medically necessary for non-Medicare.

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01/31/2022	Updated NCD 220.6.19 link
12/06/2022	Care Delivery Medical Necessity Review for ENT/OTO and Pulmonary audit has been reviewed; prior authorization with no medical review has been awarded for another year
01/10/2023	MPC approved to adopt coverage for Whole Body CT for Multiple Myeloma; 60-day notice required, effective June 1, 2023.
01/10/2023	MPC approved to adopt coverage for PET-PSMA; 60-day notice required, effective June 1, 2023. PSMA PET located in separate criteria.
1/23/2023	Added new codes A9601, A9596 effective 7/1/2023
03/03/2023	Added New HCPC code A9602 effective 10/01/2022
04/18/2023	Clarified language for imaging modality for Multiple Myeloma

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Pharmacogenomic Testing

- ALK Gene Rearrangement and Non-Small-Cell Lung Cancer
- BRAF-v600E Mutation
- Breast Cancer Index
- ChemoFx® Assay
- Conductance Regulator (CFTR) Gene
- Cytochrome P450 Genotyping Test Drug Metabolizing Enzyme Genotyping System
- EndoPredict
- Epidermal Growth Factor Receptor (EGFR) Testing for Predicting Response of Patients with NSCLC to Tyrosine Kinase Inhibitors (TKIs)
- G551D Mutation in the Cystic Fibrosis Transmembrane
- IL28B (IFNL3) Polymorphisms in Patients with Hepatitis C
- Invader UGT1A1 Molecular Assay
- KRAS/NRAS
- Oncotype DX
- Platelet Function Testing (VerifyNow P2Y12 Assay)
- Prosigna Breast Cancer Prognostic Gene Signature Assay
- Warfarin Sensitivity DNA Test

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Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage)

Prevention and Invitae Corporation is the preferred lab for genetic testing when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae/Prevention.*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions
For the genetic test(s) listed below, please use the lab specified:

- ***Next Generation Sequencing for Advanced Cancer*** **–** —Any of these three labs can be used:
  - CellNetix SymGene Panel
  - Oncoplex (University of Washington)
  - Caris Life Sciences

Related Policies:

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Genetic Panel Testing
Genetic Screening and Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	
National Coverage Determinations (NCD)	Pharmacogenomic Testing for Warfarin Response (90.1)
Local Coverage Determinations (LCD)	MolDX: Pharmacogenomics Testing (L38337) MolDX: Molecular Diagnostic Tests (MDT) (L36256) MolDX: Breast Cancer Index™ (BCI) Gene Expression Test (L37824) (CPT 81518) MolDX: ENDOPREDICT® Breast Cancer Gene Expression Test (L37311) (CPT 81522) MolDX: NRAS Genetic Testing (L36339) (CPT 81311, 81479) MolDX: Breast Cancer Assay: Prosigna (L36386) (CPT 81520)
Local Coverage Article	Billing and Coding: MolDX: Pharmacogenomics Testing (A57385)

Palmetto GBA is the Medicare contractor for Molecular Diagnostic Testing – this site has the most up to date Medicare coverage guidelines for genetic testing.
MolDX® Program (Administered by Palmetto GBA)

For Non-Medicare Members

Members must meet **ALL the following** criteria:

1. The member is at clinical risk for a genetic condition because of current documented symptoms being displayed or a strong family history of the condition.
2. The test is scientifically valid and can be adequately interpreted.
3. The results will directly affect a member's clinical management or reproductive decisions.
4. After appropriate clinical work-up, and informed consent by the appropriate practitioner, the genetic test is indicated.

Genetic testing is not covered for the medical management of a family member who does not have Kaiser Permanente coverage.

*For **specific tests listed** below the member must meet the criteria above **AND** the specific test criteria below:
For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.

Genetic Test	Criteria Used
Abacavir HLA-B*5701 CPT 81381	This test is covered when: 1) Prior initiation of therapy with abacavir

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Genetic Test	Criteria Used
Anaplastic Lymphoma Kinase (ALK) Gene Rearrangement Testing for Locally Advanced or Metastatic Non-Small-Cell Lung Cancer CPT 88377	**Effective until 05/01/2023:** This test is covered when: 1) Crizotinib is being recommended, AND 2) A positive test is required to initiate use of this drug **Effective 05/01/2023:** No longer requires review
Breast Cancer Index™ CPT 81518	There is insufficient evidence in the published medical literature to show clinical utility.
Carbamazepine Pharmacogenetics - HLA-B*1502 Allele CPT 81381	MCG* A-0649 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
ChemoFx Assay CPT 89240, 81535, 81536	There is insufficient evidence in the published medical literature to show clinical utility.
Colorectal Cancer - BRAF V600E Testing CPT 81210	Does not require medical review
Colorectal Cancer - KRAS and NRAS Genes	Does not require medical review
ENDOPREDICT® CPT 81522	There is insufficient evidence in the published medical literature to show clinical utility.
GenoSure Archive CPT 87900, 87901, 87906	These tests are covered when: 1) Maraviroc is being considered, AND 2) A positive test is required to initiate use of this drug
Trofile DNA phenotype CPT 87999	
CYP2:	
• CYP2B6/CYP3A4/CYP2A6 Efavirenz CPT 80299, 81401, 81479 • CYP2C19 Proton Pump Inhibitors (PPI) for Treating Helicobacter Pylori CPT 81225, 81226, 81227, 81401, 81479 • Immunosuppressants for Organ Transplant CYP3A5 and CYP3A4 CPT 81401	There is insufficient evidence in the published medical literature to show clinical utility.
Clopidogrel (Plavix) Pharmacogenetics - CYP2C19 Gene CPT 81225	MCG* A-0631 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Tamoxifen Pharmacogenetics – CYP2D6 Gene CPT 81226, 0070U, 0071U, 0072U, 0073U, 0075U, 0076U	MCG* A-0647 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Epidermal Growth Factor Receptor (EGFR) Testing for Predicting Response of Patients with NSCLC to Tyrosine Kinase Inhibitors (TKIs) Such as VeriStrat CPT 81235	**Effective until 05/01/2023** Epidermal Growth Factor Receptor Testing is covered when: 1) Diagnosis of NSCLC **Effective 05/01/2023** No longer requires review
IFNL3 (previously IL28B) Polymorphisms in Patients with Hepatitis C CPT 81283	There is insufficient evidence in the published medical literature to show clinical utility.

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Genetic Test	Criteria Used
5-Fluorouracil Pharmacogenetics - DPYD, MTHFR, and TYMS Genes CPT 81232, 81291, 81346	MCG* A-0665 - Kaiser Permanente will not cover this per MCG guideline. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Irinotecan Dosing - UGT1A1 Gene (Invader) CPT 81350	MCG* A-0624 Current role remains uncertain For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
KRAS and/or NRAS KRAS: CPT 81275, 81276, 0111U NRAS: CPT 81311, 0111U	**Effective until 05/01/2023** The following criteria must be met: 1) The test is ordered by the treating oncologist 2) The test is being used to determine whether the patient has the mutant KRAS or NRAS genes and the presence of the mutation would change treatment decisions with Cetuximab or Panitumumab. **Effective 05/01/2023** No longer requires review
Malignant Melanoma (Cutaneous) - BRAF V600 Testing CPT 81210	Does not require medical review
Oncotype Dx – Breast CPT 81519, S3854 Oncotype DX – Colon Cancer CPT 81525 Oncotype DX – Prostate CPT 0047U	Covered when the following criteria are met: 1. Axillary node biopsy is negative for tumor or is positive only for micrometastasis, defined as no focus of tumor > 2 mm diameter. 2. Newly diagnosed invasive ductal carcinoma of breast, stage I or II 3. Outcome of testing will guide decision making regarding adjuvant chemotherapy. 4. Patient is female. 5. Primary tumor is estrogen receptor positive. 6. Primary tumor is HER-2 receptor-negative. Colon MCG* A-0651 and Prostate MCG* A-0712- Current Role Remains Uncertain. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Opioid Pharmacogenetics - CYP450 Polymorphisms, OPRM1 Gene, and Gene Panels CPT 81225, 81226, 81227, 81230, 81231, 0031U, 0070U, 0071U, 0072U, 0073U, 0075U, 0076U, 0078U	MCG* A-0992 Current role remains uncertain For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Platelet Function Testing (VerifyNow P2Y12 Assay) CPT code 85576	Medical necessity review no longer required

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Genetic Test	Criteria Used
Psychotropic Medication Pharmacogenetics - CYP450 Polymorphisms CPT 81225, 81226, 81479, 0070U, 0071U, 0072U, 0073U, 0075U, 0076U Psychotropic Medication Pharmacogenetics – ABCB1, ADRA2A, BCNF, COMT, DRD, FKBP5, GNB3, HTR, MC4R, OGFRL1, SLC6A4, and TPH1 Genes CPT 81403, 81479, 0032U, 0033U	MCG* A-0692 Current role remains uncertain. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*. MCG* A-0859 Current role remains uncertain For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Prosigna Breast Cancer Prognostic Gene Signature Assay CPT 81520	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Rasburicase Pharmacogenetics - G6PD Gene CPT 81247, 82148, 81249	MCG* A-0653 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Statin Pharmacogenetics - SLCO1B1 Gene CPT 81328	MCG* A-0981 Current role remains uncertain. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Azathioprine and 6-Mercaptopurine Pharmacogenetics - NUDT15 and TPMT Genes CPT 0034U, 0169U, 81335	MCG* A-0628 Current role remains uncertain For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Warfarin Sensitivity DNA Test CPT 81227, 81355, G9143	This test is covered once in a lifetime to guide the Warfarin dosing strategies when the patient has had no more than 5 doses of Warfarin prior to testing.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting any of these services, please send the following documentation to support medical necessity:

- Any genetic counseling notes if applicable
- Last 6 months of specialist notes of that is being reviewed (neurological - neurology notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Pharmacogenetics is defined as the study of the genetic basis for differences in a population's response to a drug. It seeks to identify polymorphisms (genetic variations) that result in different systemic concentration levels of drugs, which may help explain differing responses to the same medication. The field of pharmacogenetics began as the study of gross ethnic variations (e.g., variation by ethnic groups) and evolved into the study of variations of genes and proteins within individuals. Kaiser Permanente is evaluating the evidence for each test as the evidence is published.

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Evidence and Source Documents

ALK Gene Rearrangement and Non-Small-Cell Lung
Breast Cancer Index
Cancer BRAF-v600E Mutation
ChemoFx Assay
Cytochrome P450 Genotyping Test Drug Metabolizing Enzyme Genotyping System
Epidermal Growth Factor Receptor (EGFR) Testing for Predicting Response of Patients with NSCLC to Tyrosine Kinase Inhibitors (TKIs)
IL28B (IFNL3) Polymorphisms in Patients with Hepatitis C
Invader UGT1A1 Molecular Assay
KRAS
Oncotype DX
Platelet Function Testing (VerifyNow P2Y12 Assay)
Prosigna Breast Cancer Prognostic Gene Signature Assay
Warfarin Sensitivity DNA Test

Medical Technology Assessment Committee (MTAC)

ALK Gene Rearrangement and Non-Small-Cell Lung Cancer

BACKGROUND

Lung cancer is one of the most common causes of cancer death, accounting for over 1 million deaths annually. Lung cancer is comprised of two histological types: small-cell lung cancers and non-small-cell lung cancers. Non-small-cell lung cancer (NSCLC) accounts for approximately 85% of lung cancers. Traditionally, treatment decisions have been based on histological type. For patients with NSCLC, platinum-based chemotherapy constitutes standard first-line treatment. However, a therapeutic plateau has been reached with conventional chemotherapy for NSCLC patients. Advances in the knowledge of molecular mechanisms of carcinogenesis have led to a change in the treatment strategy for patients with NSCLC. Research efforts are now focusing on new therapies that target molecular subtypes of NSCLC (Janku 2010, Pao 2011, Sasaki 2010). Anaplastic lymphoma kinase (ALK) is a tyrosine kinase that is not normally expressed in lung cancer. Fusions of ALK with echinoderm microtubule-associated protein-like 4 (EML4), an upstream promoter, were found in NSCLC in 2007. However, EML4 does not appear to be the exclusive fusion partner with ALK. Biologically, these fusions result in constitutive activation of the kinase. It has been reported that approximately 3 to 7% of tumors harbor EML4-ALK fusions. Although associations with clinical and pathological characteristics are not well established, research suggests that EML4-ALK fusions are associated with never smokers or light smokers, younger patient age, patients with adenocarcinomas, and patients with more advanced NSCLC. While the frequency of epidermal growth factor receptor (EGFR) mutations also increases in patients with these characteristics, EML4-ALK rearrangements are generally not found in patients with EGFR or KRAS mutations (Janku 2010, Pao 2011, Sasaki 2010). Currently, clinical trials are underway to determine the safety and efficacy of ALK kinase inhibitors for the treatment of NSCLC in patients with EML4-ALK rearrangements.

08/15/2011: MTAC REVIEW

ALK Gene Rearrangement and Non-Small-Cell Lung Cancer

Evidence Conclusion: Analytic validity: Several methods are available for detecting EML4-ALK rearrangements in patients with NSCLC; however, there is currently no gold standard method. Clinical validity: There is insufficient evidence to determine the clinical validity of testing for EML4-ALK rearrangements in patients with NSCLC. Clinical utility: There is insufficient evidence to determine the clinical utility of testing for EML4-ALK rearrangements in patients with NSCLC.

Articles: Assessment objective: Analytic validity: Are the clinical assays for the detection of ALK gene rearrangements accurate and reliable? Clinical validity: Does the presence of an ALK gene rearrangement predict clinical outcome? Clinical utility: Will the results of the clinical assays for the detection of ALK gene rearrangements alter clinical management and improve clinical outcomes? Several methods including polymerase chain reaction (PCR), immunohistochemistry (IHC), and fluorescence in situ hybridization (FISH) are currently being evaluated for the detection of ELM4-ALK rearrangements. Each of these methods has its advantages and limitations. Currently, there is no gold standard method for detecting EML4-ALK rearrangements in patients with NSCLC (Sasaki 2010). A small retrospective cohort study was identified that addressed the clinical validity of testing patients with NSCLC for EML4-ALK gene rearrangements; however, this study was not selected for review as it only included 19 patients with EML4-ALK rearrangements. Results from this study suggest that patients with EML4-ALK rearrangements have

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similar response rates to platinum-based combination chemotherapy as patients without these mutations. Additionally, patients with EML4-ALK rearrangements do not appear to respond to tyrosine kinase inhibitors (Shaw 2009). Larger studies are needed to confirm these findings. To date there are no FDA approved agents for the treatment of NSCLC in patients with EML4-ALK gene rearrangements. Results from a phase 1 open-label, prospective case-series that included 82 subjects with EML4-ALK rearrangements suggest that crizotinib, an orally available small-molecule inhibitor of the ALK tyrosine kinase, may be effective for the treatment of NSCLC in patients with EML4-ALK rearrangements. The overall response rate, which included confirmed partial and complete responses, was 57% and 33% of patients had stable disease. The most commonly reported adverse effects were nausea (54% of patients) and diarrhea (48% of patients) (Kwak 2010). Phase 3 clinical trials are now underway to determine the safety and efficacy of crizotinib compared to pemetrexed or docetaxel in patients with advanced NSCLC and EML4-ALK gene arrangements (ClinicalTrials.gov number, NCT00932893).

The use of ALK gene rearrangement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

BRAF^{V600E} Mutation

BACKGROUND

In the past year, several therapies for late-stage melanoma have been approved, including peg-interferon α-2b (Sylatron) and ipilimumab (Yervoy). Until now, ipilimumab was the only agent to demonstrate an improvement in overall survival for patients with advanced melanoma. Vemurafenib is approved for the treatment of advanced melanoma as well but targets a specific patient population. It is an inhibitor of mutated forms of BRAF serine-threonine kinase, including BRAF^{V600E}, and also inhibits other kinases at similar concentrations. Some mutations in the BRAF gene, including V600E, result in constitutively activated BRAF proteins, which can cause cell proliferation in the absence of growth factors that would normally be required for proliferation. Confirmation of BRAF^{V600E} mutation-positive melanoma as detected by the cobas® 4800 V600 Mutation Test, is required for selection of patients prior to administration of vemurafenib. This test is designed to detect BRAF^{V600E} mutations in DNA isolated from formalin-fixed, paraffin-embedded human melanoma tissue. This test is marketed by the same company that manufactures vemurafenib, and its FDA approval is based on the same data that supported approval of vemurafenib.

09/2011: Pharmacy and Therapeutics Committee (P&T) BRAF^{V600E} Mutation

Evidence Conclusion: From P&T Committee: Evidence of benefit[2-4]: Preliminary data from BRIM-2, a phase 2 trial, showed that patients with BRAF^{V600E} mutation + melanoma who had received prior treatment and were subsequently treated with vemurafenib, had an objective response rate >50%. Based on this data, the FDA recommended modification of the statistical plan for BRIM-3, a phase 3 trial, to accommodate an interim analysis and accelerate the approval process. Median follow-up in BRIM-3 was ~3 months. In the BRIM-3 trial, vemurafenib, 960mg BID was superior to dacarbazine in progression-free survival (5.3 months vs 1.6 months; p<0.001) and objective tumor response rate (48% vs 5%, p<0.001).

Complete responses were seen in 2 patients (0.9%) of patients in the vemurafenib group and 0 in the dacarbazine group. Median overall survival was not reached in the vemurafenib group, but was 7.9 months in the dacarbazine group. At 6 months, overall survival was 84% in the vemurafenib group and 64% in the dacarbazine group; p<0.001. In BRIM-2 and BRIM-3, all enrolled patients tested positive for the BRAF^{V600E} mutation using the cobas® 4800 V600 Mutation Test. Evidence of harm[1-3]: The most common adverse reactions of any grade (≥ 30% in either study) reported in patients receiving vemurafenib were arthralgia, rash, alopecia, fatigue, photosensitivity reaction, nausea, pruritus and skin papilloma. The most common (≥5%) Grade 3 adverse reactions were cutaneous squamous cell carcinoma (cuSCC) and rash; 24% of patients treated with vemurafenib were reported to have at least one cuSCC. These lesions were excised, and none required dose-modifications. The incidence of Grade 4 adverse reactions was ≤ 4% in both studies. In BRIM-3, the incidence of adverse events resulting in discontinuation was 7% in the vemurafenib arm and 4% for the dacarbazine arm. There are no contraindications to vemurafenib. Safety issues addressed in the package insert include cuSCC, serious hypersensitivity reaction, Stevens-Johnson syndrome and toxic epidermal necrolysis, QT-prolongation, liver laboratory abnormalities, photosensitivity, uveitis and other ophthalmologic reactions, and new primary malignant melanomas. Pregnancy category D, may cause fetal harm based on its mechanism of action. Women of childbearing potential and men should be advised to use appropriate contraceptive measures during therapy and for at least 2 months after discontinuation.

Articles: Table 1. Summary of results from BRIM-2: an open-label, single-arm, Phase II trial

Study population	Outcome	Vemurafenib 960mg BID (95% CI) , n=132

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BRAF^{V600E} mutation + melanoma who have completed prior 1st line therapy	Best overall response rate	52.3% (43, 61)
	Median duration of response	6.8 months (5.6, not reached)
	Median PFS	6.2 months (5.6, 6.8)

Table 2. Summary of results from BRIM-3: a randomized double-blind placebo-controlled Phase III trial

Study population	Outcome	Vemurafenib n=337	Dacarbazine n=338	HR (95% CI) *p*-value	ARR (95% CI)	NNT (95% CI)
Unresectable stage IIIC or IV melanoma, + BRAF^{V600E} mutation, treatment naïve	Overall survival	Median not reached 84% at 6 months	7.9 months (7.3, 9.6) 64% at 6 months	0.37 (0.26, 0.55) *p*<0.001	20% (13, 26)	5 (4, 7)
	Progression-free survival	5.3 months (4.9, 6.6)	1.6 months (1.6, 1.7)	0.26 (0.2, 0.33) *p*<0.001	NA	NA
	Objective tumor response rate	48% (n=219)	5% (n=220)	*p*<0.001	43% (35, 50)	2 (2, 3)

HR – Hazard ratio ARR – Absolute Risk Reduction NNT – Number Needed to Treat to benefit one person

This was not considered at MTAC but went to P&T instead.

Breast Cancer Index

BACKGROUND

Breast cancer is the most common cancer diagnosed and the second most common cause of cancer death in women in the United States. Patients with breast cancer can present with a variety of symptomatology that originates from heterogeneous molecular pathology (Dowsett et al., 2010). Breast cancer can be staged using the Tumor, Node, Metastases classification (TNM). The treatment of invasive breast cancer is based on the stage and involves radiation, surgery, and adjuvant therapy. The management based on adjuvant therapy derives from many factors such as the TNM characteristics, the grade, the presence or absence of estrogen and progesterone receptors, and the human epidermal growth factor 2 (HER2) receptor. However, some patients are still mistreated. Molecular tests that can predict the prognosis and the response to adjuvant therapy might accurately evaluate the recurrence risk and impact disease management. The literature has described several molecular tests including the Breast Cancer Index (BCI).

The BCI is a reverse transcriptase polymerase chain reaction (rt-PCR) test that helps to guide treatment decision in women with early stage breast cancer who are ER+, LN- or LN+, and are distant recurrence-free (https://www.breastcancerindex.com/). The test assesses the overall (10 years) and late distance recurrence (5-10 years) (prognostic) and who benefits from extended endocrine therapy (predictive) after an initial 5-years of endocrine therapy (https://www.breastcancerindex.com/). The test can also be performed after treatment has begun to determine late distance recurrence and the likelihood of benefit from extended endocrine therapy.

The assay is a combination of two markers, the HOXB13/IL17BR (H/I) which is based on two genes, and a proliferation marker which is the molecular grade index (MGI) (based on 5 genes) (Sanft et al., 2015; Dennis C Sgroi, Carney, et al., 2013). These markers evaluate the prognostic component by generating a risk score that varies from 0 to 10. For overall risk, BCI score is classified into three categories: BCI score <5.1 is low risk; 5.1 ≤ BCI score ≤6.5 is intermediate risk, and BCI score ≥6.5 is high risk (Sanft et al., 2015). For the risk of late distant recurrence in patients with lymph node negative, BCI score is classified as low risk BCI < 5.0825 and high risk BCI ≥ 5.0825 (Hayes, 2016). In addition to gene expression, BCI score is determined in N1 patients by adding tumor size and grade (https://www.breastcancerindex.com/about-breast-cancer-index).

The predictive part is based on the quantitative molecular assessment of estrogen signaling pathways (based on H/I) and is indicative of who benefits from extended endocrine therapy after an initial course (5 years) of endocrine treatment (https://www.breastcancerindex.com/about-breast-cancer-index#).

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Evidence Conclusion: Analytical validity: One study (Zhang et al., 2013) assessed the analytical validity of the BCI assay. The authors reported a coefficient of variation (CV) ranging from 0.9 to 1.77% when the assay was run four times over a period of two weeks by three different operators. Furthermore, the CV is in the same range (0.86 to 1.40%) when the assay was run in 42 independent batches with the universal reference RNA as a positive control. In addition, the intra-assay reproducibility varied from 0.19% to 2.23%. The findings suggest that BCI has a high reproducibility in ER+, LN- patients since all the included patients were LN-. Limitations included: financial ties with manufacturer and lack of assessment of coefficient of variations (CV) for the BCI tests scores. Overall, this study provides low quality evidence to support the analytical validity of the BCI assay. **Clinical validity:** Four studies (Sanft et al., 2015; Dennis C Sgroi, Carney, et al., 2013; Dennis C Sgroi, Sestak, et al., 2013; Zhang et al., 2013) were reviewed. One study assessed clinical validity as well as clinical utility (Sanft et al., 2015); another study evaluated analytical validity and clinical validity (Zhang et al., 2013). Sample size ranges from 83 to 665 patients. Patients were ER+, LN- or LN+, postmenopausal (for the majority) and treated with an initial course (5 years) of endocrine therapy. **For early distant recurrence** (0-5 years): the distant recurrence is higher as the BCI score increases(Dennis C Sgroi, Sestak, et al., 2013; Zhang et al., 2013). Early distant recurrence rates for BCI Low risk, intermediate, and high risk are 2, 5, 12% respectively with P=0.006 (Zhang et al., 2013). Similarly, early distant recurrence rates for BCI Low risk, intermediate risk, and high risk are 1.3, 5.6, and 18% respectively (Dennis C Sgroi, Sestak, et al., 2013). Likewise, the distant recurrence-free survival (DRFS) is 98, 95, and 88% for low BCI risk, intermediate, and high BCI risk respectively (Zhang et al., 2013). **For late distant recurrence** (5-10 years): late distant recurrence is 3, 7, and 10% for low BCI risk, intermediate, and high risk with P=0.015 (Zhang et al., 2013). Another study (Dennis C Sgroi, Sestak, et al., 2013) reported 3.5, 13.4, and 13.3% for low BCI risk, intermediate, and high risk respectively. Similarly, the DRFS is 97, 93, and 90% for low, intermediate and high risk (Zhang et al., 2013). The distant recurrence over 10 years shows similar pattern (D. C. Sgroi et al., 2016; Dennis C Sgroi, Sestak, et al., 2013). One study (Dennis C Sgroi, Sestak, et al., 2013) reported that BCI was superior to Oncotype Dx assay in distant recurrence over 10years. The results indicate that early and distant recurrences rates increase as BCI risk increases. Also, the DRFS decreases and BCI risk increases. It is also worth noting that, in one study, the distant recurrence rate was stable for intermediate as well as high risk. Limitations included: financial ties with manufacturer, chemotherapy use by some patients; lack of extrapolation since only postmenopausal women and LN- were included; manufacturer personnel undertook BCI assays in one study. Based on Simon (Simon, Paik, & Hayes, 2009), the level of evidence is IB. **For predictive effect**: One study (Sanft et al., 2015) reported likelihood of endocrine benefit after 5 years of endocrine Rx of 37% (for high likelihood) vs. 1.7% (for low likelihood) in patients with BCI high risk. In contrast, in patients with BCI low risk, the same probability is 35% (for high likelihood) vs. 76%. However, the finding is 27% (for high likelihood) vs. 21% (for low likelihood) among patients in intermediate risk. Another study (Dennis C Sgroi, Carney, et al., 2013) reported recurrence free-survival (at 5 years) of 89.5% (95% CI = 80.3% to 94.5%) among high risk patients (initially treated with endocrine therapy) who received letrozole compared to 73% (95% CI = 56.6% to 84.1%) in high risk patients who were treated with placebo; in low risk patients, the recurrence free-survival is the same between both groups.
The findings of the studies investigating the predictive value suggest that there is extended endocrine therapy benefit after initial course of endocrine therapy in high risk patients; no benefit in low risk patients, and slight to no benefit in patients in intermediate risk. Limitations included: the lack of extrapolation of findings, small sample size, and selection bias inherent to retrospective design. The risk of bias is also high. Overall, these studies provide low evidence to support extended use of endocrine therapy in high risk patients after being treating with endocrine therapy for 5 years. **Clinical utility:** One study (Sanft et al., 2015) was identified. Patients were ER+, LN- or LN+, postmenopausal (though 23% was premenopausal).The authors reported 26% change in treatment decision and a reduction in recommendations for extended endocrine therapy (ranged from 74 to 54%) (OR: 0.14 (0.04–0.46); p=0.0003). Improvement in anxiety (31.3 vs. 29.1; p = 0.031) and patient decision conflict (20.9 vs 10.8; p<0.001) was also reported. Limitations include: the non-randomized nature of the study; generalizability of findings is compromised since the population was Caucasian and patients were from academic medical center. Based on Simon (Simon et al., 2009), the level of evidence is III C. Conclusion to support for or against the clinical utility of BCI assay cannot be made.

Other studies:

Author/Design	Population/Findings	Conclusion/LOE
(D. C. Sgroi et al., 2016) Retrospective-prospective study	**Population:** ER+, LN-(51%), LN+ (49%) **Recurrence free Survival:** HR 2.34, 95% CI 1.33 - 4.11; p = 0.004 BCI low risk: 87.5%,	BCI had prognostic effect on early invasive BC patients with LN- or LN+, treated with tamoxifen or tamoxifen + octreotide. LOE: IB

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Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

	Intermediate risk: 83.9% High-risk: 74.7%	
(Sestak et al., 2016) Retrospective-prospective study	**Population:** ER+, LN- **Findings:** BCI & RS were prognostic of DR over 10 years; but the association is higher for BCI than RS (BCI: HR 3.24 (2.31-4.54); RS: HR 1.39-1.94)). BCI provided additional prognostic information than RS (BCI: LR-X2 11.09 (P=0.0009); RS: LR-X2 2.22 (P=0.1)). When BCI restratified RS low & RS intermediate risk groups, the DRs were significantly different; suggesting that the groups identified by BCI may be treated with extended endocrine therapy	BCI provided additional prognostic information beyond frequently known clinical factors and RS in ER+, LN-, treated with endocrine therapy. LOE: IB

LOE, level of evidence (based on Simon et al. 2009 revised determination of levels of evidence using elements of tumor marker studies);

Conclusion

- Analytic validity: there is insufficient evidence to recommend for or against the analytical validity of the BCI assay in ER+, LN- or LN+ breast cancer patients.
- Clinical validity:
  - Level IB evidence (based on Simon et al. 2009 revised determination of levels of evidence using elements of tumor marker studies) supports the prognostic effect of early recurrence, distant recurrence, and distant recurrence over 10 years in ER+, LN- breast cancer patients. In addition, there is insufficient evidence to assess clinical validity in LN+ patients.
  - Low evidence supports extended use of endocrine therapy in high risk patients with ER+, LN- breast cancer patients.
- Clinical utility: there is insufficient evidence to make a conclusion on the clinical utility of the BCI assay in ER+, LN- or LN+ breast cancer patients.

Articles: PubMed was searched through April 10, 2017 with the search terms breast cancer index bci with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded 20 articles; however, six met our criteria.

The use of Breast Cancer Index for predicting response of solid tumors to chemotherapeutic agents does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

ChemoFx® Assay

BACKGROUND

It is widely recognized that patients with the same histological stage and grade of cancer may vary considerably in their clinical response and tolerability to chemotherapy. An individual may be resistant to one chemotherapeutic and sensitive to another, suggesting that there is considerable clinical heterogeneity in tumor chemosensitivity. Unfortunately, resistance to chemotherapy cannot be predicted by clinical or histological examination. The administration of an ineffective therapy is associated with unnecessary toxicity, delay of potentially useful drug, added risk of the development of resistant clones, and needless cost. Many attempts have been made over the years to develop an ex-vivo test that would provide clinically relevant tumor-specific information, i.e. measures how a patient cancer cells respond to specific types, doses and combinations of chemotherapy (Gallion 2006, Cree 2007). A number of in-vitro chemosensitivity response tests have been, and are currently used. These include assays that measure cellular metabolic activity, tests that measure radioactive precursor incorporation, and tests that measure cell viability. Chemoresponse assays are not intended to be used as an alternative to the traditional empiric methods for selecting chemotherapy but as an aid to the oncologists when selecting the most appropriate chemotherapy regimens on an individual basis especially when a number of equivalent options are available (Ness 2002, Gallion 2006, Cree 2007). ChemoFx® (Precision Therapeutics) is an ex-vivo, cell death

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assay based on the biological phenomenon that when cells that grow adherent in culture as a monolayer, die they lose their adherent qualities and lift from the culture surface. The test is reported to use as little as 35 mg of tissue, and have the results available in about 3 weeks after receiving the specimen. It involves growing tumor cells (excised from individual cancer patients through biopsy or surgery, or recovered from fluid specimens), in primary cultures as monolayers. Once a sufficient number of cells are grown, they are exposed to a variety of chemotherapeutic agents in a range of concentrations. A full dose-response curve is generated for each drug evaluated, and the data are presented graphically as the cytotoxic index (% kill), defined as 1-[No of cells in treated wells/No. of cells in control wells] x100. Features of each dose-response curve are used to score a tumor's response to each ex vivo treatment as responsive, intermediate response, or nonresponsive. Drug responses are scored from 0-5 and is determined by the number of drug doses where the cytotoxic index was >35%. Collectively these scores may be used by the oncologist in his treatment decisions (Peters 2005, Zhibao 2008).

10/05/2009: MTAC REVIEW
ChemoFx® Assay
Evidence Conclusion: Clinical validity: ChemoFx assay was not prospectively compared head to head to another cellular or molecular chemo responsive test or gold standard. Two retrospective cases series correlated the results of ChemoFx with cancer free survival in ovarian cancer patients, and one small series correlated its results with pathological complete response of small breast lesions to neoadjuvant therapies. Gallion, and colleagues 2006, retrospectively correlated the results of ChemoFx assay to progression free interval (PFI) in a case series of 304 patients with ovarian or peritoneal carcinoma. The study was a case series with potential selection and observational biases. It was not blinded, had no comparison group, and while selection of chemotherapy was at the discretion of the treating physician, some used the results of the assay to help determine the appropriate regimen. Overall, the results of show that 256 cases had an exact or partial match between drugs assayed and received, and 135 cases had an exact match. In the latter group the median PFI was 9 months for patients treated with drugs assayed as resistant, 14 months for those treated with drugs assayed as intermediate and had not been achieved (during study period) for those with drugs assayed as sensitive. The calculated hazard ratio for progression of the resistant group vs. the sensitive group was 2.9 (95% CI: 1.4-6.3), and that of the intermediate vs. sensitive group was 1.7 (95% CI; 1.2-2.5). Clinical utility: The literature search did not identify any published randomized or nonrandomized controlled trials that evaluated the effect of ChemoFx testing on individualizing chemotherapeutic regimen and /or its impact on survival. Other observational non-comparative prospective studies examining the outcomes associated with the use ChemoFx are underway. Conclusion: There is insufficient evidence to date to determine the clinical validly and utility of ChemoFx in selecting the most appropriate chemotherapy regimens and improving survival of cancer patients.
Articles: The published literature on ChemoFx® is very limited. There were only two case series (N=304, and N=18) that retrospectively evaluated the predictive value of ChemoFx assay by correlating its results with progression free interval (PFI) in patients with ovarian cancer, and another small case series among 34 women with breast cancer, that correlated the pathological complete response to a neoadjuvant chemotherapy with the results of ChemoFx® testing. As regards the clinical utility of the test, the literature search did not reveal any randomized or non-randomized controlled trials that compared outcomes among patients managed with and without ChemoFx® testing. The larger case series on the predictive value of ChemoFx was critically appraised Gallion H, Christopherson WA, Coleman RI, et al. Progression –free interval in ovarian cancer and predictive value of an ex vivo chemo responsive assay. Int J Gynecol Cancer 2006;16:194-201. See Evidence Table

The use of ChemoFx Assay for predicting response of solid tumors to chemotherapeutic agents does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Cytochrome P450 Genotyping Test Drug Metabolizing
BACKGROUND
Pharmacogenetics is the study of the genetic causes of individual variation in drug response. There has been growing interest in the use of pharmacogenetics to predict response to medications in terms of safety and efficacy. Cytochrome P450s, in particular CYP3A4, CYP2D6, CYP2C19, CYP1A2, and CYP2B6, have a central role in the metabolism of many clinically used drugs. Genetic polymorphisms in the cytochrome P450 enzymes may help to explain the observed variation in the concentrations of certain drugs and their metabolites. Genetic variability can significantly affect drug metabolism and lead to distinct subgroups of the populations that differ in their ability to metabolize various drug. The resulting phenotypes are poor metabolizers (PM), intermediate metabolizers (IM), extensive metabolizers (EM), and ultra-rapid metabolizers (UM). Clinically, the most important phenotypes are ultra-rapid metabolizers and poor metabolizers. Subjects who possess the ultra-rapid metabolizer phenotype may

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experience a reduced response to standard doses of medications because their ability to rapidly metabolize these medications makes it difficult to sustain therapeutic levels. They are also more likely to suffer from adverse drug reactions due to the formation of toxic metabolites and excess levels of the active drug. Because poor metabolizers have low metabolic capacity, usual doses may lead to higher than expected drug concentrations, placing them at increased risk for adverse drug reactions. Additionally, PM may not respond to drugs that require activation by the enzyme in question (Ingelman-Sunberg 2010). It is thought that knowledge of the genetic metabolizer status may enable physicians to more accurately identify the appropriate drug and/or drug dose that maximizes efficacy and minimizes toxicity in each individual patient. The AmpliChip test uses microarray DNA chip technology developed by Affymetrix. The microarray chip is similar to a computer microchip, but instead of circuits, the microarray chip contains millions of DNA fragments, called probes, that are chemically synthesized at precise locations on the coated quartz surface. The genetic test is performed by extracting DNA from the patient's blood. Prepared DNA samples are applied to the array and matched to the sequence of the probe molecules. The AmpliChip cytochrome P450 genotyping test was cleared for marketing by the FDA in December 2004. It is the first FDA-approved laboratory gene test to evaluate genetic information for medication selection.

PLAVIX In the Unites States, cardiovascular disease is the leading cause of death in both men and women (Heron 2009). Clinical trials have shown that clopidogrel (Plavix), an anti-blood clotting medication, reduces the morbidity and mortality associated with several cardiovascular diseases. However, there is a significant amount of inter-individual variability in clopidogrel responsiveness, which leads some patients to experience decreased platelet inhibition (poor response) with clopidogrel (Momary 2010b). It is thought that the primary source of variability in clopidogrel responsiveness lies in the pharmacokinetics of clopidogrel. Clopidogrel is a pro-drug that is metabolized into its active metabolite through the action of several enzymes (CYP2C19, CYP1A2, CYP3A4, CYP3A5, and CYP2B6). A polymorphism in any of the enzymes could result in decreased responsiveness. One of the enzymes associated with clopidogrel non-responsiveness is CYP2C19. Patients with the wild-type CYP2C19*1 allele have normal metabolic activity. However, four variant CYP2C19 alleles are associated with reduced metabolic activity. Drug interactions, clinical factors, such as diabetes and increased weight, and patient non- compliance are other proposed mechanisms of clopidogrel non-responsiveness. The prevalence of clopidogrel resistance varies from 3-30% (Momary 2010a, Momary 2010b, Ma 2010). On March 12th, 2010, the FDA added a boxed warning to the label for clopidogrel to alert healthcare professionals and patients of the reduced effectiveness of clopidogrel for patients who are poor metabolizers and includes information on the role of CYP2C19 genotype in clopidogrel responsiveness. There has been growing interest in the use of CYP2C19 genotyping to identify patients who are non-responsive to clopidogrel. The AmpliChip CYP450 Test (Roche Diagnostics Inc, Indianapolis, IN) has received FDA approval for CYP2C19 genotyping.

TAMOXIFEN Aside from non-melanoma skin cancer, breast cancer is the most common form of cancer in women. It is the number one cause of cancer death in Hispanic women, and the second leading cause of cancer death in white, black, Asian/Pacific Islander, and American Indian/Alaska Native women (CDC 2010). Tamoxifen is used as an adjuvant endocrine therapy to prevent estrogen receptor-positive breast cancer recurrence, as a treatment for metastatic breast cancer, and to prevent disease in high-risk women with ductal carcinoma in situ (Lash 2009). Tamoxifen is a "pro-drug", several enzymes (CYP2B6, CYP2C8, CYP2C9, CYP2C10, CYP3A4, CYP3A5, and CYP2D6) transform the pro-drug into its active metabolites 4-hydroxytamoxifen (4-OH tamoxifen) and 4-hydroxy-N-desmethyltamoxifen (endoxifen). Research indicates that both endoxifen and 4-OH tamoxifen have nearly 100-fold higher affinity for estrogen receptors than tamoxifen; however, endoxifen is found at a 6 to 12 fold higher concentration than 4-OH tamoxifen. Every secondary tamoxifen metabolite except for endoxifen is formed by two enzymes CYP3A4 and CYP3A5. Endoxifen production is almost totally dependent on the enzymatic activity of CYP2D6. In vivo studies suggest that endoxifen is the major active metabolite of tamoxifen (Higgins 2009). The observed variation in the concentrations of tamoxifen and its metabolites might be explained through genetic polymorphisms in the genes that encode the CYP2D6 enzyme. There are more than 100 allelic variants of CYP2D6 with incidence varying according to race and ethnicity. The most prevalent allele is the wild-type allele CYP2D6*1. Patients with two copies of this allele produce an enzyme with normal activity. Because individuals have two CYP2D6 alleles, various combinations of the alleles result in a spectrum of CYP2D6 function ranging from no activity to increased activity. In the Caucasian population, approximately 5-10% of patients are poor metabolizers and 10-15% of patients are intermediate metabolizers of tamoxifen. It is thought that tamoxifen- treated patients who are poor metabolizers and intermediate metabolizers are at an increased risk for recurrence (Dezentjé 2009, Higgins 2009, Lash 2009). CYP2D6 inhibiting drugs, such as SSRIs, may also decrease tamoxifen metabolism (Lash 2009). Due to the association between tamoxifen metabolism and the CYP2D6 genotype, there is growing interest in the use of CYP2D6 genotyping to direct treatment for patients with breast cancer. *Atomoxetine* Atomoxetine is a norepinephrine reuptake inhibitor that is used to treat attention-deficit hyperactivity disorder (ADHD). Atomoxetine is metabolized via the CYP2D6 enzyme and has a broad therapeutic window. Currently,

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dosing is determined by the patient's weight with dose adjustments according to clinical response and adverse effects. Studies have suggested that in PM the plasma concentration of atomoxetine is higher and the half-life is longer compared to EM (Michelson 2007). *Codeine for nursing mothers*
Opioid analgesics, such as codeine, are commonly used for pain relief in labor and postpartum. Codeine is a pro-drug that is predominantly metabolized by the CYP2D6 enzyme into morphine. While codeine is effective for the majority of individuals, a subset of patients, CYP2D6 poor metabolizers, do not possess any active gene copies and experience poor analgesia due to the deficient formation of the active metabolite (morphine). Additionally, approximately 2-40% of individuals (depending on ethnic background) are ultra-rapid metabolizers and possess functional duplications of the CYP2D6 gene. These duplications lead to enhanced biotransformation of codeine into morphine and have been associated with adverse effects including death in breastfed infants (Madadi 2009a, Alfirevic 2010). *Efavirenz* Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI). Treatment with efavirenz plus two nucleoside reverse transcriptase inhibitor (NRTI) is recommended among the first line regimens in patients initiating highly active antiretroviral therapy (HAART). In addition, efavirenz is used with other antiretroviral agents as a part of post exposure prophylaxis regimen to prevent HIV transmission. Efavirenz is metabolized primarily by CYP2B6 with partial involvement from CYP3A4 and CYP2A6. It is hypothesized that polymorphisms in these genes may contribute to interindividual differences in efavirenz plasma concentration and half-life. Studies have found that poor metabolizers were at greater risk of high plasma levels of efavirenz. It had been suggested that high plasma levels may be associated with central nervous system (CNS) side effects, such as abnormal dreams, dizziness, somnolence, insomnia, and impaired concentration (Rakhmanina 2010, Tozzi 2010). *Proton pump inhibitors (PPI) for treating Helicobacter pylori* H. pylori infection is closely related to many gastrointestinal diseases, including gastritis, peptic ulcer disease, and gastric cancer. Eradication of H. pylori is important for reducing the relapse rate of ulcers and the risk of gastric cancers. Current treatment for the eradication of H. pylori consists of a PPI and two antibiotics (amoxicillin and either clarithromycin or metronidazole). The majority of proton pump inhibitors are metabolized primarily by the CYP2C19 enzyme. PPIs work by raising the intragastric pH, which increases the stability and bioavailability of antibiotics making them more effective. Factors associated with treatment failure include, but are not limited to: antibiotic resistance, non- compliance, smoking habits, bacterial and host-related factors, and CYP2C19 genotype (Yang 2010, Sugimoto 2009). *Immunosuppressants for organ transplant*
Immunosuppressant drugs are used in transplant patients to prevent rejection. Regimens usually include a combination of different drugs. Immunosuppressants have a narrow therapeutic range. Overdosing can lead to infection, malignancy, and organ toxicity, whereas under dosing can lead to rejection. The current approach to prevent over- or under dosing is therapeutic drug monitoring where blood or plasma concentrations are measured and dosage is adjusted to ensure that drug concentrations remain within a narrow therapeutic range. The first 72 hours after transplantation is the most critical time as inadequate drug exposure increases the risk for rejection. Therapeutic drug monitoring is not useful for predicting the initial dose.
Thus, there has been growing interest in using a pharmacogenetic approach to predict initial dose. Tacrolimus is a calcineurin inhibitor that is metabolized by CYP3A5 and CYP3A4. Patients with a functional copy of the CYP3A5 enzyme are referred to as functional expressers; patients without a functional copy of the CYP3A5 enzyme are referred to as functional non-expressers. CYP3A5 expression is thought to be associated with reduced tacrolimus exposure following oral administration, thus patients who are functional expressers may be more likely to experience rejection (Ware 2010, Staatz 2010). *Selective serotonin reuptake inhibitors (SSRIs)*
SSRIs are a popular class of antidepressant medications. CYP2D6 and CYP2C19 are the primary CYP450 enzymes involved in the metabolism of SSRIs. Other CYP450 and non-CYP450 enzymes also play a role in the metabolism of some SSRIs. It is thought that polymorphisms in the CYP450 enzymes can lead to variability in response to some SSRIs. Knowing a patients genotype may be helpful in choosing an initial SSRI that is more likely to be effective (Berg 2007).

10/03/2005: MTAC REVIEW
Cytochrome P450 Genotyping Test Drug Metabolizing
Evidence Conclusion: There is no published evidence on using the AmpliChip cytochrome P450 genotyping test to help select medications or doses of medications. The ideal study would compare the safety and effectiveness of medications selected with and without the results of the AmpliChip cytochrome P450 genotyping test, preferably in a randomized trial. This type of study has not been published.
Articles: No empirical studies were identified that reported on medication selection using the AmpliChip test, or clinical outcomes following medication selection guided by the AmpliChip test. Several articles on the Affymetrix GeneChip were identified, but none of the mentioned using the technology with the AmpliChip test. In addition, the studies on the Affymetrix GeneChip used it for genetic profiling (e.g., to estimate prognosis of colon cancer patients), not to aid physicians in the selection of medications.

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The use of in the evaluation of does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/16/2010: MTAC REVIEW
Cytochrome P450 Genotyping Test Drug Metabolizing Evidence Conclusion: *Plavix:* Analytic validity
No published studies on the accuracy of commercially available tests for detecting CYP2C19 variants were identified. Clinical validity A recent meta-analysis investigated the relationship between CYP2C19*2 polymorphisms and adverse clinical outcomes in patients with coronary artery disease (CAD) being treated with clopidogrel. Results from this analysis showed that the presence of the CYP2C19*2 allele was associated with an increased risk of a subsequent cardiovascular event (RR 1.96, p=0.02) and stent thrombosis (RR 3.82, p<0.01). There was significant heterogeneity between the studies. Studies varied with regard to clopidogrel dose, duration of follow-up, and patient type. Additionally, not all studies adjusted for confounding factors. Because only one CYP2C19 variant was studied misclassification is possible (Sofi 2010). While the majority of data suggest that patients possessing at least one variant CYP2C19 allele are at an increased risk for adverse cardiovascular events, not all studies have found this association. A genetic sub-study of the Impact of the Extent of Clopidogrel- Induced Platelet Inhibition on Clinical Event Rate (EXCELSIOR) study, found that the CYP2C19 genotype was not associated with risk of death or myocardial infarction (MI); however, increased platelet reactivity was associated with the risk of death or MI and patients with at least one CYP2C19*2 allele had increased platelet reactivity. The study was not powered to address this issue (Trenk 2008). Clinical utility No published studies were identified that prospectively compared patient outcomes managed with and without CYP2C19 genotyping. Conclusion: Analytic validity: There is insufficient evidence to determine whether CYP2C19 genotyping assays accurately and reliably detect variant CYP2C19 alleles. Clinical validity: There is insufficient evidence to determine whether the presence of CYP2C19 variant genotypes predict clinical outcomes. Clinical utility: There is insufficient evidence to determine if using CYP2C19 gene testing for predicting clopidogrel responsiveness will improve clinical outcomes.
Tamoxifen: Analytic validity No published studies on the accuracy of commercially available tests for detecting CYP2D6 variants were identified. Clinical validity the results of the published studies on the clinical validity of CYP2D6 gene testing for tamoxifen metabolism were conflicting. Goetz et al conducted a retrospective review of archived sample of patients from the North Central Cancer Treatment Group RCT (89-30-52) tamoxifen only arm. The objective of this study was to determine the effect of CPY2D6 metabolism on breast cancer recurrence and survival. By taking into account genotype and CYP2D6 inhibitor use, patients were classified as either poor metabolizers, intermediate metabolizers, or extensive metabolizer (normal). When extensive metabolizers were compared to decreased metabolizers (intermediate and poor metabolizers), patients with decreased metabolism had significantly shorter time to recurrence (p=0.034), relapse-free survival (p=0.017), and disease-free survival (p=0.027). Overall survival did not differ significantly between extensive and decreased metabolizers. When poor metabolizers were compared to extensive metabolizers, poor metabolizers had significantly shorter time to recurrence (p=0.007), relapse-free survival (p=0.005), and diseases-free survival (p=0.008) than extensive metabolizers. Overall survival did not differ significantly between poor and extensive metabolizers. There was no significant difference in any of the measures of recurrence or survival between intermediate and extensive metabolizers. The major advantage of this study is that is accounted for CYP2D6 inhibitor use. One of the limitations of this study is that there were only sixteen poor metabolizers and forty intermediate metabolizers. Because of the small number of subjects, the study may lack the power to detect significant differences. Also, the study only accounts for one CYP2D6 variant. Because only one variant was studied there is the possibility for misclassification (Goetz 2007). A retrospective analysis of 1,325 subjects from German and U.S. cohorts found that patients with reduced or absent CYP2D6 function had significantly shorter time to recurrence, event-free survival, and disease-free survival compared to extensive metabolizers. There was no difference in overall survival between decreased and extensive metabolizers. Patients from the 89-30-52 trial, the same population studied by Goetz, were included in this analysis. One of the limitations of the study was that the cohorts that were combined had different lengths of follow-up. Additionally, the study did not account for CYP2D6 inhibitor use. Advantages of this trial include its size and that it accounted for 5 different variant alleles (Schroth 2009). Another retrospective cohort study also found that relapse-free survival and event-free survival were significantly poorer for decreased metabolizers compared to extensive metabolizers (Schroth 2007). Not all studies have shown an association between CYP2D6 metabolism and treatment outcomes. Nowell and colleagues conducted a retrospective review of 337 archived samples. The objective of this study was to determine whether genetic variability in the tamoxifen metabolic pathway influenced overall survival in breast cancer patients treated with tamoxifen. In the study, extensive metabolizers were compared to decreased metabolizers (intermediate and poor metabolizers). Relapse- free and overall survival did not differ significantly between extensive and decreased metabolizers. One of the limitations of the study was that the authors did not control for CYP2D6 inhibitor use. Because of the small number of subjects the study may lack

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power to detect significant differences. There is a potential for misclassification as only one CYP2D6 allele was accounted for. Additionally, the effects of CYP2D6 genotype on tamoxifen metabolism were not assessed separately for poor and intermediate metabolizers (Nowell 2005). Clinical utility
No published studies were identified that prospectively compared patient outcomes managed with and without CYP2D6 genotyping. Conclusion: Analytic validity: There is insufficient evidence to determine whether CYP2D6 genotyping assays accurately and reliably detect variant CYP2D6 alleles. Clinical validity: There is insufficient evidence to determine whether the presence of CYP2D6 variant genotypes predict clinical outcomes.
Clinical utility: There is insufficient evidence to determine if using CYP2D6 gene testing for predicting tamoxifen metabolism will improve clinical outcomes.
Articles: *Plavix:* Assessment objective: Analytic validity: Do the CYP2C19 genotyping assays accurately and reliably detect variant CYP2C19 alleles? Clinical validity: Does the presence of CYP2C19 variant genotypes predict clinical outcome? Clinical utility: Will the results of the CYP2C19 genotype assay alter clinical management and improve clinical outcomes? Medline was searched through June 2010 with the search terms *clopidogrel*, *Plavix*, and *CYP2C19* with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Sofi F, Giusti B, Marcucci R, et al. Cytochrome P450 2C19*2 polymorphism and cardiovascular recurrences in patients taking clopidogrel: a meta-analysis. *Pharmacogenomics J 2010;* 30 March 2010. [Epub ahead of print] See Evidence Table *Tamoxifen:* Assessment objective: Analytic validity: Do the CYP2D6 genotyping assays accurately and reliably detect variant CYP2D6 alleles? Clinical validity: Does the presence of CYP2D6 variant genotypes predict clinical outcome? Clinical utility: Will the results of the CYP2D6 genotype assay alter clinical management and improve clinical outcomes? No randomized controlled trials were identified. The literature consisted mainly of retrospective case series and cohort studies. The results from the studies evaluating the association between tamoxifen metabolism and breast cancer recurrence and survival were conflicting, with some showing a positive association and some showing a negative association. The study by Goetz et al was selected because it took into account CYP2D6 inhibitor use. Goetz MP, Knox SK, Suman VJ, et al. The impact of cytochrome P450 2D6 metabolism in women receiving adjuvant tamoxifen. Breast Cancer Res Treat 2007; 101:113-121**.** See Evidence Table U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2006 Incidence and Mortality Web-based Report. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute; 2010. Available at: http://www.cdc.gov/uscs.

The use of in the evaluation of Plavix and Tamoxifen metabolization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/20/2010: MTAC REVIEW
Cytochrome P450 Genotyping Test Drug Metabolizing
Evidence Conclusion: *Atomoxetine* The literature search did not reveal any studies pertaining to the analytic validity or clinical utility of CYP2D6 genotyping to predict response to atomoxetine. Several studies were found that combined data from various clinical trials to address the clinical validity of CYP2D6 genotyping. The results from these studies are presented below. Michelson et al combined data from multiple studies to examine the effect of CYP2D6 on the efficacy and safety of atomoxetine. Efficacy data was available for 589 patients (559 EM and 30 PM). The primary outcome measure was defined as a ≥25% decrease in ADHD total symptoms measured using the Attention-Deficit Hyperactivity Disorder Rating Scale-Parent Version: Investigator Scored and Administered (ADHDRS-IV-Parent:Inv). Significantly more PM than EM responded to treatment (80% vs. 59.4%, P=0.033). However, PM were more likely to experience insomnia (P=0.035), abrasion (P=0.012), tremor (P<0.001), and decreased appetite (P=0.008) compared to EM. Limitations: small sample size, power was not addressed, not controlled for concomitant medications or other confounding factors, subjects were grouped into either PM or EM, included studies differed with regard to dosing and follow-up, and the research was funded by Eli Lilly (Michelson 2007). Another study combined data from two clinical trials to determine the effect of CYP2D6 genotype on the efficacy and tolerability of atomoxetine. Data was available for 1,326 patients (1,239 EM and 87 PM). Unlike the Michelson study, Trazepacz and colleagues did not find a significant difference in response, defined as a ≥25% decrease in the ADHDRS-IV-Parent:Inv, between PM and EM (84.9% vs. 81.6%, P=0.56). There were no significant differences in adverse events or treatment discontinuation. Limitations: power was not addressed, not controlled for concomitant medications or other confounding factors, subjects were grouped into either PM or EM, and the research was funded by Eli Lilly (Trzepacz 2008). Ramoz and colleagues combined data from two cohort studies and also found no significant difference in treatment response, defined as a ≥25% decrease in the ADHDRS-IV-Parent:Inv, between PM and EM (Ramoz 2009). Codeine for nursing mothers No randomized controlled trials or cohort studies were identified pertaining to the analytic validity, clinical validity, or clinical utility of genotyping nursing

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mothers for CYP2D6 status before prescribing codeine. The literature search revealed one case-control study with 17 infants with symptoms of opioid toxicity, central nervous system (CNS) depression, and 55 infants without symptoms of opioid toxicity following exposure to codeine while breastfeeding. Findings from this study indicate that there was good concordance between maternal and infant CNS depression. When the baby exhibited CNS depression, there was a 71% probability (12/17) that the mother also exhibited such signs.
Mothers of symptomatic infants were 8 times more likely to have the combined CYP2D6 UM and UGT2B7*2 genotype. UGT2B7*2 is also associated with higher production of the active morphine metabolite. Results from this analysis are inconclusive as there were only 2 women with the combined genotype (Madadi 2009b).
Efavirenz No studies were identified that addressed the analytic validity or clinical utility of genotyping to predict dosing of efavirenz. The literature pertaining to clinical validity consisted mainly of small cohort studies. Several small studies have demonstrated an association between CYP2B6 poor metabolizers and efavirenz plasma concentration. However, the number of poor metabolizers included in these studies ranged from 6 to 14. Additionally, not all individuals who were poor metabolizers had higher plasma concentrations (Haas 2004, Gatanaga 2007, Leger 2009). CYP2B6 polymorphisms are not the only factors that affect plasma levels, other drugs and enzymes may also predict efavirenz plasma concentration. To date there is insufficient evidence regarding the effects of CYP2B6 polymorphisms on clinical outcomes such as long-term virological and immunological response to efavirenz therapy. Proton pump inhibitors The literature search revealed several studies pertaining to the clinical validity of genotyping to predict response to proton pump inhibitors. The majority of these studies were small and performed in Asian populations, which are known to have a higher percentage of CYP2C19 poor metabolizers, as such the results may not be generalizable to other populations. A small randomized controlled trial was identified that compared *H. pylori* eradication rates in patient receiving rabeprazole with different antibiotic regimens was not selected for review as it did not have adequate power to address differences in eradication rates by CYPC19 metabolizer status (Yang 2009). A meta-analysis of 20 observational studies was selected for review (Zhao 2008). No studies were identified that addressed the analytic validity or clinical utility of genotyping to predict response to proton pump inhibitors. The objective of the meta-analysis was to determine whether CYP2C19 polymorphisms affect *H. pylori* eradications rates obtained with first-line PPI- based triple therapies. Eradication rates using the PPI lansoprazole and omeprazole were significantly higher for PM and IM compared to EM; however, there was no significant difference between PM and IM. There was no significant difference in eradication rates among the three genotypes for therapies using the PPI rabeprazole. The studies included in this analysis were mostly observations and thus are more prone to bias and confounding.
Studies using difference antibiotic combinations were analyzed together. Additionally, other factors such as antibiotic resistance rates may affect *H. pylori* eradication rates (Zhao 2008). Not all studies have found an association between CYP2C19 genotype and *H. pylori* eradication rates. A cohort study conducted in Korea that included 174 subjects and was published after the meta-analysis found no significant difference in eradication rates by CYP2C19 genotype for patient treated with pantoprazole, amoxicillin, and clarithromycin twice daily. As this study was not randomized it may be prone to bias. There were only 39 poor metabolizers included in the study, so it may lack the statistical power to detect a difference between the CYP2C19 genotypes (Oh 2009).
Immunosuppressant for organ transplantation The literature search did not reveal any studies addressing the analytic validity of genotyping to predict response to tacrolimus. With regard to clinical validity, several cohort, case-control, and cross sectional studies were identified that looked at the effect of CYP3A5 polymorphisms on tacrolimus concentrations. A prospective cohort study was selected for review (Hesselink 2008). One randomized controlled trial was identified that addressed the clinical utility of genotyping to predict initial does; however, this study was not selected for review as patients were genotyped after transplantation and tacrolimus was not initiated until 7 days after transplantation (Thervet 2010). RCT are currently underway to determine the efficacy of genotype guided initial dosing. A recent prospective cohort study compared the effect of CYP3A5 genotype on (weight-adjusted) tacrolimus exposure and dose, as well as the incidence of acute rejection after kidney transplantation. Results from this study suggest that CYP3A5 expressers require higher drug doses than non-expressers to reach target pre-dose concentrations. The overall daily tacrolimus dose was 60% higher for CYP3A5 expressers compared to non-expressers (95% CI, 35-89%, P<0.001). Additionally, significantly more CYP3A5 expressers had a pre-dose concentration below 10 ng/ml, which is the recommended minimum pre-dose concentration in the early phase after transplantation, compared to non-expressers on day 3 after transplantation (28 vs. 10%, P=0.02). On study day 10 and thereafter pre-dose concentration was comparable between the two groups. There was no statistically significant difference in the incidence of biopsy-proven acute rejection (P=0.36) (Hesselink 2008). A prospective study of 44 renal transplant patients also failed to find an association between genotype and risk of rejection; however, this study did find that CYP3A5 expressers required a higher dose of tacrolimus to reach target concentrations (Roy 2006). It should be noted that the pharmacogenetics of tacrolimus are complex. Other factors such as genetic polymorphisms in drug transporters, differences between the donor organ and recipient's intestinal

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genotype, and drug interactions may all contribute to differences in the pharmacogenetics of tacrolimus. Selective serotonin reuptake inhibitors (SSRIs) The literature search revealed several case-control and cohort studies pertaining to the clinical validity of genotyping patients to predict their response to SSRIs. No studies were identified that addressed analytic validity or clinical utility. In general, studies of clinical validity were limited by inadequate power, poor and intermediate metabolizers were analyzed together, studies grouped different SSRIs together or with other classes of antidepressant medications, and studies did not provide information on variables such as diet, other medications, race/ethnicity, and other genetic factors that may influence SSRI efficacy and tolerability. The majority of studies evaluating the clinical validity of genotyping patients to predict their response to SSRIs found no association between genotype and adverse drug reactions (Murphy 2003, Roberts 2004, Suzuki 2006, Peters 2008). One study did find an association between genotype and the occurrence of adverse events; however, there were only 8 (29%) poor metabolizers and 3 (19%) UM included in the study (Rau 2004). Conclusion**:** There is insufficient evidence to determine the analytic validity, clinical validity, or clinical utility of genotyping for the following indications: Atomoxetine (dosing), Codeine (deciding whether to prescribe codeine for nursing mothers), Efavirenz (dosing), *Helicobacter pylori* (managing treatment), Immunosuppressant for organ transplantation (dosing), Selective serotonin reuptake inhibitors (selection or dosing)
Articles: There is limited evidence pertaining to the analytic validity, clinical validity, and clinical utility of CYP450 genotyping. The majority of studies identified were small observational studies that addressed the association between CYP450 genotype and intermediate outcomes. A prospective cohort study that evaluated the effect of CYP3A5 genotype on tacrolimus exposure, dose, and incidence of acute rejection, and a meta-analysis that looked at the association between CYP2C19 polymorphisms and H. pylori eradication rates were selected for review. The following studies were critically appraised: Zhao F, Wang J, Yang Y, et al. Effect of CYP2C19 genetic polymorphisms on the efficacy of proton pump inhibitor-based triple therapy for Helicobacter pylori eradication: a meta-analysis. Helicobacter 2008; 13:532-541. See Evidence Table Hesselink DA, van Schaik RHN, van Agteren M, et al. CYP3A5 genotype is not associated with a higher risk of acute rejection in tacrolimus-treated renal transplant recipients. Pharmacogenetic Genomics 2008; 18: 339-348. See Evidence Table

The use of in the evaluation of Atomoxetine, Codeine for nursing mothers, Efavirenz, Proton pump inhibitors (PPI) for treating Helicobacter pylori, Immunosuppressants for organ transplant, and selective serotonin reuptake inhibitors (SSRIs) metabolization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/13/2012: MTAC REVIEW
Cytochrome P450 Genotyping Test Drug Metabolizing
Evidence Conclusion: Analytic validity No published studies on the accuracy of commercially available tests for detecting CYP2C19 variants were identified. Clinical validity Results from the 2010 MTAC review were based on a meta-analysis that included 7 cohort studies. Results from the meta-analysis showed that the presence of CYP2C19*2 allele was associated with an increased risk of a subsequent cardiovascular event (RR 1.96, p=0.02) and stent thrombosis (RR 3.82, p<0.01); however, there was significant heterogeneity between the studies. Studies varied with regard to clopidogrel dose, duration of follow-up, and patient type. Because of this, it was determined that there was insufficient evidence to determine whether the presence of CYP2C19 variant genotypes predict clinical outcomes (Sofi 2011). Results from both of the most recent meta-analyses suggest that there is no significant association between major cardiovascular events and CYP2C19 genotype. Both studies also found some evidence that the loss of function genotype may be associated with stent thrombosis; however, the quality of this evidence is weak due to evidence of publication bias. Meta-analyses are only as good at the studies that they include. The majority of the studies included in these analyses were small, there was variation between the studies with regard to the components of the primary endpoint, and misclassification is possible as not all alleles were typed (Bauer 2011, Holmes 2011).Clinical Utility No published studies were identified that prospectively compared patient outcomes managed with and without CYP2C19 genotyping.
Articles: The literature consisted mainly of cohort studies and genetic sub-studies of randomized controlled trials. No studies were identified that examined the analytic validity of CYP2C19 genotyping. Several meta-analyses were identified that evaluated the association between CYP2C19 and the clinical efficacy of clopidogrel. However, only 2 of these analyses included additional studies that were not included in the 2010 MTAC review. Both of these meta-analyses were selected for review. Several studies were identified that looked at the effect of higher doses of clopidogrel or other medications on platelet reactivity in patients with the CYP2C19 loss of function genotype; however, since platelet reactivity is an intermediate marker, none of these studies were selected for review. No studies were identified that looked at the effect of CYP2C19 genotyping on long term clinical outcomes such as major cardiovascular events. The following studies were critically appraised:
Bauer T, Bouman HJ, van Werkum JW, Ford NF, ten Berg JM, Taubert D. Impact of CYP2C19 variant genotypes

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on clinical efficacy of antiplatelet treatment with clopidogrel: systematic review and meta-analysis. *BMJ.* 2011;343:d4588. See Evidence Table Holmes MV, Perel P, Shah T, Hingorani AD, Casas JP. CYP2C19 genotype, clopidogrel metabolism, platelet function, and cardiovascular events: a systematic review and meta-analysis. *JAMA.* 2011;306:2704-2714. See Evidence Table

The use of in the evaluation of Plavix and Tamoxifen metabolization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

EndoPredict

BACKGROUND

Breast cancer is the most common cancer diagnosed and the second most common cause of cancer death in women in the United States. Patients with breast cancer can present with a variety of symptomatology that originates from heterogeneous molecular pathology (Dowsett et al., 2010). Breast cancer can be staged using the Tumor, Node, Metastases classification (TNM). The treatment of invasive breast cancer is based on the stage and involves radiation, surgery, and adjuvant therapy. The management based on adjuvant therapy derives from many factors such as the TNM characteristics, the grade, the presence or absence of estrogen and progesterone receptors, and the human epidermal growth factor 2 (HER2) receptor. However, some patients are still mistreated. Molecular tests that can predict the prognosis and the response to adjuvant therapy might accurately evaluate the recurrence risk and impact disease management. The literature has described several molecular tests including the EndoPredict test. Based on the manufacturer, a tumor section from the FFPE block is needed to perform the test. The tissue collected is treated and the RNA is isolated. The reverse transcription and quantitative PCR are performed, and the levels of gene expression are measured. These genes include eight disease-genes and four reference genes. Results are exported from the EP device into the EP software which generates EP scores and classifies patients into low or high risk of distant metastasis within 10 year. The EP score is a number that ranges from 0 to 15; EP score ≤ 5 is indicative of low distant recurrence risk under endocrine therapy; EP score > 5 indicates high distant recurrence risk. The molecular features are coupled with clinicopathological parameters including tumor size and nodal status to determine the EPclin score. The test is believed to predict distant metastasis in ER-positive, HER2-, node negative or node positive breast cancer treated with endocrine treatment alone (Kronenwett et al., 2012). It is also believed that it can be performed in decentralized laboratories (Denkert et al., 2012; Kronenwett et al., 2012).

06/05/2017: MTAC REVIEW

EndoPredict

Evidence Conclusion: Analytical validity: Three studies were identified (Denkert et al., 2012; Kronenwett et al., 2012; Varga et al., 2013). Two were validation studies and one was a retrospective comparison between EndoPredict and the Oncotype Dx. Patients were ER+, HER2-. Sample size ranged from 10 to 34. The majority of the sample was node negative in two studies; node status is unknown in the second study. The studies show that EndoPredict test is reproducible (correlation coefficient: 0.994 to 0.995). The test is also reliable (variance of EP scores 0.15 for proficiency test to 0.18 in an independent lab). Sensitivity and specificity were evaluated in one study and were 100% (Denkert et al., 2012). Analytical accuracy was evaluated in one study (Kronenwett et al., 2012) and found that the difference between reference EP scores and reported EP scores was less than 1.0 EP units for 9 out of 10 samples with mean deviation of 0.15. The study that compared EndoPredict to Oncotype Dx showed moderate positive linear correlation and concordance between these tests.

Nevertheless, the results should be interpreted with caution due to the small sample size, and financial ties between authors and Sividon, the reference laboratory. In light of these limitations, the studies provide low to moderate evidence to support the reproducibility and reliability of the test. **Clinical validity:** Seven studies (Bertucci, Finetti, Viens, & Birnbaum, 2014; Buus et al., 2016; Dubsky, Filipits, et al., 2013; Filipits et al., 2011; Fitzal et al., 2015; Martin et al., 2014; Martin et al., 2016) were identified. The studies were retrospective-prospective in design. Patients were ER+, HER2-, LN- or LN+, treated with endocrine therapy alone or chemotherapy or chemotherapy followed by endocrine therapy. Sample size was up to 1702 patients and age ranged from 23-80 years. Patients were postmenopausal women in four studies. Most of these studies were conducted in Europe. The primary outcome was the assessment of prognostic performance of EndoPredict test. The prognostic performance was evaluated by assessing distant recurrence, or metastasis-free survival (MFS), or distant-relapse free survival (DRFS). One study (Bertucci et al., 2014) assessed the predictive value of the test; another study compared EP versus Oncotype Dx (Buus et al., 2016). These studies demonstrate that the EndoPredict test is highly prognostic of distant recurrence or metastasis-free survival. Based on Simon et al. 2009 (Simon, Paik, & Hayes, 2009), the studies provide level IB

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evidence. However, limitations include one or more of the following: lack of data on premenopausal women, lack of assessment of the predictive value of the test, low to moderate quality trials, clinicopathological factors varied between studies, small sample size, financial ties with manufacturer, and low events suggesting an overestimation of the prognostic performance. **Clinical utility:** One retrospective study (Muller et al., 2013) with 167 patients reported that EP may change treatment decision in ER+, HER2-, LN+/LN- breast cancer patients. The change in treatment decision occurred in 38% of patients with 25% changed to endocrine treatment alone. The main limitations include the retrospective nature of the study.

Other studies:

Author, year	Findings
(Dubsky, Brase, et al., 2013)	HR: 2.80 (1.81–4.34) P<0.001 first 5 years HR: 3.28 (1.48–7.24) P=0.002 after 5 years EP is highly prognostic of distant recurrence
(Muller et al., 2012)	Correlation r=0.92 between biopsies and surgical specimens

Conclusion

- Analytic validity: Three studies with low to moderate evidence show that EndoPredict may be reproducible and reliable in ER+, LN-, or LN+ breast cancer patients.
- Clinical validity: Seven studies with level IB evidence show that EndoPredict test may be prognostic of distant recurrence in ER+, LN-, or LN+ breast cancer patients. In addition, studies assessing the predictive value of the test are lacking and women who benefit from chemotherapy are unknown.
- Clinical utility: One study, that provides low evidence, assessed the impact of EndoPredict on treatment decision; thus there is insufficient evidence to recommend for or against the clinical utility of the test.
- Based on one study, EP may be more prognostic than Oncotype Dx.

Articles: PubMed was searched through March 28, 2017 with the search terms EndoPredict with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. A total of 14 studies were identified; however, 12 studies were reviewed. The main findings of the two remaining were included under other studies.

The use of in the evaluation of EndoPredict test for breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Epidermal Growth Factor Receptor (EGFR)

BACKGROUND

Lung cancer is one of the most common causes of cancer death, accounting for over 1 million deaths annually. Non-small-cell lung cancer (NSCLC) accounts for approximately 80% of lung cancers and the majority of cases present at an advanced stage. For patients with good performance status, platinum-based chemotherapy constitutes standard first-line treatment. However, a therapeutic plateau has been reached with conventional chemotherapy for NSCLC patients. Advances in the knowledge of molecular mechanisms of carcinogenesis has led to the development of new molecular-targeted agents. Current research efforts focus on a number of promising agents targeted against the epidermal growth factor receptor (Yoshida 2010, Campbell 2010). The epidermal growth factor receptor (EGFR) is normally present on the surface of epithelial cells, and plays an important role in regulating cellular processes such as proliferation, differentiation, survival, and maintenance of normal epidermal tissues. Researchers observed that when the function of EGFR becomes deregulated, it contributes to the growth and survival of cancer cells (Huang 2004, Ettinger 2006). The role of EGFR in carcinogenesis led to the development of several therapeutic agents which specifically target growth factor pathways that are deregulated in tumor cells. Tyrosine kinase inhibitors (TKIs) are one of these agents. Results of clinical trials on TKIs are conflicting and show a significant variability in response and survival rates. Some trials showed an improved survival when used after first or second-line chemotherapy, while others failed to show significant response and/or survival benefit. The investigators attributed the lack of benefit to the lack of patient selection in the trials, i.e. the inclusion of unselected NSCLC population in the studies. This was based on the observation that cancer cell lines and tumors are selectively susceptible to inhibition of the EGFR pathway. Results of subgroup analysis of data from observational studies suggest that the response to TKIs is also associated with a number of clinical and biological factors including gender, ethnic origin, smoking status,

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and histology of the cancer. More recently in 2004, the clinical responsiveness to the TKIs gefitinib and erlotinib were correlated to specific somatic EGFR mutations in the TK domain in NSCLC. The two most common activating mutations seen in patients are exon 19 deletions, and the exon 21 mutation L858R. Data from retrospective studies suggested that these mutations occurred more frequently among females, non-smokers, patients from East Asia, and those with adenocarcinoma histology (Linardou 2009). Extensive research is underway to identify the optimal molecular or genetic biomarkers that can predict the efficacy of a therapeutic agent for treating NSCLS and other malignancies. Predictive biomarkers include EGFR protein expression, gene copy number, mutation status, and others. A qualitative immunohistochemical (IHC) kit for EGFR gene expression testing (the Dako Cytomation EGFR pharmaDx ™ assay) was approved by the FDA in 2004 as an aid to identify colorectal cancer patients eligible for treatment with the cancer drug cetuximab. In June 2005, the FDA issued an alert that new patients should not be given gefitinib, and limited its use to cancer patients who have already taken the medicine and whose doctor believe it is helping them. Erlotinib is another TKI that was approved by the FDA for treatment of locally advanced or metastatic non- small-cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. In June, 2005 the FDA issued an alert that new patients should not be given gefitinib, and limited its use to cancer patients who have already taken the medicine and whose doctor believes it is helping them. Erlotinib is another TKI that was approved by the FDA for treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen.

08/04/2008: MTAC REVIEW
Epidermal Growth Factor Receptor (EGFR)
Evidence Conclusion: In order to identify the optimal molecular or genetic biomarkers that predict the efficacy of a therapeutic agent, the biomarker should have a plausible relationship with the biology of the disease, and should have a standardized reproducible test, as regards the reagent, performance, analysis and interpretation. There also should be standards for the tumor sample size and fixation. Several potential biomarkers have been identified, but none was validated in randomized controlled trials, to date. Moreover, as the literature indicates, there is no standardized methodology for tissue sampling, nor a standardized reproducible assay for EGFR- expression that would allow a direct comparison of the results obtained from different laboratories. The majority of the published trials on EGFR testing and the use of TKIs in patients with NSCLC were small prospective and retrospective case series. There were variations in the inclusion criteria, time of taking and fixation f the tumor tissue samples, as well as other differences in the study designs, which could be potential sources of bias and confounding. In several studies, biomarker assessment was done among a small proportion of patients due to lack of tissue availability. The studies used different tests and arbitrary cut-offs for identifying EGFR mutations as well as unvalidated techniques with no standardized criteria for quantification, processing, scoring, and reporting of the results. Most importantly TKI therapy was not compared to an alternative therapy. Without an appropriate control it is not possible to differentiate between the predictive and prognostic significance of a biomarker.* Moreover, the published trials retrospectively correlated the response to TKIs treatment and/or survival with the EGFR status based on tumor specimens collected at initial diagnosis. This may confound the correlation analysis of EGFR mutations and response as additional mutations could have occurred during therapy. In conclusion, the role of EGFR expression testing as a predictive factor is not well defined. There is insufficient evidence from the published studies, to determine whether EGFR mutation is a predictive marker of clinical benefit from treatment with TKIs or only a prognostic biomarker of better survival, independent of TKI treatment. * A prognostic marker is defined as a characteristic associated with prognosis or outcome, usually in terms of relative hazard, whereas a predictive marker is defined as a characteristic that is associated with, and predicts, treatment response. **Articles:** The literature search revealed over 800 articles on epidermal growth factor receptor (EGFR) and TKIs. There were 4 meta-analyses of observational studies, and a number of phase II and phase III clinical trials that studied the effects of specific TKIs and retrospectively correlated the outcomes with EGFR. The phase III trial (Tsao 2005) that compared erlotinib (a TKI) to placebo retrospectively correlated the outcome to EGFR mutation. The three most recent meta-analyses were critically appraised. Nakamura H, Kawasoki N, Taguchi, et al. Survival impact of epidermal growth factor receptor overexpression in patients with non-small cell lung cancer: a meta- analysis. *Thorax* 2006;61:140-145. See Evidence Table Costa DB, Kobayashi S, Tenen DG, et al. Pooled analysis of the prospective trials of gefitinib monotherapy for EGFR-mutant non-small cell lung cancers. Lung cancer 2007;58:95-103. See Evidence Table Wu y-L, Zhong W-Z, Li L-Y, et al. Epidermal growth factor receptor mutations and their correlation with gefitinib therapy in patients with non-small cell lung cancer: A meta-analysis based on updated individual patient data from six medical centers in Mainland China. *J Thorac Oncol* 2007;2:430-
439. See Evidence Table

The use of Epidermal growth factor receptor (EGFR) testing in the treatment of NSCLC to Tyrosine Kinase

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Inhibitors (TKIs) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
Epidermal Growth Factor Receptor (EGFR) Evidence
Conclusion: Analytic validity
There are a variety of methods used to detect EGFR mutations. Each of these assays has its advantages and limitations. Rapid detection of EGFR mutations with multiplex PCR and primer was found to be highly accurate compared to direct sequencing. In a sample of 81 tumors the two methods identified the same 26 mutations (Lin 2010). Clinical validity The Iressa Pan-Asian Study (IPASS) was a phase 3, multicenter, randomized, open-label trial comparing gefitinib with carboplatin plus paclitaxel as first-line treatment in 1217 clinically selected patients in East Asia with advanced non-small-cell lung cancer. In the overall population, the median progression-free survival (PFS) was 5.7 months in the gefitinib group and 5.8 months in the carboplatin plus paclitaxel group. The probability that a patient would be free of disease progression was greater with carboplatin-paclitaxel in the first 6 months and greater with gefitinib in the following 16 months. The objective response rate was significantly higher with gefitinib that with carboplatin plus paclitaxel. Overall survival did not differ between the two treatment groups; however, there were less than 100 events in each group. A preplanned subgroup analysis by EGFR mutation status was also performed. EGFR mutation status could be determined for 437 subjects (35.9%). Patients with sensitive EGFR mutations who received gefitinib had longer PFS, higher response rates, and a lower rate of adverse events compared to patients with sensitive EGFR mutations taking carboplatin plus paclitaxel. However, results should be interpreted with caution as EGFR status could only be evaluated for 35.9% of the original study population and patients were not randomized based on EGFR status. The results from this study are generalizable to patients of Asian ethnicity, who were nonsmokers or former light smokers, and had adenocarcinoma of the lung. Another limitation of this study lies in the analysis. The Cox proportional-hazards model is based on the assumption that the hazard ratio of the two treatments is constant overtime. Since the curves cross, this assumption is violated. However, in the subgroup analysis (patients with EGFR mutations) this assumption is not violated (Mok 2009). The results from a preplanned subgroup analysis of the INTEREST trial, a RCT comparing gefitinib to docetaxel in a Western pretreated population, were consistent with the results from the IPASS trial.
However, only 44 subjects in the study were EGFR mutation-positive (Douillard 2010). Clinical utility Two RCT recently evaluated the efficacy of gefitinib compared to chemotherapy in patients with sensitive EGFR mutations and non-small-cell lung cancer. The first trial compared gefitinib to carboplatin plus paclitaxel chemotherapy. Patients treated with gefitinib had significantly longer progression-free survival than patients treated with carboplatin plus paclitaxel (median 10.8 vs. 5.4 months, P<0.001) and higher response rates (73.7% vs. 30.7%, P<0.001). There was no difference in overall survival between the two groups; however, the incidence of severe toxic effects was significantly higher in the chemotherapy group than in the gefitinib group (71.1% vs. 41.2%, P<0.001). The results from this trial are generalizable to nonsmoking patients from Asia who had not previously received chemotherapy (Maemondo 2010). The second RCT assessed the efficacy of gefitinib compared to cisplatin plus docetaxel chemotherapy in patients with sensitive EGFR mutations. Findings from this trial are similar to the afore mentioned trial with progression-free survival being longer (9.2 vs. 6.3 months, P<0.001) and response rate being higher (61.2% vs. 32.2%, P<0.001) in patients treated with gefitinib compared to patients treated with cisplatin plus docetaxel. Results for overall survival could not be determined as data were immature and follow-up is still ongoing. Results from this study are generalizable to patients of Asian origin (Mitsudomi 2010). Conclusion: Analytic validity: There is fair evidence that rapid detection of EGFR mutations with multiplex PCR and primer extension produce good results compared to direct sequencing. However, there is insufficient evidence concerning the reproducibility of this test. Clinical validity: There is fair evidence that for patients with EGFR mutations the use of the tyrosine kinase inhibitors gefitinib and erlotinib is associated with an improvement in progression-free survival and response rate. Clinical utility: There is fair evidence that patients managed with the genetic test had better outcomes than patients managed without the genetic test.
Articles: There were several articles that addressed analytic validity. One of the most recent articles was selected for review. Several trials assessed the clinical validity and clinical utility of EGFR testing. Trials were selected for review if they were published after the 2008 review and addressed the safety or efficacy of TKI in patients with EGFR mutations.

The use of Epidermal growth factor receptor (EGFR) testing in the treatment of NSCLC to Tyrosine Kinase Inhibitors (TKIs) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

***Genetic Testing for IL28B Polymorphisms in Patients with Hepatitis* C**
BACKGROUND
Hepatitis C virus (HCV) is a single-stranded, enveloped RNA virus that is spread through contact with the blood of

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an infected person. In the United States, roughly 4.1 million Americans have been infected with the HCV, making it one of the most common blood borne pathogens. After acute infection with HCV, approximately 70-80% of infected individuals will go on to develop chronic HCV, which is a leading cause of cirrhosis, liver cancer, and liver transplant in the western world (Armstrong 2006, CDC 2009, Rosen 2011). For patients with chronic HCV infection, treatment includes a combination of pegylated interferon (PEG-INF) plus ribavirin given for 24 or 48 weeks depending on genotype. Results from recent RCTs also suggest that treatment for patients with HCV genotype 1, the most common isolate in the United States, may also include a protease inhibitor in conjunction with PEG-INF plus ribavirin. Treatment success, referred to as sustained viral response (SVR), is defined as the absence of virus 24 weeks after treatment completion. Less than 50% of patients HCV genotype 1 respond to therapy with PEG-INF plus ribavirin compared to around 80% of patients with HCV genotype 2 and 3. Besides genotype, female gender, white ethnicity, age less than 45 years, low HCV RNA levels at baseline, and lack of cirrhosis are considered to be predictors of viral response. Treatment for HCV is expensive and associated with numerous side effects such as anemia and neutropenia, which can lead to dose reduction or premature termination, thus increasing the risk of treatment failure. Research is currently underway to identify factors that could help patients and clinicians make more informed decisions regarding the risk and benefit of treatment and the likelihood of treatment response. Recent studies suggest that polymorphisms in the IL28B gene may be a useful predictor of treatment response (Clark 2011, Ghany 2009, Mangia 2011, Rauch 2010, Rosen 2011).
The IL28B gene encodes interferon (INF) lambda, a cytokine that shares the same intercellular pathway of INF alpha, the drug currently used in combination with ribavirin for the treatment of chronic HCV. Genome wide association studies suggest that polymorphisms in the IL28B gene may be associated with response to antiviral treatment with PEG-INF plus ribavirin in patients with HCV genotype 1. However, it is important to note that IL28B polymorphisms do not explain all treatment failure, and patients with the non-responder genotype may still respond to therapy (Ahlenstiel 2010, Mangia 2011).

10/17/2011: MTAC REVIEW
Genetic Testing for IL28B Polymorphisms in Patients with Hepatitis C
Evidence Conclusion: Analytic validity
No studies were identified that evaluated the analytic validity of genetic testing for IL28B polymorphisms in patients with chronic hepatitis C infections. Clinical validity A recent genome-wide association study (GWAS) identified seven single nucleotide polymorphisms (SNPs) around the IL28B gene that were associated with SVR in patients with chronic genotype 1 HCV infection. The most strongly associated SNP was rs12979860 followed by rs8099917. Results from this study suggest that the rate of viral response in European-Americans and Hispanics with the CC genotype was twofold higher compared to patients with the TT genotype. The rate of viral response in African Americans was threefold higher compared to patients with the TT genotype. No replication cohort was performed (Ge 2009). Two other GWAS in different populations also found that polymorphisms on the IL28B gene locus were associated with SVR. The first study found that the rs8099917 SNP on the IL28B gene was associated with SVR in Australian patients with chronic HCV infection. These results were replicated in an independent cohort of Europeans from the United Kingdom, Germany, Italy, and Australia (Suppiah 2009). The second study found that in Japanese patients with genotype 1 HCV, SNPs near the IL28B chromosome (rs8099917 and rs12980275) were associated with SVR. These results were replicated in an independent cohort on Japanese patients with HCV infection (Tanaka 2009). Clinical utility No studies were identified that evaluated the clinical utility of genetic testing for IL28B polymorphisms in patients with chronic hepatitis C infections. Conclusion:
Analytic validity: No studies were identified that evaluated analytic validity of genetic testing for IL28B polymorphisms in patients with chronic hepatitis C infections. Clinical validity: Results from several GWAS suggest that SNPs around the IL28B gene may be associated with SVR in patients with chronic genotype 1 HCV infection. Clinical utility: No studies were identified that evaluated the clinical utility of genetic testing for IL28B polymorphisms in patients with chronic hepatitis C infections.
Articles: The literature search identified several genome-wide association studies that identified polymorphisms near the IL28B gene locus as predictors of response to treatment in patients with chronic hepatitis C infection. The largest study was selected for review. No studies were identified that evaluated the analytic validity or clinical utility of genetic testing for IL28B polymorphisms in patients with chronic hepatitis C infection. The following study was critically appraised: Ge D, Fellay J, Thompson AJ, et al. Genetic variation in IL28B predicts hepatitis C treatment-induced viral clearance. *Nature.* 2009;461:399-401. See Evidence Table

The use of IL28B polymorphisms does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

KRAS Mutation Testing for Predicting Response to Treatment in Patients with Advanced Colon Cancer
BACKGROUND
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Nearly a million new cases of colorectal cancer (CRC) are diagnosed worldwide each year, and about half a million people die from CRC annually. In the United States, CRC is the most common form of cancer in people aged 75 and older (Boyle and Leon, 2002). The length of survival of people with metastatic colorectal cancer has increased from approximately 12 months to 20 months in the past decade. This improvement has been attributed largely to the introduction of new treatments, including chemotherapeutic agents and novel targeted drugs (Di Fiore et al., 2007). Novel therapies include those that target the epidermal growth factor receptor (EGFR) signaling pathway which is believed to be involved in colorectal carcinogenesis. EGFR expression has been found in 60-80% of colorectal tumors (Heinemann et al., 2008). Two new monoclonal antibody inhibitors, cetuximab (Merck) and panitumumab (Amgen), are designed to block EGFR, thereby preventing the activation of downstream signaling pathways and inhibiting tumor cell proliferation. The new targeted therapies are costly and potentially increase the toxicity of treatment. It is thus desirable to select the patients most likely to respond to these treatments. Research is underway to identify biomarkers that predict response to the EGRF inhibitors. One biomarker under investigation is mutations in the K-ras gene (KRAS). KRAS mutations occur in approximately 20-50% of CRC tumors. It is believed that, in patients with mutant KRAS genes, treatment with the new monoclonal antibody inhibitors does not prevent signaling of EGFR, and consequently that the therapies should only be given to patients with wild-type (i.e. non-mutant) KRAS genes (Heinemann et al., 2008). Research first suggested that KRAS mutation selection might be useful for metastatic CRC patients who failed initial chemotherapy and are considering second-line treatment with cetuximab, as monotherapy, or in combination with irinotecan. KRAS mutation selection is also being proposed for first-line treatment with FOLFIRI, with or without cetuximab.
A genetic test is available to determine whether the KRAS gene contains mutations. Response Genetics (Los Angeles) has a PCR-based test. KRAS mutation testing for colorectal cancer patients has not been previously reviewed by MTAC.

02/02/2009: MTAC REVIEW
KRAS Mutation Testing for Predicting Response to Treatment in Patients with Advanced Colon Cancer
Evidence Conclusion: Analytic validity: No published articles on the accuracy of commercially available tests for detecting KRAS mutations were identified. Clinical validity: The three retrospective cohort studies evaluated (Lievre et al. 2008; DeRoock et al., 2008; DiFiore et al., 2007) all found that second-line treatment with cetuximab monotherapy or combination treatment was not effective in any of the patients with mutant KRAS genes (0% treatment response). The response rate in patients without mutations varied from 28-44%. Two of the three studies found a significantly higher rate of progression-free survival in patients with wild-type KRAS versus mutant forms. Only two studies reported overall survival; both found a significantly higher rate in patients with wild-type versus mutant KRAS. Limitations common to the three studies is that the analyses were retrospective, and subject to confounding--there may have been other differences between patients with wild-type and mutant KRAS genes that affected outcome. In addition, the vast majority of patients in the cohort studies received combination therapy as second-line treatment. Thus, one cannot disentangle the effectiveness of cetuximab from the irinotecan-based chemotherapy. This makes it difficult to make conclusions about what treatment patients should receive. Even if one concluded that KRAS mutation status impacts treatment outcomes, it is not possible from these studies to conclude that a monoclonal antibody inhibitor is necessary for treatment success. The Bokemeyer RCT provides some evidence on the added impact of treatment with cetuximab, as first-line treatment. Overall, there was no significant difference in response rate when cetuximab was added to FOLFOX-4 compared to FOLFOX-4 alone. However, in the sub-analysis by KRAS mutation status, there was a better response when cetuximab was added to chemotherapy for patients with wild-type KRAS genes. Clinical utility: No published articles were identified that prospectively managed patients with and without KRAS mutation testing were identified.
Articles: No published articles were identified on the accuracy of any commercially available test for detecting KRAS mutations. There were several retrospective cohort studies that evaluated the statistical association between KRAS mutation status and clinical outcomes with second-line treatment. Three studies (Lievre et al. 2008; DeRoock et al., 2008; DiFiore et al., 2007) were critically appraised. In addition, there was one published RCT evaluating first-line treatment, with a secondary analysis by KRAS mutation status (Bokemeyer et al., 2008), and this was critically appraised. Two unpublished RCTs were also identified that included analyses of outcomes by KRAS status. Both trials were presented as abstracts at the 2008 annual meeting of American Society of Clinical Oncology. The CRYSTAL study (Van Cutsem et al., 2008) evaluated patients receiving first-line treatment and the EVEREST study (Tejpar et al., 2008) evaluated second-line treatment. In terms of clinical utility of KRAS mutation testing for treatment selection, the ideal study would randomize patients to be managed with and without KRAS testing. For those managed with KRAS mutation testing, only patients with wild-type KRAS genes would receive cetuximab (second-line treatment) or FOLFIRI with or without cetuximab (first-line treatment). No randomized or non-randomized controlled trial that prospectively conducted KRAS testing was identified.

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Citations for the studies that were reviewed are as follows: Bokemeyer C et al. Fluorouracil, leucovorin, and oxaliplatin with and without cetuximab in the first-line treatment of metastatic colorectal cancer. J Clin Oncol 2008 (Epub ahead of print). See Evidence Table. Lievre A et al. KRAS mutations as an independent prognostic factor in patients with advanced colorectal cancer treated with cetuximab. J Clin Oncol 2008; 26: 374-379. See Evidence Table DeRoock W et al. KRAS wild-type state predicts survival and is associated to early radiological response in metastatic colorectal cancer treated with cetuximab. Ann Oncol 2008; 19: 508-515. See Evidence Table DiFiore F et al. Clinical relevance of KRAS mutation detection in metastatic colorectal cancer treated by cetuximab plus chemotherapy. Br J Cancer 2007; 96: 1166-1169. See Evidence Table

The use of KRAS mutation testing for predicting response to treatment in patients with advanced colon cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/16/2010: MTAC REVIEW
KRAS Mutation Testing for Predicting Response to Treatment in Patients with Advanced Colon Cancer
Evidence Conclusion: Analytic validity No studies were identified that directly compared the Response Genetics test to another test. A recent study compared four different methods of *KRAS* mutation testing–Sanger sequencing, array analysis, melting curve analysis, and pyrosequencing. The study included samples from 263 patients with colorectal cancer. Results from this study indicate that there was very good agreement between the four methods (κ >0.9). As to date there is no reliable, predetermined gold standard method for comparison, direct estimates of the sensitivity and specificity of the respective methods is not possible (Weichert 2010). Clinical validity Treatment regimens differed across the studies; however, there was a consistent message that for patients with mutant *KRAS* tumors the addition of the monoclonal antibodies cetuximab and panitumumab did not increase progression-free, overall survival, or response rate compared to mutant *KRAS* tumor patients who were not treated with a monoclonal antibody. *First-Line* Three RCTs conducted retrospective subgroup analyses to investigate the influence of *KRAS* mutation status on progression-free survival (PFS), overall survival (OS), and response rate. The Von Cutsem study analyzed data from the CRYSTAL trial. This trial was a randomized, open- label, multi-centered study that compared 14-day cycles of cetuximab plus FOLFIRI to FOLFIRI alone. For patients with mutant *KRAS* tumors, there was no difference between response rate, PFS, or OS between the two treatment groups. When patients with wild-type *KRAS* tumors were compared to patients with mutant *KRAS* tumors there was no difference between the groups for PFS or OS; however, the response rate was higher for patients with wild-type tumors (Von Custem 2009). Tol et al analyzed data from the CAIRO2 trial. This was an open-label randomized trial that evaluated the addition of cetuximab to capecitabine, oxaliplatin, and bevacizumab as first-line treatment in patients with metastatic colorectal cancer. Patients with mutant *KRAS* tumors who did not take cetuximab had significantly longer PFS and OS and higher response rates compared to patients who took cetuximab. Compared to patients with mutant *KRAS* tumors taking cetuximab, patients with wild-type *KRAS* tumors taking cetuximab had longer PFS, OS, and higher response rates. There was no significant difference in PFS, OS, or response rates for between mutant and wild-type patients not taking cetuximab (Tol 2009). Hecht and colleagues used data from the PACCE trial that evaluated panitumumab added to bevacizumab and oxaliplatin- based chemotherapy (cohort 1) or irinotecan-based chemotherapy (cohort 2). There was no significant difference in PFS or OS for patients with mutants *KRAS* tumors in either cohort (Hecht 2008). *Second-Line* No new information was identified since the 2008 MTAC review. Evidence for the 2008 MTAC review: The three retrospective cohort studies evaluated (Lievre 2008; DeRoock 2008; DiFiore 2007) all found that second-line treatment with cetuximab monotherapy or combination treatment was not effective in any of the patients with mutant *KRAS* genes (0% treatment response). The response rate in patients without mutations varied from 28- 44%. Two of the three studies found a significantly higher rate of progression-free survival in patients with wild- type *KRAS* versus mutant forms. Only two studies reported overall survival; both found a significantly higher rate in patients with wild-type versus mutant *KRAS* tumors. *Third-Line* Two RCTs conducted retrospective subgroup analyses to investigate the influence of *KRAS* mutation status on progression-free survival (PFS), overall survival (OS), and response rate. Amado and colleagues used data from a trial that that evaluated panitumumab monotherapy versus best supportive care (BCS) for patients with chemotherapy-refractory metastatic colorectal cancer. In this trial, patient in the BSC arm could receive panitumumab after disease progression. The effects of panitumumab on PFS were significantly greater for patients with wild-type tumors compared to patients with mutant tumors. As this was a crossover study, reliable overall survival measures cannot be obtained. Response rate data were missing for 19% of the population (13% wild-type *KRAS* and 26% mutant *KRAS*). For patients with wild-type *KRAS* taking panitumumab 17% had a partial response; no responders were identified in any other group (Amado 2008). Karapetis and colleagues used data from a phase 3 trial that examined the effects of cetuximab on patients with chemotherapy-refractory colorectal cancer versus BSC. There was no difference in PFS or OS for patients with mutant *KRAS* tumors between the treatment groups. The effects of cetuximab on PFS and OS were

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significantly greater for patients with wild-type tumors compared to patients with mutant tumors. In the cetuximab group, the response rate was 12.8% for wild-type *KRAS* tumors and 1.2% for mutant *KRAS* tumors. None of the patients in the BSC group had an objective tumor response (Karapetis 2008). All analyses were retrospective and therefore are subject to confounding – other differences between patients with wild-type and mutant *KRAS* genes could have affected the outcome. Patients in the RCTs were not randomized based on their *KRAS* mutation status. A subset of subjects from the RCT was used for analysis. Samples could only be obtained from 45%-92% of the primary analysis populations. Not all *KRAS* mutations were assessed. Mutations in codon 62 would have been missed even though this is a less prevalent mutation (~3% of mutations) it still may result in misclassification. The trials received industry funding. In the study conducted by Hecht and colleagues, censoring could have altered the PFS results. Additionally, response rate data was missing from 19% of the subject in the Amado study. Clinical utility
No studies were identified that specifically addressed clinical utility. However, identifying patients who will not respond to therapy will avoid the administration of an ineffective treatment and its associated toxicities.
Conclusion: A medical technology review from Blue Cross Blue Shield (BCBS) in conjunction with Kaiser Permanente from 2008 was identified. BCBS found sufficient evidence to approve the use of *KRAS* mutation analysis to predict non-response to the anti-EGFR monoclonal antibodies cetuximab and panitumumab based on retrospective genetic sub-studies from randomized controlled trials. Analytic validity: There is fair evidence that there is very good agreement between Sanger sequencing, array analysis, melting curve analysis, and pyrosequencing for the detection of a KRAS mutation. However, there is insufficient evidence concerning the sensitivity, specificity, and reproducibility of these tests. Clinical validity: There is fair evidence that for patients with *KRAS* mutations the use of the monoclonal antibodies cetuximab and panitumumab in not associated with an improvement in overall or progression-free survival. Clinical utility: There is insufficient evidence to determine that patients managed with the genetic test had better outcomes than patients managed without the genetic test.
However, identifying patients who will not respond to therapy will avoid the administration of an ineffective treatment and its associated toxicities.
Articles: A number of studies comparing different methods of *KRAS* mutation detection were identified. The trial with the largest sample size was selected for review. Several randomized controlled trials were identified that included a retrospective subset analysis of treatment efficacy in relations to *KRAS* mutation status. No studies were identified that addressed the clinical utility of *KRAS* mutation testing. A recent retrospective cohort study that evaluated the efficacy of cetuximab in patients with chemotherapy-refractory metastatic colorectal cancer treated with cetuximab plus chemotherapy was not included in this review as the study population was heterogeneous with regard to treatment regimen and line of chemotherapy. Additionally, approximately one third of the study population was included in previous reports.

The use of KRAS mutation testing for predicting response to treatment in patients with advanced colon cancer does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Oncotype DX

BACKGROUND

Breast Cancer- Breast cancer is the most common cancer diagnosed and the second most common cause of cancer death in women in the United States. Patients with breast cancer can present with a variety of symptomatology that originates from heterogeneous molecular pathology (Dowsett, Cuzick et al. 2010). Breast cancer can be staged using the Tumor, Node, Metastases classification (TNM). The treatment of invasive breast cancer is based on the stage and involves radiation, surgery, and adjuvant therapy. The management based on adjuvant therapy derives from many factors such as the TNM characteristics, the grade, the presence or absence of estrogen and progesterone receptors, and the human epidermal growth factor 2 (HER2) receptor. However, some patients are still mistreated. Molecular tests that can predict the prognosis and the response to adjuvant therapy might accurately evaluate the recurrence risk and impact disease management. The literature has described several molecular tests including the oncotype Dx breast cancer assay. The oncotype Dx breast cancer assay is a molecular diagnostic test used in patients with early stage invasive breast cancer. In addition to standard measurements used to make treatment decision, the assay provides three advantages including the assessment of gene expression, the determination of recurrence, and the prediction of chemotherapy benefit. Scientists at Genomic Health, the manufacturer of the assay, utilize the reverse-transcriptase polymerase chain reaction (RT-PCR) to analyze a set of 21 genes in several samples and developed a mathematical formula that led to the breast recurrence score result. The score is also known as the recurrence score (RS). A lower score is indicative of a lower chance of recurrence or a smaller chemotherapy benefit. A higher score suggests a higher likelihood of recurrence or a significant chemotherapy benefit. In general, RS less than 18 suggests a low RS; a RS between18-30 indicates an intermediate RS and RS more than or equal to 31 indicates a high RS.

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Eligible patients are patients who are medically eligible for chemotherapy and have been diagnosed with stage I, II or IIIa invasive breast cancer, and whose breast cancer is estrogen-receptor positive (ER+) and Human Epidermal growth factor Receptor-negative (HER2-). The oncotype DX breast cancer assay was initially developed in patients with estrogen receptor-positive (ER+) and lymph node-negative (LN-) early invasive breast cancer. However, the test is believed to predict recurrence and chemotherapy benefit on candidates with lymph node-positive breast cancer. The test is being assessed for the first time on Medical Technology Assessment Committee (MTAC) and has been exempt from FDA clearance. **Colorectal Cancer -** Nearly a million new cases of colorectal cancer (CRC) are diagnosed worldwide each year and about half a million people die from CRC annually. In the United States, CRC is the most common form of cancer in people aged 75 and older (Boyle 2002). The length of survival of people with metastatic colorectal cancer has increased from approximately 12 months to 20 months in the past decade. This improvement has been attributed largely to the introduction of new treatments, including chemotherapeutic agents and novel targeted drugs (DiFiore 2007). Several randomized controlled trials (RCT) have shown that adjuvant chemotherapy improves overall survival in patients with stage III disease; however, a clear benefit for patients with stage II disease has not been established. Findings from the QUASAR trial, a RCT designed to determine the effects of 5-FU/LV (fluorouracil/leucovorin) compared to observation in patients with predominantly stage II colorectal cancer, suggest that stage II patients may benefit from 5-FU-based adjuvant therapy. However, since the majority of patients with stage II disease can be cured with surgery alone it is important to identify patients who are likely to develop metastasis and who will benefit from adjuvant chemotherapy (Gangadhar 2010). Currently, the risk of recurrence in stage II disease is clinically determined by histologic staging, extended to include evidence of lymphatic or vascular invasion, tumor grade, and the number of lymph nodes identified and examined in the surgical specimen (Midgley 2010). Biomarkers could also be useful in this assessment. Recently, a quantitative multigene expression assay has been developed with the aim of improving treatment decision-making in the setting of stage II colon cancer and is now being marketed as the Oncotype DX® colon cancer assay (Genomic Health Inc., Redwood City, CA). The Oncotype DX® colon cancer assay was derived from an initial set of 761 candidate genes to create a 12-gene panel assay that uses real-time PCR to measure the expression of 7 genes prognostic for relapse-free survival 5 reference genes used for normalization. The assay is performed on excised tumors and yields a prognostic recurrence score that ranges from 0 to 100. The recurrence score is used to improve patient selection criteria for adjuvant chemotherapy (Kerr 2009).

04/04/2005: MTAC REVIEW
Oncotype DX
Evidence Conclusion: Oncotype Dx is a test that is used to predict risk of distant recurrence in women with node-negative and estrogen-receptor-positive breast cancer. There is one published validation study (Paik, 2004) in which Oncotype test results were divided into three risk categories (low, intermediate or high) and the risk categories were correlated with the likelihood of distant recurrence over 10 years. Significantly fewer patients who were categorized as low-risk experienced distant recurrence compared to those categorized as high-risk (6.8% vs. 30.5%). The risk score contributed information on recurrence beyond that provided by age and tumor size. The Paik study included only patients who were treated with tamoxifen. The primary authors of the published study have substantial financial links to the Genomic Health Inc., the company that developed Oncotype Dx. There are no published data on the use of Oncotype Dx on women who are not treated with tamoxifen. There is no evidence that the recommendation for chemotherapy would change based on Oncotype Dx results or that changing treatment based on Oncotype Dx results would improve health outcomes.
Articles: The search yielded 43 articles. Many were on technical aspects of developing genetic assays. There was one published article on methods used to develop the test; this was not evaluated further because it did not address test accuracy. One published validation study was identified and this was critically appraised. There were also several unpublished abstracts and posters, including presentations at the 27th San Antonio Breast Cancer Symposium (SABCS) in December 2004. One of the SABCS posters reported on a case-control study conducted at Kaiser, Northern California to evaluate the Oncotype Dx recurrence score (Habel et al, unpublished manuscript). The study includes both women treated with and without tamoxifen. In the presentation, findings were primarily presented on the group treated with tamoxifen. The unpublished abstracts and posters do not meet the Kaiser Permanente criteria for evaluable evidence. *The reference for the published validation study is as follows:* Paik S, Shak S, Tang G. et al. A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. *NEJM* 2004; 351: 2817-2826. See Evidence Table

The use of Oncotype Dx in the evaluation of the likelihood of distal recurrence in patients with estrogen-dependent, node-negative breast cancer does not meet the *Kaiser Permanente Medical Technology*

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Assessment Criteria.

10/18/2010: MTAC REVIEW
Oncotype DX
Evidence Conclusion: There is insufficient evidence to determine the analytic validity, clinical validity, and clinical utility of the *Oncotype DX®* colon cancer assay.
Articles: No articles were identified that addressed the analytic validity, clinical validity, or clinical utility or the *Oncotype DX®* colon cancer assay. Conclusion: There is insufficient evidence to determine the analytic validity, clinical validity, and clinical utility of the *Oncotype DX®* colon cancer assay.

The use of Oncotype Dx in the evaluation of the colorectal cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/16/2010: MTAC REVIEW
Oncotype DX
Evidence Conclusion: Analytic validity No studies were identified that assessed the sensitivity and specificity of the *Oncotype DX®* colon cancer assay. Clinical validity A recent retrospective analysis of the Quick Simple and Reliable (QUASAR) trial evaluated whether the Oncotype® DX assay can provide clinically relevant information to assist treatment decision making in patients with resected stage II colon cancer. The assay yields a prognostic recurrence score that ranges from 0 to 100 and a treatment score. Results from this trial suggest that recurrence score (RS) was significantly associated with the risk of recurrence even after controlling for other factors such as tumor location, T stage, grade, nodes examined, lymph vascular invasion, and MMR deficient. The estimated recurrence risk at 3 years was 12% for the low recurrence risk group (RS<30), 18% for the intermediate recurrence risk group (RS 30-40), and 22% for the high recurrence risk group (RS≥40). The treatment score was not predictive of chemotherapy benefit (Gary 2011). Clinical utility No studies were identified that assessed the clinical utility of the *Oncotype DX®* colon cancer assay.
Conclusion: Analytic validity: There is insufficient evidence to determine the analytic validity of the *Oncotype DX®* colon cancer assay. Clinical validity: Results from a retrospective analysis suggest that the *Oncotype DX®* colon cancer assay recurrence score may be associated with recurrence risk in patients with stage II colon cancer. Results from this study also suggest that the *Oncotype DX®* colon cancer assay treatment score was not predictive of chemotherapy benefit. Clinical utility: There is insufficient evidence to determine the clinical utility of the *Oncotype DX®* colon cancer assay.
Articles: Screening of articles: No studies were identified that addressed the analytic validity or clinical utility of the Oncotype DX® colon cancer assay. The following study was selected for critical appraisal: Gray RG, Quirke P, Handley K, et al. Validation study of a quantitative multigene reverse transcriptase-polymerase chain reaction assay for assessment of recurrence risk in patients with stage II colon cancer. J Clin Oncol. 2011;29:4611-4619.
See Evidence Table

03/20/2017: Oncotype DX
Evidence Conclusion: Analytic Validity: There was insufficient evidence to determine the analytic validity of Oncotype DX breast cancer assay in lymph node-positive breast cancer patients. **Clinical validity:** (Albain et al., 2010) (Evidence table 1) performed a retrospective assessment of the phase 3 trial SWOG-8814. Women with node-positive breast cancer were treated with cyclophosphamide, doxorubicin, fluorouracil followed with tamoxifen (CAF-T) or tamoxifen alone. Patients were postmenopausal women with node positive, ER positive breast cancer. Recurrence score (RS) was found to be highly prognostic (Disease free survival) in the tamoxifen group (HR 2.64, 95% CI, 1.33 – 5.27; p=0.006). The same trend was found for overall survival (OS); HR 4.42 (95% CI 1.96, 9.97; p<0.001). Furthermore, there was no chemotherapy benefit in the low RS; however, disease-free survival was improved with high RS, independent of the number of positive nodes (HR 0.59, 95% CI, 0.35- 1.01; p=0.033). For DFS (disease free survival) as well as OS (overall survival), trend was similar; this means that RS significantly predicted chemo benefit (p=0.053 for DFS and p=0.026 for OS). However, this effect was not constant after 5 years (except for higher RS). The cumulative chemotherapy benefit persisted to 10years. Limitations included a specific population consisting of postmenopausal women limiting extrapolation of finding in premenopausal women. In addition, the sample size was small and some co-authors had ties with the manufacturer. (Dowsett et al., 2010) investigated whether the Recurrence Score (RS) provided information on the risk of distant recurrence (DR) in the tamoxifen and anastrozole arms of the Arimidex, Tamoxifen, alone or in Combination (ATAC) Trial. Outcomes were time to distant recurrence (TTDR), time to recurrence (TTR) and overall survival (OS).Three hundred and six (306) lymph node-positive (LN+) breast cancer in post-menopausal women were examined out of 1231 evaluable

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patients; the median follow-up was 8.5 years. Seventy-four (74) distant recurrences occurred in LN+ patients. In LN+ patients, 52%, 31% and 17% had an RS of <18, 18-30, and ≥31 respectively. The authors reported that the RS was predictive of TTDR in LN+ (HR=3.47, 95% CI = 1.64-7.38; **P=0.002**). After adjusting for clinical variables, the HRs between high and low RS and low to intermediate RS were 2.7% and 1.8% respectively. The 9-year DR rates in LN+ were 17%, 28%, and 49% in the RSs <18, 18-30 and ≥31 respectively. The same trend was observed for OS. The risk of DR was linearly associated with increasing RS. The risk of DR was higher for LN+ than LN- patients. RS was predictive of DR in the same way in patients treated with tamoxifen or anastrozole. Limitations included the small sample size, a specific population consisting of postmenopausal women and the lack of assessment of the chemotherapy benefit. Some authors had financial interest with the manufacturer of the oncotype DX assay. Mamounas (Mamounas et al., 2012) evaluated the association between RS and Paclitaxel (Pac) benefit. The sample used in the current study derived from a study that assessed doxorubicin/cyclophosphamide (AC) with AC followed by Pac (AC→Pac); patients were also treated with tamoxifen. This current study enrolled 1065 patients with ER+, LN+ breast cancer; the median follow-up was 11.2 years. 36%, 34% and 30% had low, intermediate and high RSs respectively. The authors found that RS was significantly predictive of loco-regional recurrence (LRR), disease free survival, distant recurrence and death in patients treated with AC as well as AC→Pac (findings can be seen in the table below).

10-year cumulative incidence (%) of LRR, DFS, DR and death

	Low RS	Intermediate RS	High RS	Log-rank p
LRR				
AC	3.4 (1.4 – 70)	8.3 (4.8 – 13.3)	13.2 (8.3 – 19.1)	**0.004**
AC→Pac	3.1 (1.4 – 6.3)	6.2 (3.3 – 10.4)	11.4 (7.0 – 17.0)	**0.037**
	HR 1.19 (0.45 – 3.16)	HR 0.75 (0.34 – 1.65)	HR 0.80 (0.42 – 1.52)	
DFS				
AC	24.5 (18.8- 31.5)	46.6 (39.5 – 54.4)	54.7 (47 – 62.8)	**<0.001**
AC→Pac	23.9 (18.5 – 30.6)	39.6 (32.8-47.1)	49.5 (42 – 57.5)	**<0.001**
	HR 1.01 (0.69 – 1.47)	HR 0.84 (0.62 – 1.14)	HR 0.81 (0.60 – 1.10)	
DR & death				
Similar trend				

LRR, Loco-Regional Recurrence; RS, Recurrence Score; DFS, Disease Free Survival; DR, Distant recurrence

Furthermore, patients with high or intermediate RS benefited the most from Paclitaxel indicating that chemotherapy may not be warranted in patients with low RS.

On-going trial:
NCT01272037: A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer

Clinical Utility: Summary of evidence Eight observational studies were identified. The studies were retrospective or prospective in design and evaluated the impact of the oncotype DX assay recurrence score on treatment recommendations, patient decisional conflict, patient satisfaction and physician confidence in recommending treatment. Sample sizes were small and ranged from 20 to 282 patients with lymph node-positive, ER+, HER2- breast cancer. Most of the included patients received hormonal therapy or chemo hormonal therapy. These studies showed a change in the treatment recommendations after the oncotype Dx assay was performed. The proportion of the change ranged from 26% to 51%. The principal change was the removal of chemotherapy from the initial treatment recommendation. This suggests that the oncotype DX testing may impact decision-making or treatment plan and reduces the adverse effects caused by chemotherapy. Other findings included patient satisfaction, reduction of decisional conflict. Limitations included the small sample size, the difference between the groups with respect to characteristics of the tumors, and the financial ties between the manufacturer and some authors.
In addition, the retrospective analysis of RCT (evidence table 1) included in the clinical validity section (Albain et al., 2010) found that the addition of anthracycline-based chemotherapy improved disease-free survival (0.59 (0.35 – 1.01); P=0.033) and overall survival (P=0.0271) in patients with high recurrence score.
In conclusion, well-design studies with larger sample size are warranted to assess the patients reported outcomes which evaluate the clinical utility of molecular tests.

Studies assessing clinical utility (Bargallo et al., 2015) in a prospective study (evidence table 2) evaluated the

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impact of the recurrence Score result on the adjuvant therapy decision-making process. The authors reported that for LN+, the change occurred for 41% of the patients. Similarly, treatment recommendations changed for 32% for all patients irrespective of lymph node status and with the use of the oncotype DX assay. A retrospective study (Stemmer et al., 2013) (evidence table 3) compared treatment decisions in N1+/ER+/ HER2-negative breast cancer patients who underwent the oncotype DX assay with a control group composed of patients for whom treatment decisions were solely based on clinicopathologic criteria. Both groups received hormonal therapy with or without chemotherapy. Data of 282 patients who underwent the assay and 669 controls were analyzed. Some differences were noted on the tumor characteristics with patients on oncotype DX group with smaller tumor, lower frequencies of grade 3 tumors and number of positive nodes. The authors reported a lower utilization of chemotherapy in patients who were tested with the assay compared to the control (24.5 vs. 70.1%). In addition, the assay testing was significantly associated with a lower chance of receiving chemotherapy (OR 0.16; P<0.0001) after adjusting for age, tumor size, tumor grade, and nodal status. Nevertheless, limitations included the dissimilarity among groups and the change in adjuvant treatment recommendations for this population. A prospective German study (Eiermann et al., 2013) of 366 patients, of whom 122 were LN+ and 244 were LN- reported a change in treatment decision in 39% of women with LN+ (for LN-, A change of 30% was observed) after performing the oncotype Dx assay. The principal change was from chemo hormonal therapy (CHT) to hormonal therapy (HT) in 28% of all LN+ patients. Similarly, a reduction in chemotherapy was observed. Patient decisional conflict was also reduced by 6% and for both LN- and LN+ patients. Physician confidence in recommending treatment was increased in 45% for both LN- and LN+ patients. However, this was an industry funded study; therefore results should be interpreted with caution. (De Boer, Baker, Speakman, & Mann, 2011) reported that in 50 patients of LN+ patients, a change in treatment decision occurred in 26% of patients. The main change was from chemo hormonal therapy to hormonal therapy alone. Another study (Oratz et al., 2011) showed that 51% (70/138) patients with LN+ early breast cancer had their treatment recommendations changed after undergoing the oncotype Dx assay. The main change included the elimination of chemotherapy from the initial recommendation. A retrospective analysis of a sample of 40 patients with LN+ breast cancer (Nguyen et al., 2014) showed that the oncotype Dx assay was linearly associated with the use of chemotherapy. However, the small sample size constituted a limitation. A prospective study (Yamauchi et al., 2014) of the effect of the 21-gene assay on adjuvant clinical decision-making in Japanese women with hormone-receptor positive, LN- and LN+ breast cancer reported that of the 20 LN+ patients, 65% (95% CI, 41 -85%) had their recommendations changed. 87% (13/15) of LN+ patients had their initial recommendation for chemo hormonal therapy changed to hormonal therapy after performing the oncotype Dx assay. No patients, out of 5 LN+ patients, had their initial recommendations for hormonal to combined chemo hormonal. The results should be interpreted with caution because of the small sample size.

Conclusion:

- Analytic validity: There was insufficient evidence to determine the analytic validity of Oncotype DX breast cancer assay in lymph node-positive breast cancer patients.
- Clinical validity: Moderate evidence shows that the oncotype DX assay predicts recurrence in lymph- node positive breast cancer patients. However, the evidence was insufficient for the predictive effect. Studies with larger sample size are needed to optimally determine who will benefit from chemotherapy (particularly among patients with low or moderate recurrence score).
- Clinical utility: The oncotype DX assay may improve outcomes; however well design studies with larger sample size are warranted.

The use of Oncotype DX for breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Invader UGT1A1 Molecular Assay

BACKGROUND

The Invader UGT1A1 molecular assay tests variations in a gene called UGT1A1 that produces the enzyme UDP-glucuronosyltransferase. The UDP enzyme is active in the metabolism of certain drugs, including irinotecan, a chemotherapy agent commonly used to treat colorectal and lung cancer. The active metabolite of irinotecan, SN-38, is glucuronidated by hepatic UGTs. The main dose-limiting toxicity of irinotecan treatment is diarrhea, which is believed to be secondary to the biliary excretion of SN-38. Diarrhea associated with irinotecan-treatment can be serious and often does not respond to conventional antidiarrheal agents. The diarrhea may be due to direct enteric injury caused by the active metabolite of irinotecan, SN-38. A phase 1 clinical trial found an inverse relationship between SN-38 glucuronidation rates and severity of diarrheal incidence in patients treated with increasing doses of irinotecan. This suggests that decreased glucuronidation of SN-38 increases the risk of

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irinotecan-induced toxicity. Differential rates of SN-38 glucuronidation may help explain individual variation in toxicity rates among cancer patients treated with irinotecan. There may be a genetic predisposition to the metabolism of irinotecan.
Research has found that the UGT1A1 gene is responsible for SN-glucuronidation. Patients with low UGT1A1 activity, such as those with Gilbert's syndrome, may be at increased risk of irinotecan-induced toxicity. The Invader UGT1A1 molecular assay is marketed as a test to aid physicians in making individualized decisions about treatment and medication dosage. By detecting variations in the UGT1A1, the Invader UGT1A1 molecular assay might be able to predict which patients are at an increased risk of toxicity from irinotecan. The Invader UGT1A1 molecular assay was approved by the FDA in 2005 as substantially equivalent to the AmpliChip cytochrome P450 genotyping test. Both are genetic tests that detect single nucleotide polymorphisms. Since it was approved as substantially equivalent to an existing test, the manufacturer was not required to data on clinical sensitivity and specificity to the FDA. (References: Innocenti and Ratain, 2003; Iyer et al., 1998; Rouits et al. 2004; FDA documents).

06/05/2006: MTAC REVIEW
Invader UGT1A1 Molecular Assay
Evidence Conclusion: There is insufficient evidence to draw conclusions on the diagnostic accuracy of the Invader UGT1A1 molecular assay. No published peer-reviewed studies were identified. The only article with empirical data is a letter to the editor of Clinical Chemistry. The authors of the letter reported that findings from the Invader assay had a high rate of agreement with direct DNA sequencing for detecting UGT1A1 polymorphisms in 60 patients. Diagnostic accuracy studies that are published and peer-reviewed are needed. There is insufficient evidence that more appropriate therapy is used after application of the Invader assay than would be used if the test were not available. There was no published evidence on the impact on health outcomes of using UGT1A1 genotype information from the Invader test to adjust irinotecan treatment. There is some evidence that the UGT1A1 genotype is associated with irinotecan-induced toxicity. The studies reviewed found statistically significant associations between UGT1A1 genotype and irinotecan-induced toxicity. Two of the three studies (Marcuello et al., 2004; Ando et al., 2000) used multivariate analysis. In general, limitations of the studies were that they had relatively small sample sizes and estimates may be imprecise. Their findings provide preliminary data suggesting that information on UGT1A1 genotype may help physicians make better treatment decisions. Results of the studies reviewed cannot necessarily be generalized to use of the Invader assay to identify UGT1A1 polymorphisms, since this test was not used in any of the studies.
Articles: Accuracy of Invader UGT1A1 molecular assay: No published peer-reviewed studies were identified on the accuracy of the invader test for identifying variations in the UGT1A1 gene. There was a letter to the editor that presented data on test accuracy. Letters to the editor do not meet MTAC criteria for acceptable evidence because the scientific methods are not peer reviewed. Does adjusting the dose of irinotecan treatment based on UGT1A1 genotype identified using the Invader assay result in improved health outcomes? No published studies that directly address this question were identified. However, several studies were identified that examined the association between UGT1A1 variants and rates of toxicity related to irinotecan treatment. If there is a significant association between UGT1A1 genotypes and irinotecan-induced toxicity, then using information on UGT1A1 genotypes to inform irinotecan dosing decisions has the potential for improving health outcomes. The three largest studies evaluating the association between UGT1A1 genotype and toxicity (two cross-sectional studies and one case-control study) were critically appraised. *The studies reviewed were:* Marcuello E, Altes A, Menoyo A et al. UGT1A1 gene variations and irinotecan treatment in patients with metastatic colorectal cancer. Br J Cancer 2004; 91: 678-682. See Evidence Table Rouits E, Boisdron-Celle M, Dumont A et al. Relevance of different UGT1A1 polymorphisms in irinotecan-induced toxicity. Clin Can Res 2004; 10: 5151-5159. See Evidence Table Ando Y, Saka H, Ando M et al. Polymorphisms of UDP-Glucuronosyltransferase gene and irinotecan toxicity: A pharmacogenetic analysis. Can Res 2000; 60: 6921-6926. See Evidence Table

The use of Invader UGT1A1 molecular assay in the treatment of polymorphisms in the UGT1A1 gene does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Platelet Function Testing (VerifyNow P2Y12 Assay)
BACKGROUND
In the Unites States, cardiovascular disease is the leading cause of death in both men and women (Heron 2009). Clinical trials have shown that clopidogrel (Plavix), an anti-blood clotting medication, reduces the morbidity and mortality associated with several cardiovascular diseases. However, there is a significant amount of inter-individual variability in clopidogrel responsiveness, which leads some patients to experience decreased platelet inhibition

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(poor response) with clopidogrel (Momary 2010).
Studies suggest that approximately 4% to 30% of patients treated with clopidogrel do not have adequate antiplatelet response. The mechanism for poor response is not fully understood; however, poor compliance, drug interaction, clinical factors such as increased body mass index and diabetes, as well as genetic factors such as polymorphisms in the enzymes that metabolized clopidogrel into its active metabolite are all proposed mechanisms of clopidogrel non-responsiveness (Fileti 2011).
Platelet function testing is a way to monitor response to clopidogrel. It has been hypothesized that monitoring platelet reactivity and then tailoring treatment accordingly may improve clinical outcomes such as major adverse cardiovascular events. There are several different laboratory-based and point-of-care testing systems used to measure platelet response. These methods all have different definitions of high on-treatment platelet reactivity and are known to correlate poorly with each other. All of these methods have advantages and limitations. This review will focus on the VerifyNow P2Y12 Assay (Acumetrics Inc., San Diego, California), which is a fast, standardized point-of-care testing system that does not require special training to perform. The VerifyNow P2Y12 Assay evaluates platelet aggregation of fibrinogen-coated beads in response to adenosine diphosphate (ADP) and prostaglandin E1. Results are expressed as P2Y12 Reaction Units (PRU) with a common cutoff of ≥240 PRU for indicating suboptimal response to clopidogrel. However, one of the limitations of this test is that the cutoff for suboptimal response has not been firmly established (Sambu 2011, Smock 2011). The VerifyNow P2Y12 Assay has received approval from the FDA.

02/13/2012: MTAC REVIEW
Platelet Function Testing (VerifyNow P2Y12 Assay)
Evidence Conclusion: Analytic validity Light transmission aggregometry (LTA) is considered by many to be the gold standard in platelet function testing; however, even though this method is the gold standard it is not without limitations. It is time consuming, it has poor reproducibility, and it requires experienced technicians (Sambu 2011). A recent study evaluated the correlation between platelet function tests to measure clopidogrel-mediated platelet inhibition in 80 patients on dual antiplatelet therapy after percutaneous intervention with stent implantation. The cut-off value for defining residual ADP-platelet aggregation despite treatment with clopidogrel was maximal aggregation ≥62% for LTA and PRU ≥273 for the VerifyNow P2Y12 Assay. There was significant correlation between the two assays (r=0.61). When using LTA as the gold standard, the VerifyNow P2Y12 Assay had a sensitivity of 55% and a specificity of 85% (Gremmel 2009). Clinical validity Results from a recent meta-analysis that included 3,058 subjects suggest that that high on-treatment platelet reactivity (PRU ≥ 230) after percutaneous coronary intervention was associated with cardiovascular events. However, the results of this analysis should be interpreted with caution due to methodological limitations. For example, study quality was not reported and confidence intervals were wide due to the small number of events (Brar 2011).Clinical utility A recent RCT evaluated the effect of high-dose compared with standard-dose clopidogrel in 2,214 patients with high on- treatment platelet reactivity after percutaneous coronary intervention (PCI). Results from this study suggest that the use of high-dose clopidogrel in patients with high on-treatment platelet reactivity after PCI did not reduce the incidence of death from cardiovascular causes, nonfatal myocardial infarction, or stent thrombosis compared to standard-dose clopidogrel. Due to the fact that fewer events occurred than anticipated, a treatment effect of high- dose clopidogrel cannot be excluded (Price 2011). Conclusion: Analytic validity: Results from a recent study suggest that when using LTA as the gold standard, the VerifyNow P2Y12 assay has a sensitivity of 55% and a
specificity of 85%. Clinical validity: Results from a recent meta-analysis with methodological limitations suggest that high on-treatment platelet reactivity may be associated with cardiovascular events. Clinical utility: Results from a recent RCT suggest that high-dose compared to standard-dose clopidogrel in patients with high on-treatment platelet reactivity may not reduce cardiovascular events.
Articles: The literature search revealed several studies and review articles addressing the analytic validity of platelet function testing. Results of a recent study are presented below. Several observational studies and meta-analyses were identified that addressed the clinical validity of platelet function testing with the VerifyNow P2Y12 Assay. Studies were excluded if they were: retrospective, did not look at clinical outcomes, were not powered to evaluate clinical outcomes, or did not measure platelet function using the VerifyNow P2Y12 Assay. A meta- analysis of studies using the VerifyNow P2Y12 Assay to measure platelet reactivity was selected for review. Two randomized controlled trials (RCTs) were identified that looked at the clinical utility of VerifyNow P2Y12 Assay to measure platelet reactivity. One trial was excluded because it had a short duration of follow-up and the results combined patients who were poor responders to clopidogrel with patients who were poor responders to aspirin and patients who were poor responders to both aspirin and clopidogrel. The GRAVITAS trial, which evaluated the effect of high-dose compared with standard-dose clopidogrel in patients with high on-treatment platelet reactivity, was selected for review. The following studies were critically appraised: Brar SS, ten Berg J, Marcucci R, et al.
Impact of platelet reactivity on clinical outcomes after percutaneous coronary intervention. A collaborative meta-

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analysis of individual participant data. *J Am Coll Cardiol.* 2011; 58:1945-1954. See Evidence Table Price MJ, Berger PB, Teirstein PS, et al. Standard- vs high-dose clopidogrel based on platelet function testing after percutaneous coronary intervention: the GRAVITAS randomized trial. *JAMA.* 2011; 305:1097-1105. See Evidence Table

The use of Platelet function testing (VerifyNow P2Y12 Assay) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Warfarin Sensitivity DNA Test

BACKGROUND

Warfarin, an anticoagulant, is used to help prevent and treat blood clots. It is commonly used to treat patients with deep vein thrombosis, atrial fibrillation, stroke, and artificial heart valves. Blood clots are potentially dangerous because they can detach and travel in the bloodstream, where they can get wedged in a blood vessel and block the blood supply to a vital organ such as the lungs, heart or brain (Yin 2007). Blood clots are initiated when platelets clump together at the site of bleeding and produce chemicals that activate clotting factors in the blood. Vitamin K is essential for the production of these clotting factors. Warfarin prevents blood clots by inhibiting the action of vitamin K, thereby preventing the activation of clotting factors. The anticoagulant effect of warfarin is measured in terms of the prothrombin time, the time taken for blood clotting to occur in a sample of blood to which calcium and thromboplastin have been added. This time is expressed as the International Normalized Ratio (INR). The higher the INR, the longer time it takes for blood to clot. If the INR is too high, there is an increased risk of bleeding. If it is too low, there may be an increased risk of clot formation. The goal is to adjust the dose of warfarin so that the INR reaches and stays within a narrow therapeutic range. The initial dose of warfarin is an approximation, generally based on a standard protocol or dosing algorithm. Over the first several weeks on the medication, the patient's INR is tested regularly, and the dose adjusted. The risk of anticoagulant-related bleeding is highest at the beginning of therapy (Tan 2010). Warfarin dosing is influenced by a variety of factors such as sex, age, smoking status, medications, diet, height, and weight. Another factor that may be associated with the optimal dose of warfarin is the presence of certain genetic variants (Jonas 2009). Two relevant genes have been identified: Vitamin K epoxide reductase (VKORC1) is a gene which codes for the enzyme that warfarin targets for its effect. Patients with the sensitive AA halotype generally require a lower dose of warfarin than average. Patients with the BB halotype generally require larger doses. The common halotype is AB. The sensitive AA variant of VK0RC1 is estimated to occur in approximately 35-37% of Caucasians, 10-23% of African Americans, and in up to 89% of Asians. Cytochrome P450 (CYP) 2C9 (called CYP2C9) is a gene which codes for the specific liver enzyme that is largely responsible for metabolizing the most active component of warfarin. Some patients have a genetic variation in the CYP2C9 enzyme that causes them to metabolize warfarin more slowly. Patients with this genetic variation generally require a lower dose of warfarin. The usual variant of CYP2C9 that is associated with normal enzyme activity is CYP2C9*1. The variants associated with slower metabolism of warfarin are CYP2C9*2 and CYP2C9*3. The prevalence of these variants varies considerably by ethnic group with Caucasians having the highest prevalence (Tan 2010). In 2007, the FDA approved new labeling for warfarin indicating that patients with variations in CYP2C9 and VCORC1 may respond differently to the drug. Due to the fact that warfarin has a narrow therapeutic window and over- or underdosing of warfarin can lead to catastrophic hemorrhagic or thrombotic complications there has been increasing interest in warfarin genotyping to aid in optimizing initial and maintenance warfarin dosing. There are several FDA-approved warfarin sensitivity genotyping test kits; all of them test for mutations in both the CYP2C9 and VKORC1 genes.

10/06/2008: MTAC REVIEW
Warfarin Sensitivity DNA Test

Evidence Conclusion: Analytic validity: No published evidence was identified.
Clinical validity: A meta-analysis of observational studies (Sanderson et al., 2005) found a statistically significant association between variants of the CYP2C9 gene and both a lower dose of warfarin and lower risk of bleeding. The meta-analysis did not study the VKORC1 gene. Two cohort studies published after the meta-analysis (Schwartz et al., 2008; Wadelius et al., 2008) found significant associations between genetic variants of VKORC1 and efficacy outcomes (time to therapeutic INR or dose of warfarin). Associations with genetic variants of CYP2C9 were significant in one study but not the other. Both cohort studies were underpowered to assess the association between bleeding and genetic variants. Clinical utility: Two RCTs, one pilot study (Hillman et al., 2005) and one completed trial (Anderson et al., 2007) compared outcomes in patients managed with pharmacogenetic-guided dosing and those managed with standard dosing. The Anderson et al., 2007 study did not find a significant difference in the primary outcome, the per-patient percentage of out-of-range INR (30.7% in pharmacogenetic-

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guided dosing, and 33.1% in standard dosing). There was also no significant between-group difference in the secondary outcomes, achieving a therapeutic INR by day 5 or day 8, or the proportion of patients with adverse events. There were, however, significantly fewer dose adjustments (mean of 3.6 vs. mean of 3.0) with pharmacogenetic-guided dosing. The Hillman et al., 2005 focused on the feasibility of pharmacogenetic-guided dosing in a clinical setting, which was found to be feasible. The study also described clinical outcomes but did not do statistical testing. Outcomes (e.g. percent time INR in range and percent of patients with maximum INR>4) were similar in the two groups and the number of adverse effects was somewhat higher in the standard-dosing group. In conclusion: There is no published evidence on the accuracy or reliability of commercially available kits for identifying variants in the CYP2C9 and VKORC1 genes. There is fair evidence that variants of the genes are associated with warfarin-related intermediate outcomes (dosing, time to therapeutic INR). There is insufficient evidence due to lack of statistical power that genetic variants are related to risk of bleeding. There is insufficient evidence to determine that managing patients using pharmacogenetic-guided dosing improves outcomes. To date, there is one published completed RCT (Anderson et al., 2007), and this study did not find significant differences in the primary outcome, percentage of out-of-range INR and most secondary outcomes. Several additional RCTs are underway.
Articles: Analytic validity: No published studies were identified that discuss the accuracy or reliability of commercially available test kits for measuring genetic variants in the CYP2C9 and VKORC1 genes. Clinical validity: There is a meta-analysis of studies evaluating the association between CYOP269 genetic variants and bleeds and drug dosing (Sanderson et al., 2005). This study, and the two largest prospective studies evaluating VKORC1 (Wadelius et al., 2008; Schwartz et al., 2008) were critically appraised. Clinical utility: There is one published RCT that compares outcomes in patients managed with pharmacogenetic-guided dosing versus standard dosing (Anderson et al., 2007). In addition, there is an earlier published pilot RCT examining the feasibility of using pharmacogenetic-guided dosing (Hillman et al., 2005). These two studies were critically appraised. The Hillman study was included because, although its primary purpose was examining feasibility, it also included some clinical outcome variables. Several additional randomized controlled trials are underway examining health outcomes in patients starting warfarin therapy who are managed with pharmacogenetic-guided dosing compared to standard methods of dosing. These include the prospective evaluation comparing initiation of warfarin strategies (PRECISE) trial, a study of patients receiving total hip or knee replacement, and a Creighton University study comparing these two types of dosing (ClinicalTrials.gov). *The following studies were critically appraised:* Sanderson S, Emery J, Higgins J. CYP2C9 gene variants, drug dose and bleeding risk in warfarin-treated patients: A HuGEnet systematic review and meta-analysis. Genet Med 2005; 7: 97-104. See Evidence Table. Schwarz UI, Ritchie MD, Bradford Y et al. Genetic determinants of response to warfarin during initial anticoagulation. NEJM 2008; 358: 999-1008. See Evidence Table. Wadelius M, Chen LY, Lindh JD et al. The largest prospective warfarin-treated cohort supports genetic forecasting. Blood 2008. June 23 (E-pub ahead of print). See Evidence Table. Anderson JL, Horne BD, Stevens SM et al. for the Couma-Gen investigators. Randomized trial of genotype-guided versus standard warfarin dosing in patients initiating oral anticoagulation. Circulation 2007; 116: 2563-2570. See Evidence Table. Hillman MA, Wilke RA, Yale SH et al. A prospective, randomized pilot trial of model-based warfarin dose initiation using CYP2C9 genotype and clinical data. Clin Med & Res 2005; 3: 137-145. See Evidence Table.

The use of a DNA sensitivity test to determine the optimal dosing of warfarin does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
Warfarin Sensitivity DNA Test
Evidence Conclusion: Analytic Validity There are several genotyping assays available to detect polymorphisms in the CYP2C9 and VKORC1 genes. King and colleagues compared the accuracy of four commercially available assays. All four methods evaluated had high accuracy compared to bi-directional sequencing (King 2009). Clinical Validity In 2008, based on the results from a meta-analysis and two cohort studies warfarin sensitivity DNA testing was found to have adequate clinical validity. Information from the 2008 review: A meta-analysis of observational studies found a statistically significant association between variants of the CYP2C9 gene and both a lower dose of warfarin and lower risk of bleeding. The meta-analysis did not study the VKORC1 gene (Sanderson 2005). Two cohort studies published after the meta-analysis (Schwartz 2008, Wadelius 2008) found significant associations between genetic variants of VKORC1 and efficacy outcomes (time to therapeutic INR or dose of warfarin). Associations with genetic variants of CYP2C9 were significant in one study but not the other. Both cohort studies were underpowered to assess the association between bleeding and genetic variants. New information since the 2008 review: A recent retrospective cohort study compared the accuracy of three different warfarin dosing

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algorithms. Results from this study suggest that the pharmacogenetic algorithm that included information on CYP2C9 and VKORC1 genotype produced initial warfarin dose recommendations that were significantly closer to the stable therapeutic dose than the clinical or fixed-dose algorithms. This analysis did not address whether a precise initial dose of warfarin would improve clinical endpoints, such as a reduction in the time needed to achieve a stable therapeutic INR, fewer INRs that are out of range, or a reduced incidence of bleeding (Klein 2009).Clinical Utility A recent cohort study compared the six month incidence of hospitalization in patients receiving warfarin genotyping versus historical controls. Compared to historic controls, patients who were genotyped for warfarin sensitivity had 31% fewer hospitalizations (P<0.001). Results from this study should be interpreted with caution. Patients were taking warfarin for a median of 32 days before the physician received the lab results. As there was no further communication with the physician after the lab results were sent, it is unknown if the genotyping results were used to inform treatment. The main limitation of this study is the use of a historical control group. Because a contemporary control group was not selected the possibility that the benefits of genotype-guided warfarin therapy may be exaggerated due to confounding, either in the vigilance by the treating physicians or in the kinds of patients who agreed to participate, cannot be ruled out. Other limitations include the fact that the genotype of the control group was unknown and baseline differences in the prevalence of hypertension and diabetes between the control and intervention group (Epstein 2010). Conclusion: Analytic validity: There is fair evidence that the commercially available assays for determining warfarin genotype are accurate compared to bi-directional sequencing. However, there is insufficient evidence concerning the reproducibility of these tests. Clinical validity: Based on information for the 2008 review, the warfarin sensitivity DNA test was found to have adequate clinical validity. Clinical utility: There is insufficient evidence to determine whether patients managed with the genetic test had better outcomes compared to patients managed without the genetic test.

Articles: The literature search revealed several articles that addressed the analytic validity of warfarin genotyping assays. The study by King and colleagues was selected for review as it assessed the accuracy of four different commercial systems. In the 2008 review, warfarin sensitivity DNA testing passed criterion 3 (clinical validity), since then several studies were identified that evaluated the clinical validity of genetic testing to predict warfarin dose. One of the larger cohort studies was selected for review. The study by Epstein and colleagues was the only study identified that addressed the clinical utility of the warfarin sensitivity DNA test. The following studies were critically appraised: King CR, Porsce-Sorbet RM, Gage BF, et al. Performance of commercial platforms for rapid genotyping of polymorphisms affecting warfarin dosing. *Am J Clin Pathol 2008;* 129:876-883. See Evidence Table. Klein TE, Altman RB, Ericksson N, et al. Estimation of the warfarin dose with clinical and pharmacogenetic data. *N Engl J Med 2009;* 360:753-764. See Evidence Table. Epstein RS, Moyer TP, Aubert RE, et al. Warfarin genotyping reduced hospitalization rates. *J Am Coll Cardiol 2010;* 55:2804-2812. See Evidence Table.

The use of a DNA sensitivity test to determine the optimal dosing of warfarin does not meet all of the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prosigna Breast Cancer Prognostic Gene Signature Assay

BACKGROUND

Breast cancer is the most common cancer diagnosed and the second most common cause of cancer death in women in the United States. Patients with breast cancer can present with a variety of symptomatology that originates from heterogeneous molecular pathology (Dowsett, Cuzick et al. 2010). Breast cancer can be staged using the Tumor, Node, Metastases classification (TNM). The treatment of invasive breast cancer is based on the stage and involves radiation, surgery, and adjuvant therapy. The management based on adjuvant therapy derives from many factors such as the TNM characteristics, the grade, the presence or absence of estrogen and progesterone receptors, and the human epidermal growth factor 2 (HER2) receptor. However, some patients are still mistreated. Molecular tests that can predict the prognosis and the response to adjuvant therapy might accurately evaluate the recurrence risk and impact disease management. The literature has described several gene expression-based tests including Prosigna breast cancer prognostic gene signature assay.

Prosigna is a genomic test that evaluates the activity of 58 genes and categorizes a patient's tumor into a subtype based on the signature (luminal A, luminal B, HER-2 enriched or basal-like) (Gordon-Craig et al., 2020). It is a gene expression-based test founded on the prediction analysis of microarray 50 (PAM50) gene (Jensen et al., 2018). The PAM50 gene is a gene expression-based test that categorizes the risk of breast cancer. It predicts distant recurrence by defining inherent breast cancer subtypes (Walden et al., 2015). It is reported that Prosigna assay has been validated as a prognostic indicator in postmenopausal patients with ER-positive early-stage breast cancer treated with endocrine therapy and who are low-risk (Alvarado et al., 2015).

Prosigna predicts the risk of distant recurrence. It determines the prognosis for postmenopausal patients with early-

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stage breast cancer who are estrogen receptor (ER)+ (Jensen et al., 2018). However, it is not clear whether Prosigna predicts chemotherapy benefit (Alvarado, et al., 2015). It is indicated in postmenopausal breast cancer women with stage I or stage II, lymph node-negative, stage II with one to three positive nodes, hormone-receptor-positive, invasive and have undergone surgery and hormonal therapy (https://www.veracyte.com/our-products/prosigna; https://www.breastcancer.org/symptoms/testing/types/prosigna).
Prosigna assesses the activity of 58 genes and produces an estimation of distant recurrence risk of breast cancer within 10 years (after diagnosis). Prosigna produces two outcomes: 1) risk of recurrence score (ROR), a numerical score (1 to 100 scale) that corroborates with the 10-year distant recurrence risk, and 2) an improved risk classification which utilizes predetermined cutoff points associated with clinical outcomes. The risk classification is reported as low, moderate, and high in cancers with negative node, and low or high for patients with positive node. Cancers with negative node are classified as low (0-40), intermediate (41-60), or high (61-100) risk whereas cancers with positive node are classified as low (0-40) or high (41-100) risk (https://www.breastcancer.org/symptoms/testing/types/prosigna).

10/12/2020: MTAC REVIEW

Evidence Conclusion:

- Analytic validity
  - Evidence is insufficient
- Clinical validity
  - Low evidence shows that Prosigna can significantly prognosticate 10-year distant recurrence in post-menopausal patients with ER+, HER2-, LN- or LN+, early breast cancer.
  - Evidence comparing Prosigna and other genomic tests are limited. Two low quality studies showed that Prosigna (ROR) has better prognostic value than Oncotype Dx (RS). According to one low quality study comparing Prosigna, BCI, EPclin, RS, Clinical tx score, immunohistochemical score, Prosigna, BCI, and EPclin provide the most prognostic information in LN- cancers during 0 to 10 years and late recurrence. In LN+, all the signatures are weakly prognostic. Similar and more comparative studies are needed to determine the best genomic test.
  - There is insufficient evidence for or against the predictive effect (chemotherapy benefit) of Prosigna.
- Clinical utility:
  - Although, two low quality studies demonstrated the utility of Prosigna, more high-quality studies are warranted to draw a strong conclusion.

Articles:

PubMed was searched through September 16, 2020 with the search terms Prosigna OR PAM50 OR Prosigna Breast Cancer Prognostic Gene Signature Assay with variations. The search was limited to English language publications and human populations. Validation studies, RCTs, and observational studies were included. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Prosigna Breast Cancer Prognostic Gene Signature Assay does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

***Note:** Codes listed in the criteria above may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
04/04/2005	06/04/2013[MPC] 08/06/2013[MPC], 06/03/2014[MPC], 04/7/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC] ,09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	12/06/2022

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MPC Medical Policy Committee

Revision History	Description
06/14/2016	Platelet function testing – VerifyNow changed to “medical review no longer required”. CPT code 85576
06/30/2015	Added additional Medicare LCD links and PROOVE® panels
09/08/2015	Revised LCD CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing L36311 and L35472, GeneSight® Assay for Refractory Depression (L36324), Genetic Testing L34101, Cytogenic Studies L34067
03/01/2016	Added Abacavir as a new test, added NRAS as an additional tumor marker, updated criteria for BRAF v600E Mutation
04/04/2017	Added MTAC review for Oncotype Assay for Lymph Node Positive Breast Cancer
08/01/2017	Added MTAC review for Breast Cancer Index and EndoPredict
04/24/2018	Added Oncotype DX Breast criteria revision
04/24/2018	Move BRAF testing to Genetic Screening Policy
06/02/2020	Added section: “Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees” Requires 60-day notice, effective date 10/01/2020.
10/06/2020	MPC approved the MCG 24th ed. guidelines for Opioid Pharmacogenetics - CYP450 Polymorphisms, OPRM1 Gene, and GeneSight Analgesic Panel: A-0992, Statin Pharmacogenetics - SLCO1B1 Gene: A-0981; added exception for NGS for Advanced Cancer (CellNetix lab) to Invitae as preferred lab section
12/01/2020	Added MTAC review for Breast Cancer Index and Prosigna Breast Cancer Prognostic Gene Signature Assay. MPC approved to adopt non-coverage policy.
05/04/2021	Updated lists of tests, criteria, and applicable codes in Medicare and Non-Medicare sections. MPC voted to adopt MCG* A-0859 for psychotropic medications – this requires 60-day notice, effective date October 1, 2021.
10/27/2022	Updated lab vendor to include Prevention and align with other genetic criteria.
11/18/2022	Updated Medicare Links
12/06/2022	MPC approved to update criteria for ALK (81401), EGFR (81235) and KRAS (CPT 81275, 81276, 0111U) and/or NRAS (CPT 81311, 0111U) testing to no longer require review. MPC also approved to move BRAF testing from the Genetic screening/testing criteria page to the pharmacogenomic criteria page. Requires 60-day notice. Effective 05/01/2023.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Photodynamic Therapy (PDT)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Ocular Photodynamic Therapy (OPT) (80.2)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Ocular Photodynamic Therapy (OPT) with Verteporfin (A52769) RETIRED
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance related to non-ocular conditions, Kaiser Permanente has chosen to use their own Clinical Review Criteria for medical necessity determinations**. For all non-ocular conditions, use the Non-Medicare criteria below**.

For Non-Medicare Members

Service	Criteria Used
PDT with Visudyne for Pathologic Myopia PDT for Advanced Esophageal Cancer and Barrett's Esophageal Disease PDT for Age-Related Wet Macular Degeneration PDT for Actinic Keratosis	Medical necessity review no longer required
Photodynamic Laser Therapy for Tracheobronchial Cancer	Covered when the patient has obstructive tracheobronchial cancer as a palliative treatment.
PDT for Brain Tumors PDT for Rosacea	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Photodynamic therapy (PDT) is a cancer treatment that destroys cancer cells selectively by an interaction between absorbed light and a retained photosensitizer. It is a two-part treatment using a photosensitizing drug, and red non-thermal laser light. The photosensitizing agent is a light activated chemical that selectively concentrates in malignant tissue. This agent is usually injected intravenously, and two days later it is activated by exposing the tissue to a laser light energy of a specific wavelength. For Photofrin, the FDA approved

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photosensitizer, the wavelength of light used for activation is 630 nm. The photosensitizer will absorb the light energy and produce toxic oxygen radicals that destroy the tumor and result in its necrosis in about 24 to 48 hours. The depth of penetration and tumor necrosis after PDT is limited to approximately 5-10 mm. This shallow depth of light penetration in the tumor provides a safety factor against perforation, but on the other hand it is a limiting factor to the effectiveness of the therapy for deeper tumors.

Photodynamic therapy is an outpatient procedure, performed with the patient sedated. It can be used together with other treatments and can be repeated several times. It does not require anesthesia or pre-dilation of the esophagus.

The side effect most commonly associated with PDT is photosensitivity. This is usually manifested as sunburn or periorbital edema. Patients are advised to avoid direct light for at least 4 weeks, after the treatment.

Evidence and Source Documents

Photodynamic Therapy (PDT) for Advanced Esophageal Cancer and Barrett's Esophageal Disease
Photodynamic Therapy for Brain Tumors
Photodynamic Laser Therapy for Tracheobronchial Cancer
Photodynamic Therapy with Visudyne for Pathologic Myopia
Visudyne with Photodynamic Therapy for Age-Related Wet Macular Degeneration

Medical Technology Assessment Committee (MTAC)

Photodynamic Therapy (PDT) for Advanced Esophageal Cancer and Barrett's Esophageal Disease

BACKGROUND

Esophageal carcinoma is the seventh most common malignancy worldwide. Its incidence is increasing rapidly in the western world mainly due to adenocarcinoma of the lower third of the esophagus and gastro-esophageal junction, which usually arises from areas of Barrett's metaplasia (Lee 2001). Approximately 13,100 new cases of adenocarcinoma were diagnosed in the United States in 2002. The overall survival rate from esophageal cancer is 5-10% (Litle 2003). Most patients present with dysphagia, which usually occurs at an advanced stage of the disease. At that time, the lumen of the esophagus is often reduced by at least 50% of its diameter among most of the patients. Radical esophageal resection is still considered the therapeutic gold standard in patients with high-grade dysplasia or early cancer. For those not legible for surgical resection, treatment is palliative to reduce the esophageal obstruction and reduce the dysphagia. Different forms of palliative treatment include external beam radiation therapy, brachytherapy, pneumatic dilatation, esophageal stenting, Nd: YAG laser, and photodynamic (PDT) therapy. Some of these therapies e.g. external radiation therapy may take several weeks to relieve the dysphagia, others like esophageal bypass have a longer recovery time, and still others are associated with severe side effects as stricture, perforation, reflux, fistula formation and others. PDT is a two-part treatment using a photosensitizing drug, and red non-thermal laser light (green light has been used in some studies). The photosensitizing agent is a light- activated chemical that is selectively retained in tumor cells, and interstitial tissue of the tumor. (McCaughan, 1996). This agent is usually injected intravenously, and two days later it is activated by exposing the tissue to a laser light energy of a specific wavelength. For Photofrin, the FDA approved photosensitizer, the wavelength of light used for activation is 630 nm. The photosensitizer will absorb the light energy and produce toxic oxygen radicals that destroy the tumor and result in its necrosis in about 24 to 48 hours. The depth of penetration and tumor necrosis after PDT is limited to approximately 5-10 mm. This shallow depth of light penetration in the tumor provides a safety factor against perforation, but on the other hand it is a limiting factor to the effectiveness of the therapy for deeper tumors. Photodynamic therapy is an outpatient procedure, performed with the patient sedated. It can be used together with other treatments and can be repeated several times. It does not require anesthesia or pre-dilation of the esophagus. Sensitivity of the patient body tissues to light always occurs once the agent is injected, and the patients should avoid direct light for at least four weeks. An important adverse effect of PDT is the potential formation of esophageal strictures due to fibrosis and scarring during the healing process. Barrett's esophagus is a condition where the squamous epithelium of the lower esophagus is substituted by specialized columnar mucosa. It is estimated to affect 700,000 adults in the United States (FDA 2003) and is believed to occur as a response to esophageal reflux of gastric contents especially gastric acid. Barrett's esophagus is regarded as a premalignant condition and is the most important risk factor for the development of adenocarcinoma (Spechler 2002). Non-dysplastic metaplasia can progress to low-grade dysplasia, high-grade dysplasia, and finally to invasive cancer (Conio 2005). Several investigators reported that the relative risk of the adenocarcinoma depends on several negative prognostic factors among which are metaplasia extension, length of the involved segment, dysplasia grading, and timing of diagnosis (Pagoni 2003). Esophageal adenocarcinoma is often diagnosed at an advanced stage of the disease, and thus has a poor prognosis with 5-year survival rates below 20% (Enzinger 2003). The increased availability of endoscopy and

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awareness of Barrett's esophagus and its associated cancer risk have led to the increased detection of the condition in premalignant or early malignant stages. Partial or total esophagogastrectomy are considered the therapeutic gold standard in patients with high-grade dysplasia or early cancer. Surgical resection may however, be associated with high morbidity and mortality rates especially in low-volume surgical centers (Birkmeyer 2002). Moreover, some patients may be unfit for surgery. Other possible strategies have been proposed to destroy Barrett's mucosa. Among these techniques are photodynamic therapy (PDT), ablation therapy with Nd-YAG laser, Argon Plasma Coagulation (APC), and endoscopic mucosal resection (EMR). The objective of all these treatments is the complete destruction of the abnormal mucosa to reduce the cancer risk. The ideal treatment would destroy columnar metaplasia and achieve regeneration of the squamous epithelium. PDT is a two-part treatment using a photosensitizing drug and red non-thermal laser light (green light has been used in some studies). The photosensitizing agent is a light- activated chemical that selectively concentrates in malignant tissue. This agent is usually injected intravenously, and two days later it is activated by exposing the tissue to a laser light energy of a specific wavelength. The photosensitizer will absorb the light energy and produce toxic oxygen radicals that destroy the esophageal mucosa in about 24 to 48 hours. Photodynamic therapy is an outpatient procedure, performed with the patient sedated. It can be used together with other treatments and may be repeated several times. It does not require anesthesia or pre-dilation of the esophagus. Sensitivity of the patient body tissues to light always occurs once the agent is injected, and the patients should avoid direct sunlight or any bright light for at least four weeks. An important adverse effect of PDT is the potential formation of esophageal strictures due to fibrosis and scarring during the healing process. Porfimer sodium (photofrin) was approved by the FDA in December 1995, to use in PDT for the palliation of patients with completely obstructing esophageal cancer, or patients with partially obstructing esophageal cancer who cannot be satisfactorily treated with Nd:YAG laser therapy. More recently, in August 2003 it was also approved for the ablation of precancerous lesions in Barrett's esophagus patients who do not undergo esophagectomy (FDA 2003).

02/06/2000: MTAC REVIEW
Photodynamic Therapy for the Treatment of Advanced Esophageal Cancer
Evidence Conclusion: Photodynamic therapy when compared to Nd:YAG thermal ablation for palliation of dysphagia from advanced esophageal cancer provides equivalent improvement in dysphagia, improved objective tumor response as measured by esophageal lumen diameter (ARR of 12% at one month in "complete response + partial response" P <0.05), and increased mild to moderate complications including sunburn in 19% of patients treated with PDT. Perforations from laser treatments or associated dilatations occurred in 1% of patients following PDT and 7% of patients following Nd:YAG treatment. (p<0.05) Termination of laser sessions due to adverse events occurred in 3% of patients receiving PDT and 19% receiving Nd:YAG. While this is an RCT, the high dropout rate and lack of blinding limit our ability to understand the difference in clinically important outcomes between Nd:YAG thermal ablation and PDT.
Articles: Articles were sorted on the basis of study type. Case series and cohort studies were not selected. Two randomized controlled trials were selected for review. One randomized controlled trial was selected (study by Heier SK et al. *Gastroenterology.* 1995; 109:63-72) was excluded because of small study size: N=44; 20 in PDT group, 22 in Nd:YAG group). An evidence table was created for the best available evidence (Lightdale CJ, et al. *Gastrointestinal Endoscopy.* 1995; 42:507-12.) Reference**:** Lightdale CJ, Heier SK, Marcon NE, et al. Photodynamic therapy with porfimer sodium versus thermal ablation therapy with Nd: YAG laser for palliation of esophageal cancer: a multicenter randomized trial. *Gastrointestinal Endoscopy.* 1995; 42:507-12. See Evidence Table.

The use of photodynamic therapy in treatment of esophageal cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*

02/11/2004: MTAC REVIEW
Photodynamic Therapy for the Treatment of Advanced Esophageal Cancer
Evidence Conclusion: Barrett's esophagus: Ackroyd's study was a small RCT with valid methodology. It is randomized, controlled, double blind, and with sufficient power to detect the difference in the treatment response between the two groups despite the small sample size. The trial however compared PDT to placebo and not to an alternative treatment. The photosensitizer used was ALA not the commonly used porphyrin-based agent, and the laser light used was the green light, not the red light described in the literature. Effect of the treatment on survival was not studied. Overall, the results of the trial show that patients treated with PDT showed significantly more macroscopic and microscopic evidence of regression and reduction in Barrett's area, compared to those who received a placebo treatment. The response to treatment observed was maintained for the follow-up duration of 24 months. The other study reviewed (Overholt 2003) was a case series with long-term follow-up. The study, like all case series, has potential threats to its internal validity, and lacks a comparison or control group. Its results show that PDT was associated with a success rate (no dysplasia with or without Barrett's) ranging from 44.4% for
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cases with early stage carcinoma to 92.9% for cases with low-grade hyperplasia. PDT was not compared to an alternative treatment. In addition, it was supplemented with Nd: YAG laser photoablation and continuous use of omeprazole, which may be responsible in part for the treatment success. Advanced esophageal cancer:
Only case series data were available. The dysphagia scores seem to significantly improve after PDT treatment in the two-series reviewed. There are no studies comparing the PDT with other treatments, so the relative effectiveness cannot be determined. Moreover, the case series studies are subject to selection and observation bias. A RCT (Lightdale, et al, 1995) with 218 patients randomized to receive either PDT or Nd:YAG was reviewed for MTAC in February 2000. It was not blinded, and had a high dropout rate, and did not provide sufficient evidence to determine the effect of the PDT on the treatment of esophageal cancer.
Conclusion: There is some weak evidence from one small RCT that PDT using ALA photosensitizer has more than a placebo effect on the regression of Barrett's area. There is insufficient evidence on the effect of PDT in the palliative treatment of advanced, and/ or inoperable esophageal cancer.
Articles: Barrett's esophagus: The search revealed 125 articles. The majority were reviews and tutorials. There was one RCT comparing the procedure to placebo, two others small RCTs comparing different methods for performing PDT, and several case series or case reports. The RCT and the case series with a relatively large sample size, and long-term follow-up were selected for critical appraisal. Ackroyd R, Brown JN, Davis MF, et al. Photodynamic therapy for dysplastic Barrett's oesophagus: a prospective, double blind, randomized, placebo-controlled trial. *Gut* 2000; 47:612-617. See Evidence Table. Overholt BF, Panjehpour M, Halberg D, et al. Photodynamic therapy for Barrett's oesophagus with dysplasia and/or early stage carcinoma: Long-term results. *Gastrointest Endosc* 2003; 58:183-188. See Evidence Table. Advanced esophageal cancer: The search on esophageal cancer in general revealed 94 articles, and that on advanced esophageal cancer revealed 21 articles the great majority of which were review articles. There were no RCTs comparing PTD to other modes of treatment. There were three case series with more than 50 patients each. One of these series compared PDT given in addition to radiotherapy. The other two were critically appraised. Luketich JD, Christie Na, Buenavantura PO, et al. Endoscopic photodynamic therapy for obstructive esophageal cancer. *Surg Endosc* 2000; 14:653-657. See Evidence Table. Moghissi K, Dixon K, Thorpe JA, et al. The role of photodynamic therapy (PDT) in inoperable oesophageal cancer. *Eur J Cardiothorac Surg* 2000; 17:95-100. See Evidence Table.

The use of photodynamic therapy in treatment of esophageal cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/06/2005: MTAC REVIEW
Photodynamic Therapy in Treatment of Barrett's Disease
Evidence Conclusion: Kelty et al's RCT compared photodynamic therapy (PDT) and argon plasma coagulation (APC) for the ablation of Barrett's esophagus. The outcomes were the number of treatments required to achieve ablation, and the complete macroscopic reversal of the columnar epithelium. All patients had a biopsy proven Barrett's epithelium, but none had any evidence of dysplasia. Thirty-four patients were randomized to each treatment group and followed for up to two years (range 6-24, median 12 months). 50% of the patients in the PDT group showed complete response to PDT, and 50% had only a partial regression. The APC therapy had significantly better outcomes with a complete response rate of 97%. Hage et al's trial was a smaller study (N=40) that also compared PDT with APC, and the primary outcome was the endoscopic reduction of the Barrett's esophagus surface. All patients had no or a low-grade dysplasia. They were randomized to receive APC therapy, single illumination (PDT 100), or a fractionated illumination (PDT 20+100), and followed for up to two years. The results of the trial show that patients who received a single illumination of PDT had a significantly lower rate of Barrett's esophagus surface reduction when compared to the PDT 20+100 group or the APC group (51%, 86% and 93% respectively). The difference between the latter two groups was insignificant. The two studies used 5-aminolevulonic acid (5-ALA); a more recent sensitizing agent and not the FDA approved photofrin (porfimer sodium). Both trials had generally valid methodology. However, they had relatively small sample sizes, and the follow-up duration of 2 years might be insufficient to study the effect of the therapy on reducing the risk of cancer. The outcome in these trials was the effect of the therapy on the reversal of the columnar epithelium and not on patient survival. Moreover, all study subjects had no or low-grade dysplasia, which might limit generalization of the results. The 2004 MTAC review only found weak evidence from one small RCT that PDT using ALA photosensitizer had more than a placebo effect on the regression of Barrett's area. The therapy failed the committee evaluation criteria. In conclusion, the studies reviewed provide some evidence that PDT may achieves complete clearance of Barrett's epithelium in at least 50% of the patients with no or low-grade dysplasia. They do not provide evidence on the effect of the therapy on higher-grade dysplasia, or its impact on cancer risk, and patient survival. Larger trials with long-term follow-up may be needed to establish these effects.
Articles: The search revealed 26 articles. The majority were review articles or opinion pieces. There were two randomized controlled trials and two case series. The two RCTs were selected for critical appraisal: Kelty CJ, Ackroyd R, Brown JN, et al. Endoscopic ablation of Barrett's esophagus: a randomized controlled trial of
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photodynamic therapy vs. argon plasma coagulation. *Aliment Pharmacol Ther* 2004; 20:1289-1296. See Evidence Table. Hage M, Siersema PD, van Dekken H, et al. 5-Aminolevulinic acid photodynamic therapy versus argon plasma coagulation for ablation of Barrett's oesophagus: a randomized trial. *Gut* 2004; 53:785-790. See Evidence Table.

The use of photodynamic therapy in treatment of Barrett's disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Photodynamic Therapy for Brain Tumors

BACKGROUND

Photodynamic therapy (PDT) refers to the use of photosensitizing agents to treat tumors. The only FDA-approved photosensitizing agent is porfimer sodium (Photofrin). The PDT process involves the infusion of photosensitizing agents intravenously that are selectively retained within tumor cells. The photosensitizing agents are activated by exposure to light and cause oxidative damage to tumor tissues in which the drug has been retained.

The use of PDT to treat cerebral gliomas (brain tumors) was first investigated in 1972 using hematoporphyrin activated by white light on glioma cells in vitro and in rat tumors. Animal models have demonstrated the selective uptake of photosensitizers into cerebral gliomas. The first examination of PDT to treat human gliomas was reported by Perria in 1980. The ideal dose of photosensitizer and light for cerebral tumors has yet to be determined (Popovic). Other treatments for cerebral gliomas include surgical resection, postoperative whole-brain irradiation and chemotherapy. The effectiveness of these treatments is limited by inadequate local control of disease. It is hoped that PDT can improve local disease control and increase survival (Rosenthal).

02/13/2002: MTAC REVIEW

Photodynamic Therapy for Brain Tumors

Evidence Conclusion: There is insufficient evidence to determine the effect of PDT on health outcomes for patients with brain tumors. Much of the research appears to focus on developing the best methods for applying PDT to the treatment of brain tumors. Few clinical data are available. Popovic reported on a series of 120 patients; few methodological details were given, and the intervention may not have been consistent. They found that the median survival among 38 patients with glioblastoma multiforme was 24 months; in a historical control group subject to selection bias, median survival in patients with a similar diagnosis was 8 months.

Articles: The search yielded 69 articles, most of which were review articles, laboratory studies, dealt with technical aspects of the procedures or addressed other, similar treatments. There were no randomized controlled trials or meta-analyses. There were several small case series, many of which did not report clinical outcomes. A recent review article with some case series data was reviewed: Popovic EA, Kaye AH, Hill JS. Photodynamic therapy of brain tumors. J of Clin Laser Med & Surg 1996; 14: 251-261. See Evidence Table.

The use of photodynamic therapy in the treatment of brain tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Photodynamic Laser Therapy for Tracheobronchial Cancer

BACKGROUND

Lung cancer is the leading cause of cancer deaths. It usually originates from bronchial cells, and grows in the bronchial lumen or peribronchially, thus, the term bronchial cancer is used synonymously with lung cancer. Resectional surgery is considered the treatment of choice, and the therapy with potential cure or long survival. However, the majority of patients diagnosed with lung cancer are at an advances stage, and only 15-20% are surgical candidates at the time of diagnosis (Fry, 1996). There are several methods used for palliative treatment for bronchial obstruction including Nd: YAG laser therapy, brachytherapy, electrocautery, balloon dilatation, stent insertion, and photodynamic therapy (PDT). PDT is a cancer treatment that destroys cancer cells selectively by an interaction between absorbed light and a retained photosensitizer. It is a two-part treatment using a photosensitizing drug, and red non-thermal laser light. The photosensitizing agent is a light activated chemical that selectively concentrates in malignant tissue. This agent is usually injected intravenously, and two days later it is activated by exposing the tissue to a laser light energy of a specific wavelength. For Photofrin, the FDA approved photosensitizer, the wavelength of light used for activation is 630 nm. The photosensitizer will absorb the light energy and produce toxic oxygen radicals that destroy the tumor and result in its necrosis in about 24 to 48 hours. The depth of penetration and tumor necrosis after PDT is limited to approximately 5-10 mm. This shallow depth of light penetration in the tumor provides a safety factor against perforation, but on the other hand it is a limiting factor to the effectiveness of the therapy for deeper tumors. Of the potential advantages of the procedure is that may be technically easier and potentially safer than other procedures, and that it is repeatable and appears to be compatible with other treatments. The procedure does not require general anesthesia, and

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only requires a prolonged bronchoscopy. The side effect most commonly associated with PDT is photosensitivity. This is usually manifested as sunburn or periorbital oedema. Patients are advised to avoid direct light for at least 4 weeks, after the treatment. The risk of serious bronchial hemorrhage, which may be fatal is another important complication associated with the PDT therapy used for treating tumors invading bronchial walls, and big vessels. Other complications include cough, dyspnea, bronchitis, and pneumonia. PDT is approved by the FDA for the palliation of airway obstruction caused by malignant tumors in patients with advanced obstructive endobronchial disease, and as an alternative to surgery in selected patient with early-stage lung cancer. PDT use in the treatment of tracheobronchial cancer was reviewed by MTAC in February 2002 and failed the committee evaluation criteria.

02/11/2004: MTAC REVIEW
Photodynamic Laser Therapy for Tracheobronchial Cancer
Evidence Conclusion: There is insufficient new evidence to determine the effectiveness of photodynamic therapy in the treatment of tracheobronchial cancer.
Articles: The search yielded 25 articles. The majority were reviews and tutorials. There was a small longitudinal study (32 patients) on all bronchoscopic treatments of occult lung cancer, another retrospective study on all palliative measures for malignant airways including 8 patients receiving PDT treatment or stents, and a small trial with 16 patients comparing 2 photosensitizers used in PDT for the treatment of malignant bronchial stenosis. None of the studies was critically appraised.

The use of photodynamic therapy in the treatment of bronchial cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

02/13/2002: MTAC REVIEW
Photodynamic Laser Therapy for Tracheobronchial Cancer
Evidence Conclusion: Early-stage lung cancer: Only case series data were available. A large proportion of the patients studied appear to have complete remission following PDT (approximately 80%); there are no studies comparing remission rates with other treatments, so the relative effectiveness cannot be determined. The case series reports are subject to selection and observation bias. The long-term effectiveness is difficult to determine because patients were permitted to have other treatments after PDT. Advanced lung cancer: The highest grade of evidence was an RCT. Diaz-Jimenez compared Nd-YAG to PDT in 31 patients. They found that patients who received PDT had a median of 12 days longer before treatment failure for any reason (50 vs. 38 days) and survived for a mean of 170 days longer (265 vs. 95 days) than the group receiving Nd-YAG. Because this is a small RCT, selection bias is likely. A greater proportion of patients assigned to the Nd-YAG group had advanced lung cancer that could at least partially explain the shorter time to treatment failure and shorter survival time. The existing evidence is insufficient to determine the effect of PDT on advanced lung cancer.
Articles: The search yielded 57 articles, many of which were review articles, opinion piece, dealt with technical aspects of the procedures or addressed other, similar treatments. Early-stage lung cancer: There were no randomized controlled trials (RCTs) or meta-analyses. The highest grade of evidence available was case series. The two largest case series were critically appraised: Furuse K, Fukoka M, Kato H, Horai T, Kubota K, Kodamo N et al. A prospective Phase II study on photodynamic therapy with photofrin II for centrally located early-stage lung cancer. J Clin Oncol 1993; 11: 1 852-57. See Evidence Table. Kato H, Okunaka T, Shimatani H. Photodynamic therapy for early stage bronchogenic carcinoma. J Clin Laser Med & Surg 1995; 14: 235-238. See Evidence Table Advanced lung cancer: There were two RCTs. The remaining empirical articles were case series. One RCT had included only 11 patients and did not compare outcomes in the two randomized groups in analysis. One RCT was critically appraised: Diaz-Jimenez JP, Martinez-Ballerin JE, Llunell A, Farrero E, Rodriguez A, Castro MJ. Efficacy and safety of photodynamic therapy versus Nd-YAG laser resection in NSCLC with airway obstruction. Eur Respir J 1999; 14: 800-805. See Evidence Table.

The use of photodynamic therapy in the treatment of bronchial cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Photodynamic Therapy with Visudyne for Pathologic Myopia
BACKGROUND
Choroidal neovascularization (CNV) in patients with pathologic myopia is a condition in which there is an abnormal growth of blood vessels under the retina due to an elongation of the back of the eye associated with severe myopia. This condition can result in a progressive and serious loss of vision. There have not been effective treatments for this disease. Photodynamic therapy using Visudyne (verteporfin for injection) involves intravenous injection of verteporfin, a light activated or “photosensitive” drug. After infusion, verteporfin is activated by illumination with laser light shone into the patient’s eye from a slit lamp of a microscope. The
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wavelength used corresponds to the wavelength at which peak absorption occurs but is not so strong as to cause thermal damage. The light is directed to the area of neovascularization and damage to the retina is minimized.
In April 2000, the FDA approved Visudyne for the treatment of the wet form of age-related macular degeneration. In August 2001, photodynamic therapy with Visudyne was additionally approved for the treatment of subfoveal choroidal neovascularization (CNV) due to pathologic myopia. Visudyne for age-related macular degeneration was found to meet MTAC review criteria in June 2000.

02/13/2002: MTAC REVIEW
Photodynamic Therapy with Visudyne for Pathologic Myopia
Evidence Conclusion: One well done randomized controlled trial (VIP study group) was reviewed. This study provides evidence that photodynamic therapy with verteporfin is effective at decreasing vision loss 12 months after treatment. 28% of patients in the verteporfin group compared to 56% in the placebo group had at least an eight-letter loss at 12 months, the study's primary outcome ($p<0.01$, NNT=4). This finding is likely to be clinically as well as statistically significant. The treatment appears to be safe. Ideally, the findings would be replicated in other studies and there would be longer-term follow-up. 24-month follow-up data will be available from the VIP study.
Articles: The search yielded 26 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There was 1 randomized controlled trial (n=120) with and 1 case series (n=13). The case series included patients with choroidal neovascularization due to several conditions, e.g. pathologic myopia, ocular histoplasmosis syndrome, angiod streaks and idiopathic causes. *The RCT was critically appraised:* Verteporfin in photodynamic therapy (VIP) study group. Photodynamic therapy of subfoveal choroidal neovascularization in pathologic myopia with verteporfin: 1-year results of a randomized clinical trial: VIP report no. 1. Ophthalmol 2001; 108: 841-52. See Evidence Table

The use of photodynamic therapy in the treatment of pathologic myopia passed the *Kaiser Permanente Medical Technology Assessment Criteria*.

Visudyne with Photodynamic Therapy for Age-Related Wet Macular Degeneration
BACKGROUND
Age-related macular degeneration (AMD) is the most common and most severe cause of vision loss in the U.S. and many developed countries. With increasing life expectancy, the prevalence of AMD (currently about 25%) in people aged 65 years and older will increase significantly, with an enormous social and financial cost. In spite of the significance of this problem, AMD's pathogenesis remains unclear and is essentially untreatable.
AMD is characterized by two forms: the "dry" and more severe "wet" form. The latter accounts for 15% of all AMD cases, but is responsible for 90% of the severe vision loss associated with this condition. Visual acuity loss usually results from choroidal neovascularization (CNV), the ingrowth of new vessels from the choriocapillaris. These new vessels are accompanied by fibrous tissue that can destroy central visual function over months to years. Standard treatment of CNV has been with a thermal laser. The drawback of this laser is that in addition to destroying the CNV it destroys the surrounding retinal tissue with immediate vision loss. Photodynamic Therapy (PDT) utilizing verteporfin (Visudyne; CIBA Vision Corp, Duluth, GA) is a new technology which completed Phase III clinical trials last year and was recently recommended for FDA approval by the Ophthalmic Drugs Subcommittee of the FDA. Verteporfin therapy involves an intravenous administration of verteporfin, a light activated drug. Laser light at the specific wavelength absorbed by Visudyne is then directed to the area of neovascularization and causes preferential closure of these vessels while sparing the overlying retina.
The articles described below evaluate PDT as a treatment for choroidal neovascularization (CNV), the type of late AMD that is the most frequent cause of visual loss.

06/14/2000: MTAC REVIEW
Visudyne with Photodynamic Therapy for Age-Related Wet Macular Degeneration
Evidence Conclusion: The prospect of verteporfin (Visudyne) as a new therapy for subfoveal wet AMD is very promising, in light of the fact AMD is an important public health problem with no currently available treatment that spares destruction of the fovea itself. However, the efficacy and safety of verteporfin cannot be fully determined from the limited evidence provided by these two studies, which were conducted by the same investigators. The findings from the case series are threatened by small sample size and possible observation and selection biases. The findings from both studies are threatened by short length of follow-up, concerns about the generalizability of the findings, and the fact that the investigators would benefit financially from FDA approval of the drug. Further studies, preferably blinded, randomized controlled trials, such as the Verteporfin in Photodynamic Therapy (VIP) Trial (to be completed this Fall), will provide further evidence regarding whether photodynamic therapy with verteporfin can safely and effectively reduce the risk of vision loss in patients with age-related macular degeneration.
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Articles: Miller JW, Schmidt-Erfurth U. Sickenberg M; Piurnaras CJ et al. Photodynamic Therapy with verteporfin for Choroidal Neovascularization caused by age-related Macular Degeneration. *Archives of Ophthalmology 1999; 117:1167-1173.* See Evidence Table. TAP Study Group. Photodynamic Therapy of subfoveal choroidal neovascularization in age-related Macular Degeneration. *Archives of Ophthalmology 1999; 117:1329-1345.* See Evidence Table.

The use of Visudyne with Photodynamic Therapy in the treatment of Age-related Macular Degeneration does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Verteporfin

CPT® or HCPC Codes	Description
J3396	Injection, verteporfin, 0.1 mg

Photodynamic Therapy

CPT® or HCPC Codes	Description
96567	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitive drug(s), per day
96570	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)
96571	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)
96573	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day
96574	Debridement of premalignant hyperkeratotic lesion(s) (ie, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/1998	04/06/2010 MDCRPC, 02/10/2011 MDCRPC, 12/06/2011 MDCRPC, 10/02/2012 MDCRPC, 8/06/2013 MPC, 11/05/2013 MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC,12/07/2021MPC,12/06/2022MPC	09/03/2019

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
06/02/2015	Added Actinic Keratosis

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10/11/2016	Added Medicare coverage article A52769
09/03/2019	MPC approved to add PDT for Rosacea to the non-covered list

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Clinical Review Criteria
PLAC Test

- Predicting the Risk of Coronary Heart Disease (Lp-PLA2)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	MolDX: Biomarkers in Cardiovascular Risk Assessment (L36362) *This test is not covered when included in a CV risk assessment panel per Medicare LCD.*
Local Coverage Article	Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Recent research suggests that inflammation plays a role in the development and progression of atherosclerosis. This observation, together with the advances in inflammatory biomarkers research, has led to the emergence of dozens of novel biomarkers that may potentially aid in predicting an individual's risk for cardiovascular disease. Among these novel biomarkers are C-reactive proteins, lipoprotein associated phospholipase A2 (Lp-PLA2), homocysteine, fibrinogen, plasminogen, interleukin-6 (IL-6), IL-18, and many others (Anderson 2008, Khakpour 2009, Packard 2009).

A novel biomarker for cardiovascular risk has clinical utility if it independently provides risk information above and beyond that provided by conventional risk factors, is easy to obtain and interpret in a primary care setting, is highly specific, accurately reproducible and contributes to patient management particularly through more accurate risk stratification and guidance in the choice of therapy (Oldgren 2007, Lerman 2008, Khakpour 2009).

Lp-PLA2, also known as platelet activating factor acetyl-hydrolase, has been proposed to be a more specific marker for vascular inflammation. It is an enzyme secreted by macrophages, monocytes, T-lymphocytes, and mast cells. Over two thirds of Lp-PLA2 circulate in the bloodstream bound to low-density lipoprotein cholesterol, and the rest travels bound to high-density and very low-density lipoproteins. For several years there has been a lot of debate on whether the enzyme has a pro- or anti-atherogenic mechanism. One viewpoint suggests that it plays a role in the production of proinflammatory mediators including oxidized free fatty acids and lysophosphatidylcholine, and another view implies that that the enzyme could be protective by reducing

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inflammation and predisposition to thrombosis in blood through its hydrolysis of platelet activating factor (Anderson 2008, Wilensky 2009).

The diaDexus PLAC test is a second generation of the enzyme-linked immunoassay (ELISA) test used in many of the population studies that investigated the association of Lp-PLA2 with cardiovascular diseases. It is based on the standard principle of a sandwich enzyme immunoassay using two specific high affinity monoclonal antibodies directed against Lp-PLA2 that show no cross-reactivity with other phospholipases. A set of Lp-PLA2 calibrators is used to plot a standard curve of absorbance (y-axis) versus Lp-PLA2 concentration in ng/ml (x-axis) from which the Lp-PLA2 concentration in the test sample can be determined. This concentration of the enzyme in each sample and control is then interpolated from the standard curve using a point-to-point curve fit with appropriate calibration curve fitting software. The test has a minimum detection limit of 1.3 ng/ml and the expected Lp-PLA2 concentrations are 120-342 ng/ml for females and 131-376 ng/ml for males. PLAC test is classified under the Clinical Laboratory Improvement Amendments (CLIA) 88 as a high-complexity test and must be run in CLIA-certified-high-complexity laboratories (Hoogerveen 2005, FDA Website).

PLAC test, diaDexus, Inc, San Francisco, CA, was cleared by the FDA in 2003, for the quantitative determination of Lp-PLA2 in human plasma to be used in conjunction with clinical evaluation and patient risk assessment as an aid for predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis (FDA website).

Medical Technology Assessment Committee (MTAC)

PLAC Test in Detecting Risk of Coronary Heart Disease

02/11/2004: MTAC REVIEW

Evidence Conclusion: Ballantyne et al's study was nested in a large prospective study. It included both men and women 45-64 years of age. In this sub-study CHD patients were compared to a random sample of 785 subjects (minus 45 cases with CHD), and not to the whole study population. The authors do not provide explanation why they selected such a design. There were several significant differences in the base-line characteristics between the cases, and non- cases. Adjustments were made for several of these variables, not for all. Other variables not adjusted for in the analysis may be potential confounders. Overall, it showed that the highest tertile of Lp-PLA_2 enzyme was associated with a higher CHD risk among patients with LDL cholesterol level <130 mg/dL. Packard's study was a case control nested in the WOSCOPS study. Participants were men 45-64 years of age, with baseline LDL cholesterol level 174 –232 mg/dL. Cases were those who developed a coronary event, and controls were men from the same cohort who did not develop a coronary event during the follow-up. Overall the results showed that lipoprotein-associated phospholipase A_2 was significantly associated with coronary events, independent of the other variables studied. Blake's study on the other hand did not detect a significant association between the enzyme and the risk of cardiovascular events among women. It was also a case control nested in a large trial, "Women's Health Study" that only enrolled women 45 years of age or older. The case control study was small, and the power might have been insufficient to detect a significant association. The different findings between the two studies may also indicate that lipoprotein-associated phospholipase levels may be predictive of coronary events in men but not women. The three studies reviewed examined Lp-PLA_2 as a marker or risk predictor for coronary events but did not study the implication of identifying this risk factor on the management of the patients or in improving the net health outcome.

Articles: The search yielded 25 articles, the majority of which were news, review articles, and tutorials. The search did not reveal any RCTs. The studies embedded in larger prospective cohort studies were identified. All three were critically appraised: Ballantyne CM, Hoogeveen RC, Bang H, et al. Lipoprotein-associated phospholipase High sensitivity C-reactive protein, and risk incident coronary heart disease in middle-aged men and women in the atherosclerosis risk in communities (ARIC) study. *Circulation* 2004; 109:837-842. See Evidence Table. Packard CJ, O'Reilly DS, Caslake MJ, et al. Lipoprotein- associated phospholipase A_2 as an independent predictor of coronary heart disease. N Engl J Med 2000; 343:1148-1155. See Evidence Table. Blake GJ, Dada N, Fox JC, et al. A prospective evaluation of lipoprotein- associated phospholipase A_2 levels and the risk of future cardiovascular events in women. J Am Coll Cardiol 2001; 38:1302-1306**.** See Evidence Table.

The use of PLAC Test in detecting risk of coronary heart disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/05/2009: MTAC REVIEW

PLAC Test in Detecting Risk of Coronary Heart Disease

Evidence Conclusion: *Lp-PLA2 as a marker for predicting future CVD risk* in the last decade, a number of epidemiologic studies investigated the association between plasma Lp-PLA2 and the cardiovascular disease risk.

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The majority were nested case-cohort studies, and the blood samples were taken only once at baseline and stored at ~ -70oC for up to 10 years before its analysis. The results were mainly presented in hazard ratios comparing the lowest with the highest tertile, quartile or quintile values. Several studies including West of Scotland Coronary Prevention Study (WOSCOPS), the Atherosclerosis Risk in Communities (ARIC) Study, and MONICA study found an association between elevated levels of Lp-PLA2 and increased risk for cardiovascular events in certain groups of patients. In the ARIC study however, the relative risk associated with the upper tertile of Lp-PLA2 became statistically insignificant when adjustments were made for traditional risk factors. Other studies including the Women's Health Study, GUSTO and FRISC did not show a significant association between Lp-PLA2 and CVD risk. A meta-analysis (Garza 2007) that pooled the results of 14 studies, showed a significant independent association between Lp-PLA2 and CVD risk. The results, however, do not provide evidence that measurement of Lp-PLA2 levels would improve risk stratification for CVD or add to the predictive value of the traditional risk factors and scoring systems used e.g. Framingham Risk Score. An analysis of the ARIC study (Folsom 2006) showed that the addition of Lp-PLA2 to the basic risk model increased the area under the receiver operating curve (AUC) from 0.774 to 0.780. Due to the large sample size, this small difference was statistically significant, but is of minor clinical significance. A statistically significant, independent association of a marker to CVD does not necessarily indicate that it improves the risk prediction beyond the traditional variables. Lp-PLA2 as therapeutic target There are no long-term published RCTs to date provide evidence that measuring LP-PLA2 would lead to meaningful changes in patient management, or improvement in clinical outcomes. In a multicenter placebo-controlled trial, Mohler and colleagues 2008 investigated the effect of darapladib, a selective Lp-PLA2 inhibitor, on the enzyme activity as well as on another panel of biomarkers. The study randomized 959 participants with stable CHD or risk equivalent, to receive a placebo or one of three doses of darapladib (40, 80, or 160mg daily), for 12 weeks, together with atorvastatin 20 or 80mg/day. The trial did not have hard clinical outcomes, instead Lp-PLA2 and other select biomarkers were used as surrogates of atherosclerosis risk, to assess the efficacy of the therapy. The results showed that darapladib given together with atorvastatin was associated with lower Lp-PLA2 activity, which appeared to be dose-dependent (darapladib 40,80, and 160 mg significantly inhibited Lp-PLA2 activity by 43%, 55%, and 66% respectively compared to placebo). This was observed in the two atorvastatin groups but without affecting the LDL levels. The study duration was too short to determine the long-term adverse events of the therapy, and its effect on CVD risk. (i.e. whether inhibition of Lp-PLA2 leads to accumulation of proinflammatory or prothrombotic factors). Intervention trials investigating the effect of LP-PLA2 inhibitors on coronary disease events are in progress. These include STABILITY trial on the effect of darapladib on CHD and FRANCIS-ACS trial that evaluates varespladib in patients with acute coronary syndrome. Diagnostic accuracy of PLAC test: The literature did not identify any study that examined the diagnostic accuracy, predictive values, or likelihood ratios of PLAC test in measuring LP-PLA2 among patients at different levels of cardiovascular disease risk. *Conclusion:* The current evidence suggests that Lp-PLA2 may be associated with vascular disease risk, but it is insufficient to show the association is causal, that measuring the enzyme level improves risk stratification for CVD, would have any impact on managing patients at high risk, or that inhibition therapy of Lp-PLA2 enzyme would improve health outcomes.
Articles: The search yielded around 33 articles. There was a meta-analysis, and a number of case control studies examining the association between Lp-PLA2 and CVD. The search also identified one randomized controlled trial on the effect of a selective Lp-PLA2 inhibitor of the enzyme activity (darapladib) in patients with CHD or risk equivalent, and another small RCT on the effect of the drug on the atherosclerotic plaque. The literature search did not reveal any published studies on the clinical benefits of screening for Lp-PLA2 in optimizing therapy and reducing cardiovascular risk, and/or events. There were also no studies on the diagnostic accuracy of PLAC test in assessing the Lp-PLA2 levels. The meta-analysis on the association between Lp-PLA2 and CVD risk, the ARIC study (FDA approval), and the RCT on the effect of darapladib on the enzyme activity in patients with CHD or risk equivalent were selected for critical appraisal: Garza CA, Montori VM, Connell JP, et al. Association between lipoprotein-associated phospholipase A2 and cardiovascular disease: a systematic review . Mayo Clin Proc.2007; 82:159-165. See Evidence Table. Ballantyne CM, Hoogeveen RC, Bang H, et al. Lipoprotein-associated phospholipase High sensitivity C-reactive protein, and risk incident coronary heart disease in middle-aged men and women in the atherosclerosis risk in communities (ARIC) study. Circulation 2004; 109:837-842. See Evidence Table. Mohler ER, Ballantyne CM, Davidson MH, et al. The effect of darapladib on plasma lipoprotein -associated phospholipase A2 activity and cardiovascular biomarkers in patients with stable coronary heart disease or coronary heart disease equivalent. The results of a multicenter, randomized double-blind, placebo-controlled study. J Am Coll Cardiol 2008; 51:1632-1641. See Evidence Table.

The use of PLAC Test in detecting risk of coronary heart disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)

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To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Dates Reviewed	Date Last Revised
02/11/2004	Initiated annual review because of Medicare criteria 04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC,10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC	09/08/2015

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
08/04/2015	Changed Medicare links
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services

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Clinical Review Criteria

Platelet Rich Plasma

- Autologous Platelet Derived Wound Healing Factors for Non-Healing Cutaneous Wounds (Autologel, Procuren, SafeBlood)
- Injections for the Treatment of Non-Healing Fractures and Tendinopathy
- Platelet Rich Plasma for Knee Osteoarthritis
- Platelet Rich Plasma for Plantar Fasciitis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Blood-Derived Products for Chronic Non-Healing Wounds (270.3)
Local Coverage Determinations (LCD)	Platelet Rich Plasma Injections for Non-Wound Injections (L39060)
Local Coverage Article	Billing and Coding: Platelet Rich Plasma Injections for Non-Wound Injections (A58790)

For Non-Medicare Members

Kaiser Permanente has elected to use the Platelet Rich Plasma (A-0630) MCG* for medical necessity determinations. The use of platelet rich plasma is not covered for any indications by MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG* are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist (Orthopedics, sports medicine, physiatrist)

Service	Criteria
• Platelet Rich Plasma for Plantar Fasciitis • Platelet Rich Plasma for Knee Osteoarthritis	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Platelets are rich in growth factors that play an essential role in tissue healing. Platelet-rich plasma (also known as platelet-enriched plasma, platelet-rich concentrate, autogenous platelet gel, or platelet releasate) is used to enhance bone and soft tissue healing by placing supraphysiologic concentrations of autologous platelets at the site of tissue damage. Platelet-rich plasma has been tried for a wide variety of clinical applications, including orthopedics, otolaryngology, and oral and maxillofacial, plastic, gynecologic, cardiac, and general surgeries. Platelet-rich plasma can be prepared from blood collected in the immediate pretreatment period using standard cell separators and salvage devices. After activation, platelet-rich plasma is usually administered by either direct application or injection into the affected area. There is little consensus regarding the production and characterization of platelet-rich plasma.

Bone Fracture Healing (GEM 21STM)

Bone fracture healing is a biological process that involves both local and systemic acute phase reactants. The physiological events occurring at the site of injury include hematoma formation, recruitment and transformation of mesenchymal cells, induction of angiogenesis, and the production and remodeling of the extracelluar matrix. Radiographic healing of a bone fracture is normally achieved in 4-13 months depending on type and location of the fracture. The rate of bone union also depends on several other factors as patient's health, compliance, nutritional status, stability of the fracture and others. Disruption of any of these factors would lead to delayed or non-union of the fracture. It was reported that approximately 10% of the bone fractures in the US are complicated by impaired healing, which has a high impact on the quality of life and burden of health costs. Several compounds and technologies have been and are being developed to enhance fracture healing and accelerate repair. These include prostaglandins, gene therapy, growth hormone, parathyroid hormone, and growth factors. Among the growth factors studied are the bone morphologic proteins, transforming growth factor B, vascular endothelial growth factor, and platelet derived growth factor (PDGF) (Axelrad 2007, Hollinger 2008).

In vitro and animal studies indicate that PDGF has the potential of accelerating the bone healing process. The experimental studies showed that PDGF receptors increase in osteoblasts as they mature, but that the response varies inversely to the number of receptors. This indicates that there is an optimal concentration and time during bone regeneration to deliver the PDGF in order to be effective (Axelrad 2007).

The GEM 21STM a device for bone grafting material containing a therapeutic tri- calcium phosphate or PDGF was approved by the FDA for periodontally related defects in November 2005.

Tendinopathy

Painful tendon disorders are common among professional and recreational athletes, and also among sedentary individuals. It is estimated that 30-50% of all sports-related injuries are painful tendon injuries. These injuries are classified as tendinitis during the acute inflammatory process and tendinosis when healing becomes chronically impaired. Clinicians are increasingly using the term tendinopathy to refer to tendon disorders without implying a specific pathology, and chronic tendinopathy for cases that are refractory to conventional treatment. If the triad of pain, swelling, and reduced load bearing capacity are present, then the correct term for the diagnosis is tendinopathy, which is a clinical and not a histopathological diagnosis. The pathophysiology of chronic tendinopathy involves the presence of degenerative changes, including disorganized collagen fibers, increased granular substance and neovascularity. Tendinopathy leads to reduction in activity levels and sometimes cessation of all sports activities. The three most common sites affected are the Achilles, patellar, and rotator cuff tendons. Other tendons affected include those around the elbow (medial and lateral epicondylitis), wrist extensors, supraspinatus tendon, and plantar fasciopathy (Maffulli 2003, de Vos 2010, Creaney 2011, Mautner 2013).

Tendinopathies are difficult to treat, and the healing response differs between load-bearing tendons such as the patellar and Achilles tendons, and non-load-bearing tendons such as the wrist extensors. Traditionally tendinopathy have been treated with oral and injectable anti-inflammatory medications, bracing, physical therapy, and heavy load eccentric training programs. The rationale for anti-inflammatory therapies for tendinopathy has been questioned recently, and currently heavy load eccentric training programs are being used by many practitioners as a first-line therapy. These training programs require high levels of patient motivation and are not always successful. When conservative therapies fail, surgery may be recommended (Krogh 2013, Mautner 2013).

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Recently, research focused on the use of complex growth factor preparations derived from the patient's blood to drive the body's own tissue healing mechanisms. The use of autologous growth factors is thought to lead to tendon repair through collagen regeneration and stimulation of angiogenesis. This concept of delivering humoral mediators to promote normal tendon healing was first reported in 2003. Platelets are the major player; in addition to their central role in the clotting cascade, they are involved in the normal healing response. The exact mechanism by which platelets promote tendon healing is unclear; however, it is theorized that the growth factors and cytokines contained in the platelets speed tissue regeneration and healing. Platelets contain alpha granules and dense granules, which when stimulated release platelet-derived growth factor, transforming growth factor (TGF), vascular endothelial growth factor (VEGF), epidermal growth factor (EGF), insulin-like growth factor (IGF) I and II, and fibroblast growth factor. These factors play an important role in cellular proliferation, chemotaxis, cellular differentiation, extracellular matrix production, and angiogenesis. The dense granules contain adenosine, serotonin, histamine, and calcium, which play a role in tissue modulation and regeneration (Foster 2009, Maffulli 2010, Thanasas 2011).

There is no standard technique for harvesting growth factors for administration, and several preparations are described in the literature as the autologous blood injection (ABI), and platelet rich plasma (PRP). PRP is defined as autologous blood with concentration of platelets higher than its physiologic concentration found in healthy whole blood. PRP contains a 2- to 8-fold increase in platelets concentration (150,000-350,000µL in blood and at least 1,000,000µL in PRP), and 1- to 25-fold growth factor concentration depending on which factor is examined. PRP is commonly prepared in the laboratory, operating suite, outpatient sports medicine clinic, or at a radiology setting. It begins with venipuncture and collection of autologous whole blood from the patient into a syringe containing anticoagulant at the point of care. The collected blood is then centrifuged in a tabletop centrifuge machine. This separates the whole blood into three layers: red blood cells, platelet poor plasma, and platelet concentrate that contains white blood cells. Typically, the red blood cells are discarded after the first spin, and a second spin yields a more concentrated platelet layer. The PRP amount is approximately 10% of the volume of whole blood collected. PRP can be categorized according to its leukocyte content into leukocyte depleted pure PRP (P-PRP) in which leucocytes are purposely eliminated, or PRP that contains a high concentration of leukocytes (L-PRP). Once prepared the PRP is maintained in a sterile environment and used immediately for the procedure (Foster 2009, de Vos 2010, Maffulli 2010, Creaney 2011, Gosens 2011, Thanasas 2011, Lee 2013).

Earlier use of PRP included its application in maxillofacial surgery, plastic surgery, cardiac bypass surgery, and orthopedics. The positive effects observed in these surgical applications have stimulated its use in sports medicine outpatient clinic setting. The use or PRP is accepted by the patients because it is produced from their own blood and the risk of adverse effects is minimal. Different types of centrifuge machines used vary in their ability to separate red blood cells from platelets which affects the platelet concentration, separating leukocytes from platelets, or shearing platelets during the centrifuge process that may cause premature platelet activation and degranulation. The variation in centrifuge machines and PRP preparation techniques cannot provide a consistently similar or standardized final product. There is also no clear definition for the optimal dose of PRP or the number of injections needed. Most physicians perform one injection, although sometimes PRP injections are given as a series of injections over several weeks. Some physicians may choose to add an activating agent (thrombin or calcium chloride) to PRP before its injection, while others only inject just the platelets based on the assumption that they can be slowly activated with the exposure to thrombin or tendon collagen. Potential risks related to PRP injection include infection, hemorrhage, and soft tissue injury. Concerns have also been raised about the potential harms of PRP in delaying tissue remodeling, excessive growth, and excessive scarring (de Vos 2011, Lee 2013),

To date, platelet rich plasma for the treatment of tendinopathy has not received FDA approval. The FDA has cleared several devices used in the preparation of PRP and has standards for the procedure of preparation of PRP.

Medical Technology Assessment Committee (MTAC)

Autologous Platelet Derived Wound Healing Factors for Non-Healing Cutaneous Wounds (Procuren)

BACKGROUND

Wound healing is a dynamic process that involves a complex interaction of several cellular and biochemical events. Tissue repair begins with a clot formation and platelet degranulation which release the growth factors necessary for wound repair. Generally, the process of normal healing takes few days to 2 weeks and involves three phases that may overlap in time: 1. inflammatory phase, 2. proliferative phase, and 3. remodeling phase. If any of these phases is compromised, healing will be delayed. Treatment of chronic non-healing

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cutaneous wounds has challenged health care providers for generations, and various strategies including devices, biologics and drug have been used to accelerate the healing process. These agents are designed to affect one of processes involved in healing (Robson 1999). Advances in biology of wound healing, showed that macrophages and platelets are the chief regulatory cells in the repair process. Platelets are known for their role in haemostasis where they help prevent blood loss at site of vascular injury. They adhere, aggregate, and form a procoagulant surface leading to thrombin generation and fibrin formation. Activated platelets release potent locally acting growth factors substances that initiate division and migration of fibroblasts and formation of new capillaries promoting wound healing (Knighton 1986, Fu 2005). Becaplermin, a topical treatment with platelet derived growth factor as its active ingredient was approved by the FDA in 1997 to treat diabetic foot and leg ulcers that extend into the subcutaneous tissue or beyond and have adequate blood supply. Platelet derived growth factor (Procuren) for the treatment of non-healing cutaneous wounds was reviewed by MTAC in February 1999, and failed MTAC evaluation criteria due to the lack of scientific evidence to determine its safety and efficacy. It is being re-reviewed based on requests for coverage from Eastern WA. ***Bone Fracture Healing (GEM 21STM)*** Bone fracture healing is a biological process that involves both local and systemic acute phase reactants. The physiological events occurring at the site of injury include hematoma formation, recruitment and transformation of mesenchymal cells, induction of angiogenesis, and the production and remodeling of the extracelluar matrix. Radiographic healing of a bone fracture is normally achieved in 4-13 months depending on type and location of the fracture. The rate of bone union also depends on several other factors as patient's health, compliance, nutritional status, stability of the fracture and others. Disruption of any of these factors would lead to delayed or non-union of the fracture. It was reported that approximately 10% of the bone fractures in the US are complicated by impaired healing, which has a high impact on the quality of life and burden of health costs. Several compounds and technologies have been, and are being developed to enhance fracture healing and accelerate repair. These include prostaglandins, gene therapy, growth hormone, parathyroid hormone, and growth factors. Among the growth factors studied are the bone morphologic proteins, transforming growth factor B, vascular endothelial growth factor, and platelet derived growth factor (PDGF) (Axelrad 2007, Hollinger 2008). In vitro and animal studies indicate that PDGF has the potential of accelerating the bone healing process. The experimental studies showed that PDGF receptors increase in osteoblasts as they mature, but that the response varies inversely to the number of receptors. This indicates that there is an optimal concentration and time during bone regeneration to deliver the PDGF in order to be effective (Axelrad 2007). The GEM 21STM a device for bone grafting material containing a therapeutic tri- calcium phosphate or PDGF was approved by the FDA for periodontally related defects in November 2005.
Tendinopathy Tendinopathy is a general term that is used to describe a tendon injury. It is characterized by pain, stiffness, and loss of strength in the affected area. Treatments for tendinopathy include, but are not limited to: rest, anti-inflammatory medication, analgesia, orthotics, physical therapy, and local steroid injections. Another more recent technology that has been proposed for the treatment of tendinopathy is platelet rich plasma injections into the ailing tendon (Kampa 2010). Platelets are small nonnucleated bloods cells that are involved in wound healing. The exact mechanism by which platelet rich plasma promotes tendon healing is unclear; however, it is thought that the growth factors and cytokines contained in the platelets speed tissue regeneration and healing. Platelets contain alpha granules and dense granules, which when stimulated release growth factors and cytokines. The alpha granules release: platelet-derived growth factor, transforming growth factor-beta, vascular endothelial growth factor, epidermal growth factor, insulin-like growth factor I and II, and fibroblast growth factor. These factors play an important role in cellular proliferation, chemotaxis, cellular differentiation, extracellular matrix production, and angiogenesis. The dense granules contain adenosine, serotonin, histamine, and calcium, which play a role in tissue modulation and regeneration (Foster 2009, Maffulli 2010). Platelet rich plasma is derived from anti-coagulated autologous whole blood, which is centrifuged to concentrate platelets in plasma. Normal platelet counts in the blood range from 150,000-350,000 µL. The goal of the devices used to create platelet rich plasma is to raise the concentration to at least one million platelets per µL. After separation, the platelet rich plasma must be clotted to allow for delivery to the desired site. This clotting leads to platelet activation, resulting in the release of growth factors and cytokines. Bovine thrombin, calcium chloride, and type I collagen are different agents used to stimulate platelet activation (clotting) (Foster 2009). One of the advantages of this approach is that because the platelet rich plasma is derived from the patient's own blood there is a low chance of rejection. However, the optimal dose range has not been defined. The injection of platelet rich plasma is a procedure and therefore not regulated by the FDA. However, several devices used in the preparation of platelet rich plasma have received FDA approved.

Platelet Derived Growth Factors
02/10/1999: MTAC REVIEW

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Evidence Conclusion: The published evidence on the effect of Procuren for treating non-healing cutaneous wounds consists of two small randomized controlled trials, one of which reports improvements in wound healing for Procuren as compared to placebo and the other trial reports worse outcomes with Procuren. The available evidence does not allow any conclusion about the effects of Procuren on non-healing cutaneous wounds.
Articles: Knighton DR, et al. Stimulation of repair in chronic, nonhealing cutaneous ulcers using platelet-derived wound healing formula. Surgery, Gyn, Obstet 1990;170:56-60.

There is insufficient scientific evidence that Procuren is medically effective and therefore does not meet *Kaiser Permanente Medical Technology Assessment Criteria*.

06/17/2003: MTAC REVIEW
Autologous Platelet Derived Wound Healing Factors in the treatment of Tendinopathy
Evidence Conclusion: *Achilles tendinopathy* De Vos and colleagues' study (2010), reviewed by MTAC earlier in 2010, is a double-blind, placebo-controlled, randomized, controlled trial that compared the effect of injecting platelet rich plasma (PRP) versus isotonic saline (placebo) in 54 patients with chronic midportion Achilles tendinopathy. After PRP injection, patients in the two study groups underwent standardized rehabilitation program including a daily eccentric exercise program for 12 weeks. The primary outcome was pain and activity level as measured with the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire. The first publication of the trial (de Vos et al, 2010) reported on the clinical outcomes at 24 weeks, and the second (de Vos, et al 2011) reported on the effect of PRP on ultrasonographic tendon structure and neovascularization at 24 weeks. This was followed by another report (de Jonge, et al 2011) on the one-year clinical and ultrasonographic outcomes for the same group of patients (evidence table 1). The results of the trial showed significant improvement in pain and activity level among patients in both the PRP group and the placebo group at 24 weeks and at one year compared to baseline values. There were no statistically significant differences for these outcomes between the two study groups. The 24-weeks follow-up also showed a significant increase in the neovascularization scores among patients in the two treatment groups when compared to baseline, but with no between-group differences at any point of time (6,12,24 weeks, or 1 year). The one-year follow-up also showed that the ultrasonographic tendon structure improved significantly in both groups with no significant difference between them. Overall, the results of the trial indicate that adding PRP injection therapy to eccentric exercises for patients with midportion Achilles tendinopathy was not superior to the addition of saline injection as regards clinical outcomes, tendon structure, or neovascularization. The trial did not compare PRP head to head with eccentric exercises, nor did it include a comparison group that received PRP without exercises, which makes it hard to determine the effect of PRP used alone, and whether the eccentric exercises have a dominating positive effect that overshadows the benefit of PRP therapy. In addition, saline injection in the tendon may have had more than a placebo effect as either or both the trauma of introducing a needle (needling) into the tendon, and the volume increase due to saline injection into the tendon may initiate a healing response as noted by several investigators. *Lateral epicondylitis (tennis elbow)*
The few published RCTs on the use of PRP injections for the treatment of lateral epicondylitis, had their limitations and showed conflicting results. In these trials PRP was compared to the injection of corticosteroids, whole autologous blood, or saline. No comparisons were made to standardized eccentric muscle strengthening exercises used alone or to watchful waiting. Patients were included in the trials if they had symptoms of epicondylitis for at least 3 or 6 months (depending on study), not allowing for the natural healing of the condition (Peerbooms 2010 indicated that the "Natural history of lateral epicondylitis predominantly results in healed patients [80%] in one year). The studies used different definitions for success as well as different tools and questionnaires for measuring the outcomes. All, except for one trial, did not use ultrasonography to evaluate the effect of PRP therapy on tissue healing. Peerbooms (2010), Gosens (2011) and colleagues (Evidence table 2) conducted a double-blind RCT to compare the efficacy of a platelet rich plasma injection versus corticosteroid injection for the treatment of lateral epicondylitis in 100 patients who had failed non-operative treatment. Patients in the two treatment groups also participated in an eccentric exercise program. The primary outcome of the trial was the difference in successful outcomes (25% reduction in the pain according to VAS score or disabilities of the arm, shoulder, and hand according to DASH Outcome Measure), without a re-intervention after one year and 2 years of follow-up. The one-year follow-up results of the trial showed a statistically significant greater improvement in pain and function in the PRP group versus the corticosteroid group. Patients in the corticosteroid group experienced a decline in function after an initial short-term improvement. The 2-year follow-up results of the trial (Gosens et al 2011) showed that the mean improvement in the pain and function scores continued to favor the PRP group. The study had valid design and analysis, however, PRP was compared to corticosteroid, the use of which in tendinopathy is currently controversial as is known to have a short-term pain relief effect and may lead to permanent adverse changes in the tendon (according to the authors). The study did not include a placebo arm to determine whether the improvement observed with the PRP was due to the treatment or to the natural course of the lateral epicondylitis. The authors indicated that the natural history of lateral epicondylitis usually results in

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healed patients (80%) within 1 year, but they included patients with lateral epicondylitis for as short as 6 months. Ultrasound evaluation was not used to determine the effect of PRP on tissue healing. There was a discrepancy in the figures and numbers presented in the two published articles reporting on the 1-year and 2-year follow-up results. Creaney and colleagues (2011) compared the injection of blood versus PRP in 150 patients who had elbow tendinopathy for at least 6 months and had failed conservative therapy including physical therapy exercises (stretches and eccentric loading). The authors did not clearly indicate whether all patients had undergone a standardized muscle strengthening eccentric exercises. Study participants were randomly assigned to receive 2 injections (one month apart) of either PRP or autologous blood injection (ABI). The primary outcome was improvement in patient-related tennis elbow-evaluation (PRTEE) score at 6 months (PRTEE is a 0- 100 composite scale that measures pain and physical function). 20 patients (13%) were lost to follow-up at six months. Analysis of the results of the remaining 130 patients (authors considered it ITT analysis) showed a higher but statistically insignificant success rate in the ABI group (72%) vs. the PRP group (66%). Success was defined as an improvement in the PRTEE score of 25 points at 6 months. The study was randomized and controlled, but it compared two forms of growth factor preparations and did not include a placebo or sham therapy group that did not undergo tendon penetration, nor did it compare growth factor injection versus a standardized program of eccentric muscle exercises that are known to have a beneficial effect. The needling effect or placebo effect of injection cannot be ruled out. The investigators were not blinded, and no ultrasound evaluation was used to determine the effect of PRP on tissue healing. In addition, the trial does not allow studying the natural course of lateral epicondylitis, and its short follow-up duration does not allow studying the long-term effects or harms associated with the therapy. In a small trial Thanasas and colleagues (2011) also compared PRP versus autologous whole blood injection (ABI) for the treatment of lateral epicondylitis. In this trial the injection of either 3 mL PRP or 3 mL whole blood was given only once under ultrasound guidance and followed by a standardized eccentric muscle strengthening. The trial had only six months of follow-up and the primary outcome was improvement in pain (using VAS score) and function (using the Liverpool elbow score). The results of the study showed that PRP was more effective that ABI in reducing pain at 6 weeks, but not at 3 or 6 months. There was no significant difference between the two treatment groups in the functional score of Liverpool. Similar to Creaney and colleagues' trail, the study does not determine whether any benefit observed was due to the injected substance, needling procedure, or the natural course of the disease. The authors of a network meta-analysis (Krogh 2012) of RCTs that assessed the comparative effectiveness and safety of injection therapies in patients with lateral epicondylitis, concluded that autologous blood products either as whole blood or PRP may have benefits over placebo, only one trial (Peerbooms 2010) was considered to be at low risk of bias, and that further high quality RCTs are needed to evaluate these therapies before any recommendation can be made. A more recent double-blind RCT (Krogh et al 2013, evidence table 3) compared the effect of a single injection of PRP to the injection of corticosteroid or saline for the treatment of lateral epicondylitis in 60 patients. The primary outcome was pain reduction at 3 months (a change from 12 months in the initial protocol due to the high dropout rate resulting from unsatisfactory pain reduction). The study had other limitations including but not limited to the inclusion of patients who were not naïve to corticosteroids (58% of the participants had received corticosteroid therapy, and 35% had received more than one injection at study entry). The study also included patients with lateral epicondylitis symptoms for as short as 3.8 months (not allowing for natural healing of the condition), and as long as 232 months and combined them in the analysis. Saline injection may not have been the appropriate placebo as it was applied through 5-7 tendon perforations. Needling and/or volume increase due to saline injection could initiate a healing process. It is reported that needling, also known as microtenotomy, involves treating a chronic tendon injury, by attempting to change a chronic injury to an acute lesion that may have greater healing potential. The disruption of the tendinosis or scar tissue by needling and consequent bleeding is thought to release tissue growth factors that stimulate a healing response (Rha et al 2012). The authors of the trial also indicated that they did not test the actual platelet content but relied on the manufacturer's description. Overall, the results of the trial show that the effect of PRP or glucocorticoids on pain was not superior to saline injection, and that steroid injection was superior to PRP and saline in reducing color Doppler activity and tendon thickness.

Rotator cuff

A published RCT (Rha et al, 2012) compared the therapeutic effect of platelet rich plasma with dry needling in 38 patients with rotator cuff disease. The trial was randomized and blinded, but had a small size, included patients with tendon tear or tendinosis, had a short follow-up of six months, and a 25% dropout rate. The study participants were randomized to receive either two PRP injections or two dry needling procedures at 4-week intervals. The primary outcome measure was Shoulder Pain and Disability Index (SPADI). This was measured at baseline, two weeks after the first injection, immediately before the second injection, two weeks after the second injection, and at the 3- and 6-month follow-up visits. The authors did not indicate whether the analysis performed was intention to treat or completer analysis. Overall, the results indicated that patients in the two treatment groups showed a significant reduction in the Shoulder Pain and Disability Index and improvement of range of motion during follow-up. The PRP injections provided more symptomatic relief and functional improvement than dry needling at six months, but there was no difference in range of motion improvement between the two groups.

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These results should be interpreted with caution due to the limitations of the trial. *Plantar Fasciitis* Aksahin and colleagues (2012) compared the effect of corticosteroids and platelet rich plasma in 60 patients diagnosed with plantar fasciitis who had failed conservative therapy. The trial was not randomized which is a potential source of selection bias. The first 30 consecutive patients received corticosteroid injections and the second 30 patients received PRP injections. All participants were followed up for 6 months and the primary outcome was improvement in the mean VAS heal pain scores. The results showed significant improvement in each of the two groups compared to baseline, but there were no significant differences between the two groups. *Conclusion:* There is some evidence that the adding PRP injection therapy to eccentric exercises for patients with Achilles tendinopathy is **not** more effective than injecting the tendon with saline also in addition to eccentric exercises. There is insufficient evidence to determine that PRP injections given alone are effective at reducing pain and improving function in patients with lateral epicondylitis. There is insufficient evidence to determine the effect of PRP injections on rotator cuff disease, plantar fasciitis or other tendinopathies. The published studies do not allow making any conclusion on whether the effect of PRP injections is due to the therapy or due to healing initiated with needling of the tendons. There is insufficient evidence to determine the effect of PRP on tissue healing. There is insufficient evidence to determine whether there is an optimal PRP dose, concentration, or number and interval of injection that would potentially reduce pain and improve function in patients with tendinopathy. There are variations among the studies as regards the preparation of PRP products, platelet concentration, presence of white blood cells, and number of injections uses, which would limit generalization of the negative or positive results of the trials published to date. Definition of treatment success varied between studies. Larger RCTs with longer follow-up duration are needed to determine the efficacy and safety of PRP in tendinopathy.
Articles: The literature search for studies published after the last MTAC review of platelet rich plasma for the treatment of tendinopathy revealed 4 randomized controlled studies on PRP injections for lateral elbow epicondylitis, one for Achilles tendon, one for rotator cuff, and one for plantar fasciitis, as well as a number of case series with no control groups. A meta-analysis of studies on the use of platelets in the treatment of Achilles tendon injuries, and another network meta-analysis on the comparative effectiveness of injection therapies were also identified by the search. The meta-analyses were not selected for critical appraisal as the one that examined the role of platelets in the treatment of Achilles tendon injuries also included models and trials on the use of the therapy for tendon rupture repairs. The network meta-analysis on injection therapies included all types of injection therapy including PRP. The individual trails on PRP in either meta-analysis was reviewed separately. The following RCTs were critically appraised: *Achilles Tendinopathy* de Vos RJ, Weir A, van Schie HTM, et al. Platelet-rich plasma injection for chronic Achilles tendinopathy. *JAMA 2010;* 303:144-149. de Vos, Weir A, Tol JL, et al. No effects of PRP on ultrasonographic tendon structure and neovascularization in chronic midportion Achilles tendinopathy. *Br J Sports Med* 2011*;* 45:387-392. See Evidence Table De Jonge S, de Vos RJ, Weir A, et al. One-year follow-up of platelet-rich plasma treatment in chronic Achilles tendinopathy: a double-blind randomized placebo-controlled trial. *Am J Sports Med* 2011; 39:16231629. *Lateral Epicondylitis* Gosens T, Peerbooms JC, van Laar W, et al. Ongoing positive effect of platelet-rich plasma versus corticosteroid injection in lateral epicondylitis: a double-blind randomized controlled trial with 2-year follow-up. *Am J Sports Med* 2011; 39:1200-1208. Peerbooms JC, Sluimer J, Bruijn DJ, and Gosens T. Positive effect of an autologous platelet concentrate in lateral epicondylitis in a double-blind randomized controlled trial. *Am J Sports Med* 2010*;* 38:255-262. See Evidence Table. Krogh TP, Fredberg U, Stengaard-Pederson K, et al. Treatment of lateral epicondylitis with platelet-rich plasma, glucocorticoid, or saline: a randomized, double-blind, placebo-controlled trial. *Am J Sports Med* 2013; 41:625-635.
Peerbooms (2010), Gosens (2011) and colleagues Krogh et al 2013, See Evidence Table

The use of Autologous Platelet Derived Wound Healing Factors in the treatment of Tendinopathy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*

Autologous Platelet Derived Wound Healing Factors
06/04/2008: MTAC REVIEW
Evidence Conclusion: *Wound Healing (Procuren)* The reviewer's conclusion in the previous MTAC report of 1999 was, "The published evidence on the effect of Procuren™ for treating non-healing cutaneous wounds consists of two small randomized controlled trials, one of which reports improvements in wound healing for Procuren™ as compared to placebo, and the other trial reports worse outcomes with Procuren™. The available evidence does not allow any conclusion about the effects of Procuren™ on non-healing cutaneous wounds." The literature search for the current review did not reveal any additional evidence that would determine the efficacy and safety of platelet derived growth factor for the treatment of non-healing cutaneous wounds.
Bone Fracture Healing (GEM 21STM) There insufficient published evidence to determine the efficacy and safety of autologous platelet derived wound healing factors for the treatment of non-healing fractures.
Articles: *Wound Healing* The search yielded around 100 articles. Many were review articles or publications not related to the current review. No meta-analyses of empirical studies, randomized or non-randomized controlled

studies, published after the last review, were identified. *Bone Fracture Healing* The literature search did not reveal any empirical studies on the use of PDGF for bone fractures. The published studies were all related to the use of PDGF for of dental implants, periodontal wounds, defects, or bone turnover during periodontal repair. None was selected for critical appraisal.

The use of Autologous Platelet Derived Wound Healing Factors in the treatment of Non-Healing Wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of Autologous Platelet Derived Wound Healing Factors in the treatment of Non-Healing Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Autologous Platelet Derived Wound Healing Factors in the treatment of Tendinopathy

02/14/2011: MTAC REVIEW

Evidence Conclusion: *Achilles tendinopathy* A recent double-blind, placebo-controlled RCT evaluated the effects of adding a platelet rich plasma (PRP) injection to an eccentric exercise program in 54 patients with chronic midportion Achilles tendinopathy. The primary outcome measures were pain and activity level, measured using the Victorian Institute of Sports Assessment-Achilles (VISA-A). In both groups, VISA-A scores improved significantly after 24 weeks; however, there was no significant difference in VISA-A score between the two groups. With regard to safety, no microbial growth was found in the collected PRP samples, and no complications (infections, hematomas, or ruptures) were reported after the treatment (de Vos 2010). *Lateral epicondylitis (tennis elbow)* A double-blind RCT that included 100 subjects compared the efficacy of a platelet rich plasma injection to a corticosteroid injection for the treatment of lateral epicondylitis in patients who had failed non-operative treatment. In addition to a platelet rich plasma injection or a corticosteroid injection subjects also participated in an eccentric exercise program. The primary outcome measures were pain, measured using the visual analog scale (VAS), and disability, measured using the disability of the arm, shoulder, hand (DASH) outcome measure. Successful treatment was defined as more than a 25% reduction in VAS or DASH without a re-intervention after 1 year. According to the VAS, treatment was successful for 73% of subjects in the platelet rich plasma group and 49% in the corticosteroid group (P<0.001). When using the DASH, treatment was successful for 73% of subjects in the platelet rich plasma group and 51% in the corticosteroid group (P=0.005). This trial did not address safety. Results from this study should be interpreted with caution as there are several methodological limitations (Peerbooms 2010). *Conclusion:* There is insufficient evidence to support the use of platelet rich plasma injection for the treatment of Achilles tendinopathy. There is evidence from one small RCT that supports the use of this technology for patients with lateral epicondylitis; however, because of methodological limitations results from this trial are insufficient to determine the safety and efficacy of this procedure. Several trials are currently underway to determine the safety and efficacy of platelet rich plasma injections for the treatment of tendinopathy.

Articles: Studies were selected for review if they included at least 25 subjects and assessed either the safety or efficacy of platelet rich plasma injections for the treatment of tendinopathy. Studies were excluded if they lacked a valid comparison group. Two RCTs were selected for review. The following studies were critically appraised: de Vos RJ, Weir A, van Schie HTM, et al. Platelet-rich plasma injection for chronic Achilles tendinopathy. JAMA 2010; 303:144-149. See Evidence Table. Peerbooms JC, Sluimer J, Bruijn DJ, and Gosens T. Positive effect of an autologous platelet concentrate in lateral epicondylitis in a double-blind randomized controlled trial. Am J Sports Med 2010; 38:255-262. See Evidence Table.

The use of Autologous Platelet Derived Wound Healing Factors in the treatment of Tendinopathy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Platelet Rich Plasma for Knee Osteoarthritis

04/21/2018: MTAC Review

Evidence Conclusion:

- The published evidence on the use of PRP for knee OA is inconclusive and do not allow making a recommendation for or against using PRP for the treatment of knee osteoarthritis. The published studies have methodological limitations and their results are mixed. It is difficult to determine whether the inconsistency in the outcomes of the individual trials and their pooled results is due to the severity of the knee OA, differences in platelet separation technique, concentration or activation, timing and frequency of administration of PRP, variations in response between the individuals, quality of the studies including blinding of the patients, or the outcome measures used. None of the published studies evaluated the effect of PRP therapy on any structural changes or remodeling of the knee joint.

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

- The published literature does not provide sufficient evidence to determine the long-term comparative efficacy and safety of PRP to other standard recommended pharmacological or non-pharmacological therapies for knee osteoarthritis.
- Additional studies are needed to determine the optimal protocol for delivering PRP, the criteria for selecting the patients who may benefit from the treatment, as well as the long-term efficacy and safety of PRP for the treatment of knee OA. An ideal study would be double-blinded RCTs with sufficient statistical power, adequate randomization, standardized inclusion/exclusion criteria for patient selection, standardized protocol for PRP preparation and delivery, valid comparator, with objective as well as the subjective outcome measures, and long-term follow-up.
- A search of the National Institute of Health Clinical Trials website for ongoing trial identified several active trials including:
  - Bone Marrow Aspirate Compared to Platelet Rich Plasma for Treating Knee Osteoarthritis ClinicalTriasl.gov Identifier NCT03289416
  - Efficacy of Hyaluronic Acid and Platelet-rich Plasma Combination in Knee Osteoarthritis ClinicalTrials.gov Identifier NCT03211650
  - Steroids, Hyaluronic Acid or Platelet Rich Plasma versus Placebo for Knee Osteoarthritis the (KIT). ClinicalTrials.gov Identifier NCT02776514
  - Intraarticular Platelet Rich Plasma Injections versus Intraarticular Corticosteroid Injections in Primary Knee Osteoarthritis. ClinicalTriasl.gov Identifier NCT01923909

  Articles: The literature search for studies on the comparative efficacy and safety of PRP and standard therapies used for knee OA revealed eight meta-analyses (MAs) published in the last 4 years, 19 relevant randomized and nonrandomized trials published in the last 10 years, and less than 10 case series/reports. The published meta-analyses were overlapping, 4 included randomized controlled trials (RCTs) as well as quasi- randomized trials and observational studies, and 4 included only RCTs. The meta-analyses of RCTs were given preference over the individual RCTs, which were small, had insufficient statistical power, and conflicting results. A meta-analysis of RCTs provides greater statistical power to detect significant differences and allows performing subgroup analyses. Three of the 4 identified meta-analyses of RCTs were selected for critical appraisal, based on their methodological quality, inclusiveness, inclusion of the more recently published RCTs, grading the quality the studies included, quantitative synthesis of the results of RCTs as a primary analysis, and/or comparing the outcomes of PRP versus an active treatment separately either as the primary analysis or in a subgroup analysis.

  A more recently published meta-analysis (See Evidence Table 1 - Zhang et al, 2018) was identified by the search but was not selected for critical appraised as it pooled the results of prospective non-randomized trials together with the RCTs, and had no subgroup analysis for the RCTs.

  Two recent trials (See Evidence Table 2 - Cole et al, 2017, and See Evidence Table 3 - Joshi Jubert et al, 2017) not included in the three meta-analyses reviewed was also selected for critical appraisal.

The use of Platelet Rich Plasma (PRP) for the Treatment of Knee Osteoarthritis (OA) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Platelet Rich Plasma (PRP) for the treatment of Plantar Fasciitis (PF) (Plantar Fasciopathy)

04/21/2018: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence to determine that the effectiveness and safety of the local injection of platelet rich plasma is equivalent or superior to local steroid injection or to other pharmacological or nonpharmacological therapies currently used for the treatment of patients with plantar fasciitis. The overall quality of published studies is poor, with some trials reporting improvement with PRP and others reporting no improvement. It is difficult to determine whether the differences in the reported results are due to differences in the platelet separation technique, concentration or activation; or due to differences in the timing and frequency of administration or outcome measures.
- There is insufficient published evidence to determine the long-term efficacy and safety of PRP in treating patients with chronic plantar fasciitis.
- Large-scale, high-quality randomized controlled trials with blinding of outcome assessment and longer follow-up are required to provide evidence on the long-term safety and effectiveness of PRP for treating patients with plantar fasciitis.
- Ongoing trials:

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- RCT Comparing Steroid Injections and Platelet Rich Plasma Injections in the Treatment of Plantar Fasciitis. ClinicalTrials.gov Identifier: NCT01957631.
- RCT Comparing ESWT with PRP for Plantar Fasciitis in High Demand Cohort. ClinicalTrials.gov Identifier: NCT02668510

Articles: The literature search for studies on the efficacy and safety of platelet rich plasma injections, published after the 2010 MTAC review identified three systematic reviews with meta-analyses, one network meta-analysis, two qualitative systematic review, and 14 small trials (10 RCTs and 4 non-randomized) that compared local injection of platelet rich plasm versus steroid injection in the majority of trials. PRP was compared to shock wave therapy in one trial, dextrose prolotherapy in another and to low-dose radiation also in one trial.
One meta-analysis (Tsikopoulos, 2016) included only 3 earlier studies and was excluded from the review. The other two meta-analyses (See Evidence Table 1 - Yang, 2017 and See Evidence Table 2, 2017 and) as well as the randomized controlled trial with the lowest risk of bias (See Evidence Table 3 - Mahindra, 2016) were selected for critical appraisal.

The use of Platelet Rich Plasma (PRP) for the treatment of Plantar Fasciitis (PF) (Plantar Fasciopathy) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare-Considered Not Medically Necessary

CPT® or HCPC Codes	Description
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment
P9020	Platelet rich plasma, each unit
S9055	Procuren or other growth factor preparation to promote wound healing

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To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Revised
04/1999	10/05/2010 MDCRPC, 04/05/2011MDCRPC, 11/01/2011MDCRPC, 09/04/2012MDCRPC, 07/02/2013MDCRPC, 08/06/2013MPC, 06/03/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC,09/04/2018MPC, 09/03/2019MPC, 09/01/2020MPC, 09/07/2021MPC, 09/06/2022MPC	09/13/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
11/22/2017	Added non-covered services LCD
05/01/2018	Added MTAC reviews for Platelet Rich Plasma (PRP) for the treatment of Plantar Fasciitis (PF) (Plantar Fasciopathy) & Knee Osteoarthrtitis
09/01/2020	Added Medicare LCA A57642
04/15/2021	Added CPT code S9055
08/02/2021	Removed LCD L35008 and LCA A57642; added LCA A58351

09/13/2021	Updated NCD version 270.3

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KAISER PERMANENTE®

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Clinical Review Criteria
Plethysmography

- Lower Limb Deep Vein Thrombosis (DVT)
- Occlusive Peripheral Arterial Disease (PAD)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Plethysmography (20.14)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Clinical review is no longer required for this service.

PADnet System for the Detection of Peripheral Vascular Disease

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Plethysmography (PG) is a noninvasive method used to measure changes in blood flow or air volume within an organ or the whole body. The term plethysmography is a combination of the ancient Greek words plethysmos, which means increase, and grapho which means write (Alnaeb 2007).Total body plethysmography measures intrathoracic gas volume and volume change, pulmonary plethysmography measures the volume of air that can be voluntarily inhaled or exhaled, limb plethysmography measures changes in the volume of a limb in response to change in blood volume, and genital plethysmography measures blood flow in the genitals.

There are several types of plethysmographic systems that measure blood flow and velocity in the carotid artery and peripheral vascular system. These include electrical impedance plethysmography, segmental plethysmography, oculoplethysmography, strain gauge plethysmography, photoelectric plethysmography, air plethysmography, and several others. These instruments indirectly detect and quantify vascular disease based in alterations in pulse wave contour, blood pressure, or arterial or venous blood flow (Barnes 1991, Graham 1996).

Oculoplethysmography indirectly measures the hemodynamic significance of internal carotid artery stenosis or occlusion by demonstration of an ipsilateral delay in the arrival of ocular pressure transmitted from branches of the ophthalmic artery. It detects only severe narrowing or blockage and is incapable of directly measuring the flow or demonstrating anatomic information or quantifying percent of stenosis. Other tests (ultrasound or angiography) are required to confirm the diagnosis and have largely replaced this technique (Graham 1996).

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Photoplethysmography (PPG) is a technique based on the determination of optical properties of the underlying tissue. It uses an optical light-emitting diodide in a sensor that is attached to the skin and transmits light through the dermis into the subcutaneous tissue. A photoelectric cell captures the reflected light to detect changes in blood volume. Changes in the beam wavelength are measured by a microcomputer and a plethysmogram representing the blood flow of the limb is produced. PPG is not strictly a plethysmographic technique as its operation is based on the principles of light densitometry and photon diffusion theory. Both PPG and light reflection rheography (also known as quantitative PPG), have been used in the detection of varicose veins, venous insufficiency, phlebothrombosis, and other peripheral venous disease (Higgins 1986, Keechi 2008, Khandanpour 2009).

Strain-gauge plethysmography (SPG) uses the technique of filling the distal veins of the lower limbs by inflation of a tourniquet around the thigh, causing occlusion of the veins, then indirectly measuring the changes in venous outflow and capacitance in response to release of tourniquet by a strain gauge placed around the calf. The strain-gauge plethysmography may also be used to assess the effectiveness of different types of compression devices on the legs of patients with venous deficiency (Siau 2010).

Impedance plethysmography is performed by placing two sets of electrodes around the patient's calf and an oversized blood pressure cuff around the thigh. The electrodes sense a change in blood volume and record it on a strip chart. Changes in venous filling are produced by inflating the thigh cuff to obstruct venous return, then deflating the cuff to re-establish blood flow. The time required for the venous volume in the calf to return to baseline is recorded. A clot in the popliteal or proximal veins will delay venous emptying. In water plethysmography, an extremity is enclosed in a water-filled chamber where volume changes can be detected. Air plethysmography is based on the same principle but uses an air-filled long cuff. As indicated these techniques depend on detecting alterations in venous outflow and capacitance in the presence of thrombi in the deep veins. Extrinsic compression of the proximal veins by pregnancy tumor, or poor venous outflow in cases of severe edema, all may lead to false positive results. It was also reported that plethysmographic techniques are inaccurate in detecting deep vein thrombosis in vessels in which the venous outflow has not been significantly impeded by the thrombus (Graham1996, Locker 2006, Mosti 2010).

Segmental plethysmography (or pulse volume recording [PVR]) is a noninvasive hemodynamic measurement that can potentially provide an initial assessment of the location and severity of peripheral arterial disease. Segmental limb plethysmography waveform analysis is based on evaluation of waveform shape and signal amplitude. Standardized criteria relating waveform changes to anatomic site and hemodynamic severity of disease are used in the diagnostic interpretation. The test involves placing cuffs around the leg at selected locations and connecting them to a plethysmograph to detect and graphically record changes in limb volume. Normally, a single, large thigh cuff is used along with regular-sized calf and ankle cuffs, plus a brachial cuff that reflects the undampened cardiac contribution to arterial pulsatility. Once the cuff is inflated to 60–65 mmHg (a pressure sufficient to detect volume changes without resulting in arterial occlusion), pulse volume recordings are obtained. These PVRs have the potential of detecting and localizing significant occlusive lesions. The tests can also be repeated over time to follow disease progression. Segmental plethysmography is an indirect examination of the artery and may not detect multiple stenoses located at or above the level of the cuff (Gerhard-Herman 2006. Clements, TASC).

Plethysmography have the potential of providing rapid and non-invasive diagnosis of deep vein thrombosis, and peripheral arterial diseases, and was once considered to be the primary diagnostic test for noninvasive detection of deep vein thrombosis (Stevens 2007, Abbara 2010). However, it has been reported that due to its inaccuracy and with the improvements in both direct real-time ultrasonic imaging and Doppler ultrasonic flow detection and color-flow mapping, plethysmography as well s other indirect techniques are assuming a less important role in vascular diagnosis (Barnes 1991, Stevens 2007).

Several plethysmographic devices have received FDA clearance as Class II medical devices to assist in the diagnosis of vascular disease. PADnet System for the detection of peripheral vascular disease was previously reviewed by MTAC in 2005 and did not meet its evaluation criteria due to lack of evidence on the system. The current review focuses on the use of plethysmography in the diagnosis of deep vein thrombosis and occlusive peripheral arterial disease.

The PADnet lab, manufactured by BioMedix, is a noninvasive cardiovascular blood flow monitor intended for use by trained medical professionals for the early detection of peripheral vascular disease (FDA Home page). The manufacturer claims that it detects blockages in arteries and the quality of blood flow using pulse volume recording and oscillometer segmental blood pressure measurement. It is used with a pressure cuff that is applied

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and inflated to shut off the flow in the artery. When deflated the device records the oscillations and assigns a systolic pressure value and the results sent to the vascular specialists (BioMedix Web site). The device includes a laptop computer and a color printer on a medical grade car.

The FDA cleared PADnet for marketing in October 2004 based on its equivalence to legally marketed predicate devices.

Medical Technology Assessment Committee (MTAC)

PADnet system

08/01/2005: MTAC REVIEW

Evidence Conclusion: There is no published data to date on the PADnet system other than the marketing information provided by BioMedix, the manufacturer of the device, on their web site.
Articles: The search did not reveal any studies or articles on the PADnet system.

The use of PADnet system in the evaluation for early detection of peripheral vascular disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

PADnet system

06/20/2011: MTAC REVIEW

Evidence Conclusion: Use of plethysmography for detecting deep vein thrombosis. The published studies showed variable accuracies for the different plethysmographic techniques. The sensitivity ranged from 20-100% and specificity from the lower 60s to the upper 90s. The negative predictive value was as high as 100% for some systems such as digital photoplethysmography (D-PPG) used for screening asymptomatic patients at high risk for developing DVT. It performed better for proximal vs. distal (calf) DVTs. In a meta-analysis of 78 studies, Locker and colleagues (Evidence table 1) evaluated the performance of plethysmography and rheography in the diagnosis of DVT. Sensitivity and specificity were 75% and 90% respectively for impedance plethysmography, 83% and 81% for strain-gauge plethysmography, 85% and 91% for air plethysmography, and 91% and 71% for light-reflex rheography. The authors concluded that the accuracy of these techniques is insufficient to use them as stand-alone tests for screening for DVT. Siau and colleagues, 2010 (Evidence table 2) examined the accuracy of Well's clinical predictive tool, D-dimer analysis, and computerized strain-gauge plethysmography (CSGP) in the assessment of patients with suspected DVT, using imaging as a gold standard. The results showed that CSPG had a poor sensitivity and relatively low negative predictive value. CSPG performed better for above knee DVT vs. calf DVT, but still had an insufficient accuracy. Its use with D-Dimer did not add value to D-Dimer testing alone.
Williams and colleagues (2005) also assessed the clinical utility of D-Dimer, strain-gauge plethysmography and a combination of both in the diagnosis of DVT in 243 patients with low, moderate, and high clinical pretest probability (PTP) of DVT. A definitive diagnosis of the disease was made based on a compression ultrasound. The results of the study showed that the plethysmography had lower negative predictive values than those of D-dimer test for patients with low, moderate, or high PTP. The addition of strain-gauge plethysmography did not improve clinical decision making in any of the groups. Sharif-Kashani, et al (Evidence table 3) evaluated the role of digital photoplethysmography (D-PPG) in screening asymptomatic patients at high risk for developing DVT. They examined 337 lower limbs of 169 patients and showed that D-PPG had 100% sensitivity in detecting DVT in these patients at high risk. It also had a 100% negative predictive value, i.e. it is a good test for excluding the disease. However, it had a lower specificity indicating that patients with abnormal results will need further investigations. It is to be noted that all detected DVTs were proximal and the results cannot be generalized to distal vein thrombosis. There is insufficient published evidence evaluate the accuracy of plethysmography in the diagnosis of clinically suspected upper extremity DVT. Use of plethysmography for detecting occlusive peripheral artery disease (PAD). The majority of published studies on the use plethysmography for detecting lower limb peripheral occlusive disease examined the accuracy and predictive values of photoplethysmography (PPG) and/ or agreement with other standard measures of ankle brachial pressure index (ABPI). In a study of selected 131 patients diagnosed with PAD, Khandanpour and colleagues, 2009 (Evidence table 4) found a significant agreement between ankle brachial pressure index (ABPI) derived from photoplethysmography (PPG) or continuous wave Doppler (CW-Doppler). Allen et al, 2008 (Evidence table 5) assessed the diagnostic accuracy of novel bilateral photoplethysmography toe pulse measurement techniques for the detection of significant lower limb PAD. The study included 111 subjects of whom 48 (43%) had a significant disease. The study results show high accuracy and significant agreement between bilateral PPG and ankle-brachial pressure index in detecting higher grade peripheral artery disease in the lower limbs. With the pulse measurement techniques studied PPG was found to have high negative predictive value when used to screen population with low prevalence of the

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disease, and a high positive predictive value among high disease prevalence patients referred to a vascular laboratory.
Other published small studies evaluated different algorithms and devices based on PPG for the assessment of PAD and concluded that the technology may be used as a noninvasive screening tool for early detection of the disease. It was reported however, that the technology may not provide valid measurements for patients with very high systolic arterial pressure, obesity, edema, or those with stiff arteries e.g. in diabetes mellitus, hypercholesterolemia, end-stage renal disease, and advanced age (Alnaeb 2007). The effect of using plethysmography vs. other standard techniques on clinical decision making and outcome of patients diagnosed with early or significant peripheral artery disease was not studied.
Articles: The following studies were selected for critical appraisal based on their population sizes and methodological quality: Allen J, Overbeck K, Nath AF, et al. A prospective comparison of bilateral photoplethysmography versus the ankle-brachial pressure index for detecting and quantifying lower limb peripheral arterial disease. J Vasc Surg. 2008; 47:794-802. See Evidence Table. Khandanpour N, Armon MP, Jennings B, et al. Photoplethysmography, an easy and accurate method for measuring ankle brachial pressure index: can photoplethysmography replace Doppler? Vasc Endovascular Surg. 2009; 43:578-582. See Evidence Table. Locker T, Goodacre S, Sampson F, et al. Meta-analysis of plethysmography and rheography in the diagnosis of deep vein thrombosis. Emerg Med J 2006; 23:630-635. See Evidence Table. Sharif-Kashani B, Behzadnia N, Shahabi P, et al. Screening for deep vein thrombosis in asymptomatic high-risk patients: a comparison between digital photoplethysmography and venous ultrasonography. Angiology. 2009; 60:301-317. See Evidence Table. Siau K, Davies A, and Laversuch. Is there still a role for computerized strain gauge plethysmography in the assessment of aptients with suspected deep vein thrombosis? Q J Med 2010; 103:259-264. See Evidence Table.

The use of plethysmography in the evaluation of lower limb deep vein thrombosis (DVT) and occlusive peripheral arterial disease (PAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare – Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Non-Medicare – medical necessity review no longer required

CPT® or HCPC Codes	Description
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive
93922	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels)
93923	Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more levels), or single level study with provocative functional maneuvers (eg, measurements with postural provocative tests, or measurements with reactive hyperemia)
93924	Noninvasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, (ie, bidirectional Doppler waveform or volume plethysmography recording and analysis at rest with ankle/brachial indices immediately after and at timed intervals following performance of a standardized protocol on a motorized treadmill plus recording of time of onset of claudication or other symptoms, maximal walking time, and time to recovery) complete bilateral study

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Date Created	Date Reviewed	Date Last Revised
08/01/2005	08/01/2005 MDCRPC, 07/05/2011MDCRPC, 05/01/2012MDCRPC, 03/05/2013MDCRPC, 01/07/2014MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC, 03/07/2023MPC	08/02/2016

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
08/02/2016	Approved to stop clinical review for non-medicare members

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Clinical Review Criteria
Pneumatic Compression Devices

- Treatment of Lymphedema and Chronic Venous Insufficiency
- Prevention of Deep Vein Thrombosis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pneumatic Compression Devices (280.6)
Local Coverage Determinations (LCD)	Pneumatic Compression Devices (L33829)
Local Coverage Article	Pneumatic Compression Devices (A52488)

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

Prevention of Post-Operative Deep Vein Thrombosis in the outpatient setting
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

For Non-Medicare Members

***Definitions**

Edema: Edema is a non-specific term for the accumulation of fluid in tissue, most often in the extremities. There are numerous causes for edema, ranging from systemic disorders (e.g. congestive heart failure, etc.) to local conditions (post-surgery, congenital abnormalities, etc.). (Examples are not all-inclusive).

Lymphedema, as discussed below, is just one group of conditions that can be a cause of accumulation of fluid in the tissue. Lymphedema arises from disorders of the lymphatic system. It is essential to rule out other causes of edema in order to diagnose lymphedema. Edema from other causes is not classified as lymphedema for purposes of Medicare reimbursement for PCDs (E0650-E0652).

Primary lymphedema: Primary lymphedema is a disorder of the lymphatic system that occurs on its own. It is inherited and uncommon. Examples (not all-inclusive) are:

A. Congenital lymphedema due to lymphatic aplasia or hypoplasia
B. Milroy's disease, an autosomal dominant familial form of congenital lymphedema
C. Lymphedema praecox
D. Lymphedema tarda

Secondary lymphedema: Secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more common than primary lymphedema. It is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, lymphatic filariasis. Secondary lymphedema

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may also result from compression of the lymphatic and venous channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. (See below)

Chronic Venous Insufficiency (CVI): Lymphedema may also be caused by CVI when fluid leaks into the tissues from the venous system. CVI of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. The incidence of lymphedema from CVI is not well established.

Peripheral Arterial Disease (PAD)

Peripheral artery disease is a circulatory problem in which narrowed arteries reduce blood flow to limbs, resulting in compromised blood flow to the distal tissue and failure to keep up with oxygen demands.

Criteria

I. **Lymphedema**

A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema*, see definitions above, in beneficiaries with chronic and severe lymphedema when **ALL** of the following three requirements are met:

1. The beneficiary has a diagnosis of lymphedema as defined below, and
2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
   A. Marked hyperkeratosis with hyperplasia and hyperpigmentation
   B. Papillomatosis cutis lymphostatica,
   C. Deformity of elephantiasis,
   D. Skin breakdown with persisting lymphorrhea,
   E. Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial* (see below for trial guidelines):
   A. A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include **ALL** of the following:
      1. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
         a. Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
         b. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
      2. Regular exercise
      3. Elevation of the limb

II. Chronic Venous Insufficiency with Venous Stasis Ulcers (CVI)

A PCD coded as E0650 or E0651 is covered for the treatment of CVI*, see definitions above, of the lower extremities only if the patient has **ALL** of the following:

A. Edema in the affected lower extremity
B. One or more venous stasis ulcer(s)
C. The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician. (See below for trial guidelines)

Six-Month Trial for CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include **ALL** of the following:

A. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
   a. Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

b. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally

B. Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)
C. Regular exercise
D. Elevation of the limb
E. Appropriate wound care for the ulcer (including sharp debridement where appropriate)

At the end of the six-month trial, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no further improvement has occurred for a continuous period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

III. Continuation of Use
Kaiser Permanente covers continuation of use of a pneumatic compression device as medically necessary when **BOTH** of the following criteria are met:
A. there is adherence with the use of equipment as ordered by the healthcare professional
B. clinical documentation from the health care professional confirms clinical improvement (e.g., improvement in venous stasis ulcers, decrease in edema or lymphedema)

IV. Not covered
Kaiser Permanente does not cover an advanced pneumatic compression pump or a pump with additional features (HCPCS code E0652*) (e.g., specific programming to treat problem areas, a pre-therapy phase) because it has not been demonstrated to be superior to a standard segmented, calibrated gradient system, and is not considered the lowest-cost alternative and thus is not medically necessary. These devices include but are not limited to:
A. Flexitouch® System
B. Lympha Press Optimal™

*HCPCS code E0652 is covered when used to report a standard segmented, calibrated gradient system. Not covered when used to report an advanced pneumatic compression pump or a pump with additional features.

Kaiser Permanente does not cover **ANY** of the following because each is considered experimental, investigational or unproven:
A. A chest (HCPCS code E0657) and/or trunk (HCPCS code E0656, E0670) pneumatic appliance for use with a pneumatic compression pump
B. A compression garment for trunk or chest
C. A pneumatic compression device, with or without a cooling component, utilized in the home setting for ANY other indication including but not limited to the prevention of deep vein thrombosis

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

Prevention of Post-Operative Deep Vein Thrombosis in the outpatient setting
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Thromboembolic disease is a common complication following surgery particularly total joint replacement arthroplasty. It has been reported that without prophylaxis the rate of deep vein thrombosis (DVT) is as high as

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88% after total knee arthroplasty and as high as 50% after total hip arthroplasty. It is also reported that lower extremity DVT is the origin of 90% of symptomatic pulmonary embolism (PE). Prophylaxis for DVT has become the standard of care for total joint arthroplasty. Chemical prophylaxis with warfarin or low-molecular weight heparin effectively reduces the incidence of DVT but carries a risk of bleeding. Orthopedic surgeons thus often use mechanical methods of prophylaxis as an alternative to chemoprophylaxis in patients with higher bleeding risk. Other surgeons also use it in standard risk patients in conjunction with the anticoagulant-based prophylaxis (Edwards 2008, Zywiel 2010).

Graduated compression stockings (GCSs) and intermittent pneumatic compression (IPC) are the two predominant mechanical methods used for DVT prevention. These have quite different methods of action; graduated compression stockings apply a constant pressure to the limb with the aim of maintaining a reduced venous caliber and preventing the static accumulation of blood. Intermittent pneumatic compression actively empties the deep veins of the limb in a predetermined cycle of pressure, producing a pulse of blood that travels proximally preventing stasis. On deflation of the cuff, the veins will refill, the intermittent nature of the system will insure periodic blood flow through the deep veins, as long as there is a supply. The IPC cuffs are normally wrapped around a limb, secured by velcro, and attached with tubes to an electric pump to regulate the pressure applied (Morris 2004, Morris 2010, Sobieraj-Teague 2011).

GCSs do not require attachment to any device and allow the patient to move freely. They come in a range of sizes and the limb has to be measured accurately to prevent incorrect pressure gradients, which may increase the risk of DVT. Intermittent compression devices are available in different forms; the cuff can cover the whole leg, the calf, or just the feet, it may inflate uniformly or sequentially with graded pressure; and can have rapid or moderate inflation rates. These characteristics my influence patient compliance which is critical as the longer the device is used, the better is the protection. The major disadvantages for standard IPC devices used in hospitals are their size, weight, and reliance on external power source, all of which result in poor patient compliance and in turn limit the efficacy of the device (Morris 2004, Froimson 2009).

In an attempt to overcome the problem of poor patient compliance with traditional mechanical compression systems, several lightweight, portable, battery-powered devices were developed to allow their use by the patient while ambulating in the hospital or at home after discharge. Many of these devices have received FDA clearance.

Medical Technology Assessment Committee (MTAC)

Portable Compression Devices for Prevention of Post op DVT

4/16/2012: MTAC REVIEW

Evidence Conclusion: The published trials on the use of portable compression devices for the prophylaxis against DVT mainly compared the devices to chemoprophylaxis. Generally, patients randomized to the portable compression devices also received chemoprophylaxis, and in one study they also used graduated compression stockings (GCS). There were no head-to-head trials that compared the portable devices to the GCS. The trials reviewed were randomized and controlled, but were not blinded, used different definitions of major bleeds, and were financially supported by the manufacturers of the devices. Colwell and colleagues, 2010 (Evidence table 1) compared a new portable intermittent calf compression device (Continuous Enhanced Circulation Therapy Plus Synchronized Flow Technology [CECT+SFT]) versus a low molecular weight heparin (LMWH), for the prevention of thromboembolic disease after total hip replacement in 410 patients. The compression device was applied preoperatively and the LMWH was started the morning after the surgery. Patients in the compression group were allowed to receive 81mg of aspirin daily after surgery according to the surgeon's discretion. Both treatments were continued for 10 days, and the patients were followed-up clinically for 10 weeks. Bleeding was the primary outcome of the trial and rate of thromboembolic events was a secondary outcome. Overall, the results of the trials showed that the rate of major bleeds was significantly lower among the patients randomized to the portable compression group. There was no difference in the rate of thromboembolic events, but this was a secondary outcome and the study was not designed to determine equivalence. Edwards and colleagues, 2008 (Evidence table 2) compared an earlier version of the portable intermittent calf compression device (CECT) given together with LMWH versus LMWH alone in the prevention of VTE in patients undergoing either total hip or total knee arthroplasty. Patients randomized to the CECT group had the device applied in the operating room and continued during hospitalization, and the two groups received a LMWH for 7-8 days after surgery. The results of the study showed a significantly lower rate of DVT in patients in the portable compression device plus LMWH after a total knee arthroplasty compared to those using chemoprophylaxis alone, with a NNT of 8. No such significant difference was observed among those who underwent total hip replacement. In a similar trial Gelfer and colleagues (2006) compared prophylaxis with the CECT and aspirin versus LMWH and showed significant reduction in the incidence of DVT in the compression group vs. the LMWH group. In a more recent RCT, Sobieraj-

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Teague and colleagues, 2012 (Evidence table 3) examined the efficacy and tolerability of a new portable intermittent calf compression device (Venowave) in high risk neurosurgical patients. Patients were randomized to usual care alone or in addition to the portable compression device, and all participants in the two groups were prescribed below the knee graduated compression stockings. They could also receive pharmacological prophylaxis (aspirin, LMWH, or unfractionated heparin) according to the discretion of the neurosurgeon. The overall results indicate the rate of DVT was significantly lower in the study group that used a portable compression device in addition to the graduated compression stocking and chemoprophylaxis as needed in this high risk neurosurgical patients. The portable devices used in the trials had an average compliance rate around 80%, and the associated side effects were mainly discomfort especially at night, pruritis, and sweating.

Articles: The literature search revealed a number of earlier RCTs that compared the graduated compression stockings to intermittent compression therapy. However, IPC systems used in these studies were the standard devices used in the hospitals and not the portable IPCs which are the focus of this review. There were three RCTs that compared the use chemoprophylaxis given alone or with IPC using portable devices after total joint arthroplasty, and one trial that evaluated the efficacy of using a portable compression device in addition to graduated compression stockings and chemoprophylaxis in high risk neurosurgical patients. The following studies were selected for critical appraisal;

Colwell CW Jr, Froimson MI, Mont MA, et al. Thrombosis prevention after total hip arthroplasty: a prospective, randomized trial comparing a mobile compression device with low-molecular-weight heparin. J Bone Joint Surg Am. 2010; 92:527-535. See Evidence Table

Edwards JZ, Pulido PA, Ezzet K A, et al. Portable compression device and low-molecular-weight heparin compared with low-molecular-weight heparin for thromboprophylaxis after total joint arthroplasty. J Arthroplasty. 2008; 23:1122-1127. See Evidence Table

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The use of portable compression devices does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Portable Compression Devices

BACKGROUND

Thromboembolic disease is a common complication following surgery particularly total joint replacement arthroplasty. It has been reported that without prophylaxis the rate of deep vein thrombosis (DVT) is as high as 88% after total knee arthroplasty and as high as 50% after total hip arthroplasty. It is also reported that lower extremity DVT is the origin of 90% of symptomatic pulmonary embolism (PE). Prophylaxis for DVT has become the standard of care for total joint arthroplasty. Chemical prophylaxis with warfarin or low-molecular weight heparin effectively reduces the incidence of DVT but carries a risk of bleeding. Orthopedic surgeons thus often use mechanical methods of prophylaxis as an alternative to chemoprophylaxis in patients with higher bleeding risk. Other surgeons also use it in standard risk patients in conjunction with the anticoagulant-based prophylaxis (Edwards 2008, Zywiel 2010). Graduated compression stockings (GCSs) and intermittent pneumatic compression (IPC) are the two predominant mechanical methods used for DVT prevention. These have quite different methods of action; graduated compression stockings apply a constant pressure to the limb with the aim of maintaining a reduced venous caliber and preventing the static accumulation of blood. Intermittent pneumatic compression actively empties the deep veins of the limb in a predetermined cycle of pressure, producing a pulse of blood that travels proximally preventing stasis. On deflation of the cuff, the veins will refill, the intermittent nature of the system will ensure periodic blood flow through the deep veins, as long as there is a supply. The IPC cuffs are normally wrapped around a limb, secured by velcro, and attached with tubes to an electric pump to regulate the pressure applied (Morris 2004, Morris 2010, Sobieraj-Teague 2011). GCSs do not require attachment to any device and allow the patient to move freely. They come in a range of sizes and the limb has to be measured accurately to prevent incorrect pressure gradients, which may increase the risk of DVT. Intermittent compression devices are available in different forms; the cuff can cover the whole leg, the calf, or just the feet, it may inflate uniformly or sequentially with graded pressure; and can have rapid or moderate inflation rates. These characteristics my influence patient compliance which is critical as the longer the device is used, the better is the protection. The major disadvantages for standard IPC devices used in hospitals are their size, weight, and reliance on external power source, all of which result in poor patient compliance and in turn limit the efficacy of the device (Morris 2004, Froimson 2009). In an attempt to overcome the problem of poor patient compliance with traditional mechanical compression systems, several lightweight, portable, battery-powered devices were developed to allow their use by the patient while ambulating in the hospital or at home after discharge. Many of these devices have received FDA clearance.

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04/16/2012: MTAC REVIEW
Portable Compression Devices

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The use of portable compression devices does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E0650	Pneumatic compressor, nonsegmental home mode
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg

Considered not medically necessary:

HCPC Codes	Description
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
A4600	Sleeve for intermittent limb compression device, replacement only, each *(used for devices described by E0676)*

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/01/2012	05/01/2012[MDCRPC], 06/05/2012[MDCRPC], 04/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/18/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/21/2015	Title Change
03/08/2016	Updated Medicare links
05/08/2018	Added Policy article language for non-coverage of E0676
7/10/2018	Added new review criteria for pneumatic devices for Non-Medicare members with effective date 10/15/2018
04/05/2022	Updated applicable codes
04/18/2023	Updated Medicare Pneumatic Compression Devices – Policy Article A52488

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Clinical Review Criteria
Peroral Endoscopic Myotomy (POEM) for Esophageal Achalasia

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Peroral Endoscopic Myotomy (POEM) for Esophageal Achalasia*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Effective until July 1, 2023

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Effective July 1, 2023

Peroral endoscopic myotomy (POEM) is considered medically necessary when **ALL of the following** criteria are met:

- Individual is age 18 years or older
- Achalasia type III is diagnosed using esophageal manometry
- Achalasia type I and II covered only if patient is deemed not a surgical candidate
- Patient must be counseled about 20-25% risk of GERD after POEM

Peroral endoscopic myotomy (POEM) for **ANY other indication** is considered experimental, investigational, and unproven.

Contraindications for Peroral endoscopic myotomy (POEM); if **ONE of the following** conditions is present, the patient should not undergo POEM:

- Severe erosive esophagitis
- Significant coagulation disorders
- Liver cirrhosis with portal hypertension
- Severe pulmonary disease
- Esophageal malignancy
- ASA IV or greater

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-
- Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis, including recent esophageal surgery, radiation, endoscopic mucosal resection, or radiofrequency ablation

Definitions: The three types of achalasia based on the Chicago Classification of patterns of esophageal pressurization on high-resolution manometry (HRM) (CC v3.0) include the following:

- Type I (classic achalasia) – Incomplete LES relaxation, aperistalsis and absence of esophageal pressurization. Swallowing results in no significant change in esophageal pressurization and has 100% failed peristalsis with a distal contractile integral (DCI, an index of the strength of distal esophageal contraction) < 100 mmHg.
- Type II – Incomplete LES relaxation, aperistalsis and panesophageal pressurization in at least 20% of swallows. Swallowing results in simultaneous pressurization that spans the entire length of the esophagus. Type II achalasia has 100% failed peristalsis and pan-esophageal pressurization with ≥ 20 percent of swallows.
- Type III (spastic achalasia) – Incomplete LES relaxation and premature contractions (distal latency [DL] < 4.5 seconds) in at least 20% of swallows. Swallowing results in abnormal, lumen-obliterating contractions or spasms. Type III achalasia has no normal peristalsis and premature (spastic) contractions with DCI >450 mmHg-sec-cm with ≥ 20 percent of swallows (Spechler, 2021a; Schlottmann, et al., 2017).

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Esophageal achalasia (EA) is a rare esophageal motility disorder characterized by loss of peristalsis of the esophageal body and failure of the lower esophageal sphincter (LES) to relax in response to swallowing. The most common form of EA is idiopathic and the exact etiology for the disappearance of myenteric neurons that coordinate esophageal peristalsis and relaxation of LES is unknown. Esophageal achalasia results in retention of food and saliva in the esophagus leading to difficulty in swallowing, regurgitation, aspiration, chest pain, weight loss, and eventually irreversible dilatation of the esophageal body (Kumagai 2015, Patel 2016, Zhang 2016).

Esophageal achalasia is irreversible, and all current therapeutic interventions are palliative with the aim of reducing the pressure at the esophagastric junction (EGJ), to facilitate the transit of food boluses into the stomach and reduce the related symptoms. Treatment options vary from pharmacotherapy (e.g., calcium channel antagonists and nitrates), botulinum toxin injection (BTI), endoscopic pneumatic dilatation (PD), surgical myotomy of the lower esophageal sphincter, to esophagostomy for end-stage achalasia. Each of the therapeutic modalities has its indications, advantages, and limitations. e.g., pharmacological therapy does not have a durable effect and may be only suitable for patients with mild disease, elderly patients or those who cannot undergo more invasive treatment; BTI has a short-lived action; pneumatic dilatation is associated with symptom recurrence and post-procedure gastroesophageal reflux (GERD); and surgical myotomy usually requires and additional fundoplication procedure to prevent GERD (Talukdar 2015, Marano 2016, Zhang 2016).

Currently laparoscopic Heller myotomy (LHM) is the treatment of choice for patients with esophageal achalasia who are fit for surgery. It provides superior and long-lasting symptom relief compared to other treatment modalities including pneumatic dilatation of the esophagus. LHM involves full thickness myotomy along the distal 4-6 cm of the esophagus and extending to 2-3 cm on to the gastric wall allowing the LES to remain open. LMH is usually followed by partial anterior fundoplication (Dor fundoplication). The procedure is minimally invasive, yet, the surgical access to the abdomen remains a potential source of wound infection, port-site hernia formation, and immediate postoperative pain (Kumagai 2015, Wei 2015, Morano 2016, Zhang 2016, Sanaka 2017, Docimo 2017, Kahrilis 2017).

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Per-Oral Endoscopic Myotomy (POEM), was developed in Japan in 2008, and introduced into practice as a minimally invasive technique for the management of patients with achalasia. The procedure involves the creation of a submucosal tunnel followed by myotomy of the circular muscle layer to reduce pressure at the LES. It is performed under general anesthesia and consists of five major steps: 1. Patient position and planning endoscopy, 2. Entry into the submucosal space, 3. Creation of a submucosal tunnel, 4. Endoscopic myotomy of the circular muscles, and 5. Closure of the mucosal entrance. Unlike LHM which involves complete division of both circular and longitudinal LES muscle layers, POEM only cuts the inner, circular LES muscles maintaining the integrity of the longitudinal muscles. Thus, POEM has the potential advantages of both endoscopic dilatation and durable surgical myotomy in a single procedure (Talukdar 2015, Zhang 2016, Leeds 2017).

A major concern with POEM is the high rate of gastroesophageal reflux, which was observed in more than 50% of the patients undergoing the procedure despite the theoretical advantage of avoiding the esophagastric junction dissection required for the LHM. Other reported serious adverse events associated with POEM include mucosal injury, esophageal perforation, major bleeding, pneumothorax, subcutaneous emphysema, pleural effusion, and pneumoperitoneum (Akintoye 2016, Kahrilas 2017). Esophageal achalasia (EA) is a rare esophageal motility disorder characterized by loss of peristalsis of the esophageal body and failure of the lower esophageal sphincter (LES) to relax in response to swallowing. The most common form of EA is idiopathic and the exact etiology for the disappearance of myenteric neurons that coordinate esophageal peristalsis and relaxation of LES is unknown. Esophageal achalasia results in retention of food and saliva in the esophagus leading to difficulty in swallowing, regurgitation, aspiration, chest pain, weight loss, and eventually irreversible dilatation of the esophageal body (Kumagai 2015, Patel 2016, Zhang 2016).

EA is irreversible and all current therapeutic interventions are palliative with the aim of reducing the pressure at the esophagastric junction (EGJ), to facilitate the transit of food boluses into the stomach and reduce the related symptoms. Treatment options vary from pharmacotherapy (e.g., calcium channel antagonists and nitrates), botulinum toxin injection (BTI), endoscopic pneumatic dilatation (PD), surgical myotomy of the lower esophageal sphincter, to esophagostomy for end-stage achalasia. Each of the therapeutic modalities has its indications, advantages, and limitations. e.g., pharmacological therapy does not have a durable effect and may be only suitable for patients with mild disease, elderly patients or those who cannot undergo more invasive treatment; BTI has a short-lived action; PD is associated with symptom recurrence and post-procedure gastroesophageal reflux (GERD); and surgical myotomy usually requires and additional fundoplication procedure to prevent GERD (Talukdar 2015, Marano 2016, Zhang 2016).

Currently laparoscopic Heller myotomy (LHM) is the gold standard surgical treatment for patients with esophageal achalasia who are fit for surgery. It provides superior and long-lasting symptom relief compared to other treatment modalities including pneumatic dilatation of the esophagus. LHM involves full thickness myotomy along the distal 4-6 cm of the esophagus and extending to 2-3 cm on to the gastric wall allowing the LES to remain open. LMH is usually followed by partial anterior fundoplication (Dor fundoplication). The procedure is minimally invasive, yet the surgical access to the abdomen remains a potential source of wound infection, port-site hernia formation, and immediate postoperative pain (Wei 2015, Morano 2016, Zhang 2016, Sanaka 2017, Docimo 2017, Kahrilis 2017, Liu-Burdowski 2021).

Per-Oral Endoscopic Myotomy (POEM), was developed in Japan in 2008, and introduced into practice as a minimally invasive technique for the management of patients with achalasia. It is a complex procedure that requires training both in surgery and gastroenterology, good understanding of the pathophysiology of achalasia, esophageal manometry, very good knowledge of the anatomy of the mediastinum and upper abdomen, as well as endoscopic skills, judgment, and ability to manage the potential adverse events associated with the procedure. POEM involves the creation of a submucosal tunnel followed by myotomy of the circular muscle layer to reduce pressure at the LES. It is performed under general anesthesia and consists of five major steps: 1. Patient position and planning endoscopy, 2. Entry into the submucosal space, 3. Creation of a submucosal tunnel, 4. Endoscopic myotomy of the circular muscles, and 5. Closure of the mucosal entrance. Unlike LHM which involves complete division of both circular and longitudinal LES muscle layers, POEM only cuts the inner, circular LES muscles maintaining the integrity of the longitudinal muscles. Thus, POEM may have a potential advantage of performing both endoscopic dilatation and durable surgical myotomy in a single procedure (Talukdar 2015, Zhang 2016, Leeds 2017).

A major concern with POEM is the high rate of gastroesophageal reflux, which was observed in more than 50% of the patients undergoing the procedure despite the theoretical advantage of avoiding the esophagastric junction dissection required for the LHM. Other reported serious adverse events associated with POEM include mucosal

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injury, esophageal perforation, major bleeding, pneumothorax, subcutaneous emphysema, pleural effusion, and pneumoperitoneum (Akintoye 2016, Kahrilas 2017).

Medical Technology Assessment Committee (MTAC)

Peroral Endoscopic Myotomy

12/15/2014:

Evidence Conclusion: Bhayani and colleagues compared the experience of 101 patients from a single institution undergoing either LHM or POEM. Swallowing outcomes at one and six months were assessed via objective measures (manometry and pH levels). In addition, the investigators collected information regarding operative time, complications and postoperative gastro-esophageal reflux disease (GERD). Manometry indicated that there were decreases in pressure across both groups, however, the postmyotomy resting pressures were higher for the POEM group than for LHMs (16 vs. 7 mm Hg, P=0.006). The same effect was not seen between groups for relaxation pressure (9 vs. 4). Both groups experienced relief of symptoms with the POEM group showing significantly lower Eckhardt scores when compared with the LHM group at one month (0.8 vs. 1.8, P<0.0001). At six months, however, the difference was no longer significant (1.7 vs. 1.2, P=0.1). Ultimately, the investigators conclude that POEM is comparable with LHM for safe and effective treatment of EA (Bhayani, Kurian et al. 2014). While POEM appears to be comparable to LHM, the technique is still evolving. At this particular point in time, the body of evidence only reports on the success of POEM in highly select populations with short-term follow-up. To add to this, the study is not randomized and relies on a small sample or subjects. Ultimately, the literature does not support the safety and effectiveness of POEM for the treatment of achalasia when compared to LHM. Conclusions: There is insufficient evidence to support the effectiveness of POEM compared to LHM for the treatment of EA. There is insufficient evidence to support the safety of POEM compared with LHM for the treatment of EA.

Articles: The literature search revealed over 200 studies relating to the use of POEM for the treatment of achalasia. The literature was dominated by publications that introduce and describe the technique as well as studies from individual centers describing their experience with POEM with short-term follow-up. A search of the clinicaltrials.gov website revealed several ongoing studies with the aim to evaluate of the clinical utility and safety of POEM (NCT01832779). For the purposes of this review, one of the larger and more recent nonrandomized comparison studies was identified for critical appraisal. The following articles were selected for critical appraisal: Bhayani NH, Kurian AA, Dunst CM, et al. A comparative study on comprehensive, objective outcomes of laparoscopic Heller myotomy with per-oral endoscopic myotomy (POEM) for achalasia. Annals of Surgery. 2014; 259(6): 1098-1103. See Evidence Table 1.

The use of Peroral Endoscopic Myotomy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Peroral Endoscopic Myotomy

12/18/2017

Evidence Conclusion: The literature search did not reveal any randomized controlled trials that compared POEM with laparoscopic Heller myotomy, the current standard of care; only noncompetitive case series and a small number of observational nonrandomized comparative studies and meta-analyses that pooled their results were identified. **Meta-analyses of comparative studies:** The published comparative studies identified by the search were relatively small observational studies that compared the outcomes of patients with esophageal achalasia treated POEM versus matched controls who had undergone treatment with LHM. The population sizes of the studies ranged from 8 patients to ~200 participants and there may be potential overlap between the studies published by the same groups of investigators. A number of systematic reviews with meta-analysis pooled the results of the majority of these studies three of which (Bhayani 2014, Ujiki 2013, and Hugeness 2013) were included in almost all meta-analyses. Based in the inclusion /exclusion criteria of the systematic reviews, smaller and/or studies with potentially overlapping population were added or excluded from the analyses. The overall pooled results of these comparative studies, none of which was randomized) as shown in Evidence Table 1**,** show no significant differences between the two procedures as regards their effect on reducing the achalasia symptoms as measured by the Eckardt score, perioperative pain score, complication rate, and length of hospital stay. POEM however, was associated with a significantly higher rate of symptomatic gastroesophageal reflux and esophagitis that required treatment. Based on these results some investigators concluded that the efficacy and safety of POEM appear to be comparable to those of LMH, and others (Wei and colleagues 2015) concluded that POEM achieves equivalent short-term outcomes compared to LHM. However, observational studies do not allow making any conclusion on the efficacy of POEM relative to LHM or other established treatments. The studies were only observational studies with potential bias and confounding. Patients were not randomly assigned the procedures, instead, POEM was compared to historical controls, the numbers of participants were small, with

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baseline differences in their characteristics, there were significant heterogeneity between the studies, and the follow-up duration was short, all of which limit generalization of the results. Large prospective randomized controlled trials with long-term outcomes are needed to determine the relative safety and efficacy of POEM and LHM. Schlottmann and colleagues', 2017 systematic review and meta-analysis (Evidence Table 2) compared outcomes of POEM performed among different patient cohorts along the years (total N=1,958) versus LHM performed among a total of 5,834 participants. The studies included were not comparative; instead, the authors pooled the results of case series for each procedure and compared the overall summary results. This indirect comparison suggests that POEM may be more effective than LHM in reducing dysphagia symptoms in the short-term but is associated with a significantly higher incidence of pathologic reflux. These, similar to the results of other case series and nonrandomized studies, have to be interpreted with caution. **Non-comparative studies:** A large number of prospective and retrospective case series reported on the outcomes of the POEM procedure used for the management of patients with esophageal achalasia. The majority of the studies were conducted in Asia and included a small number of participants (<10-100 participants in each study). Only two case series included a little over 200 patients, and the largest reported on 500 consecutive patients treated in one center in Japan (Inoue 2015). In addition to these differences, other variations between the studies included differences in the patient characteristics, date and period the procedures were performed, technique used, length of myotomy, treatment success and other outcome measures, duration of follow-up, as well as other differences. A number of systematic review performing quantitative and qualitative analysis of the published case series were identified by the literature search (Barbieri 2015; Akintoye, 2016; and Crespin 2016). Akintoye and colleagues' 2016 meta-analysis that was more comprehensive and more inclusive was selected for critical appraisal. Akintoye et al, 2016 meta-analysis (Evidence Table 3) had generally valid methodology; however, a meta-analysis is as good as the studies it includes. All were case series subject to selection and observation bias. There was significant heterogeneity between the studies that were published over a span of 4 years and reported on outcomes of POEMs performed in different countries between 2008 and 2014. The studies varied in population sizes, many were retrospective, and had short and variable follow-up durations. According to the pooled results, a higher success rate was observed in Asian countries where the procedure had been introduced into practice earlier allowing for more development in its technique and acquisition of more skills by the interventionists. In addition, the outcomes of the studies were reported after variable follow-up durations and some e.g. symptoms relief, symptomatic gastroesophageal reflux, and esophagitis may be time dependent. Overall, the pooled results of the Akintoye's meta-analysis as well as the non-comparative case series and their pooled results suggest that POEM may be effective in reducing dysphagia symptoms in the short-term among patients with esophageal achalasia. The POEM procedure, however, is associated with a high rate of symptomatic gastroesophageal reflux, esophagitis, and abnormal acid exposure. Reported perioperative adverse events of the procedure include mucosal injury, subcutaneous emphysema, pneumoperitoneum, and other serious events that occurred at a lower rate.

Conclusions

- The published literature is insufficient to determine the effects of POEM on the net health outcomes of patients with esophageal achalasia. The studies published to date, provide weak evidence on the short-term efficacy of POEM in reducing dysphagia symptoms in patients with esophageal achalasia, but on the expense of an increased rate of symptomatic gastroesophageal reflux and esophagitis.
- There is insufficient evidence to determine the long-term efficacy and safety of POEM for the management of patient with esophageal achalasia.
- The lack of randomized controlled trials, the small number of nonrandomized observational studies, design and quality of studies, short duration of follow-up, and significant variations between the studies in the surgical techniques and learning curve, operative time, definitions and reporting of the procedural success and adverse events, do not allow supporting the use of POEM as an alternative to LHM for the management of patients with esophageal achalasia.
- Long-term large randomized controlled trials are needed to determine the safety and efficacy of POEM in the management of patients with esophageal achalasia compared to other established procedures.
- Several RCTs comparing POEM to other established procedures is ongoing and may provide more evidence on its long-term safety and efficacy. Among these are the following:
    - Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial: ClinicalTrials.gov Identifier: NCT01601678
    - Multi-center Study Comparing Endoscopic Pneumodilation and Peroral Endoscopic Myotomy (POEM). ClinicalTrials.gov Identifier: NCT01793922
    - Laparoscopy Heller Myotomy with Fundoplication Associated Versus Peroral Endoscopic Myotomy (POEM). ClinicalTrials.gov Identifier: NCT02138643

Articles: The literature search for recently published studies after the last MTAC review did not identify any randomized controlled trials that compared POEM with laparoscopic Heller myotomy or other standard treatments

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options. The published literature consisted of case series, non-randomized comparative studies, and a number of systematic reviews with quantitative meta-analyses (MAs) that pooled the results the published case series and/or nonrandomized comparative observational studies. Among these systematic reviews and meta-analyses were Barbieri, 2015, Talukdar 2015, Wei 2015, Akintoye 2016, Marano 2016, Patel 2016, Zhang 2016, Crespin 2017, Repici 2017, Schlottmann 2017, and Khan 2017. The latter examined the safety and efficacy of POEM for spastic esophageal disorders in general and was excluded from current review.

The use of Peroral Endoscopic Myotomy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Peroral Endoscopic Myotomy

12/18/2017

Evidence Conclusion:

- There is insufficient published evidence to determine that POEM is superior to LHM in alleviating the symptoms associated with achalasia.
- Moderate quality evidence from a single published open-label non-inferiority trial RCT with potential observation bias, shows that POEM was noninferior to LHM in alleviating the symptoms of achalasia in the short-term (2 years follow-up).
- There is evidence from the published RCT as well as several other non-randomized observational studies and meta-analyses indicating that POEM is associated with a significantly higher rate of developing acid reflux and /or erosive esophagitis.
- There is insufficient evidence to determine the long-term effectiveness and safety of POEM for the management of patient with esophageal achalasia.
- Long-term large randomized controlled trials are needed to determine the safety and efficacy of POEM in the management of patients with esophageal achalasia

Articles: The literature search for studies published after the 2017 review conducted for MTAC identified only one RCT that compared POEM versus laparoscopic surgical myotomy (Werner et al, 2019) and another that compared it with pneumatic dilatation (Ponds et al, 2019).The search also identified several prospective or retrospective observational studies and more than 10 systematic reviews (SRs) with or without aggregate data meta-analyses or network meta-analysis that pooled the results the published observational studies comparing POEM to other therapies used for the management of achalasia. There was a major overlap in the studies included in the systematic reviews. The RCT comparing POEM to surgical myotomy (Werner et al, 2019) was selected for critical appraisal, as well as a recent relevant, peer reviewed, and inclusive SR (Park et al, 2019) with valid methodology and analysis. The only other published RCT (Ponds et al, 2019) evaluating POEM compared to PD was briefly summarized.

Hayes Technology Assessment

POEM is a natural orifice transluminal endoscopic surgery technique. The technique involves guiding an endoscope through the esophagus, making an incision in the mucosa, creating a submucosal tunnel for access to the lower esophagus and gastroesophageal junction, and cutting the muscle fibers in the lower esophagus and proximal stomach. Internal incisions are closed with clips after myotomy is complete. Rationale for developing the POEM procedure includes the ability to combine the minimal invasiveness of endoscopic procedures, such as PD, with the therapeutic goal of a surgical myotomy, such as LHM. Natural orifice surgery, such as POEM, aims to reduce procedure-related pain and return patients to regular activities sooner than surgeries requiring external incisions.

Conclusion

The available evidence, mainly from poor-quality studies, suggests that the POEM procedure is generally safe and may achieve at least similar results to both LHM and PD for most efficacy and harms outcomes. The clinical significance of any differences detected from baseline or between groups was not discussed in the evaluated studies. The body of evidence regarding comparisons between POEM and LHM is of moderate size (16 studies), whereas evidence on POEM versus PD was presented in only 4 studies. Additional studies of fair to good quality are needed to elucidate optimal treatment protocols, patient selection criteria, and provide information for longer-term outcomes.

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Hayes Rating: C—For use of peroral endoscopic myotomy (POEM) as an alternative to laparoscopic Heller myotomy (LHM) for the treatment of adult patients with esophageal achalasia (EA). **C**—For use of POEM as an alternative to pneumatic dilation (PD) for the treatment of adult patients with EA.

Hayes. Hayes Technology Assessment. *Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia*. Dallas, TX: Hayes; December 03, 2019. Retrieved February 21, 2023, from https://evidence.hayesinc.com/report/dir.peroral3346

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Ahmed Y, Othman MO. Peroral endoscopic myotomy (POEM) for achalasia. J Thorac Dis. 2019 Aug;11(Suppl 12):S1618-S1628. doi: 10.21037/jtd.2019.07.84. PMID: 31489229; PMCID: PMC6702399.

X. Tang, W. Gong, Z. Deng, J. Zhou, Y. Ren, Q. Zhang, Z. Chen, B. Jiang, Feasibility and safety of peroral endoscopic myotomy for achalasia after failed endoscopic interventions, *Diseases of the Esophagus*, Volume 30, Issue 3, March 2017, Pages 1–6, https://doi.org/10.1111/dote.12457

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])

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Date Created	Date Reviewed	Date Last Revised
12/29/2014	01/06/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	02/07/2023

[MPC] Medical Policy Committee

Revision History	Description
02/06/2018	Added MTAC review for Per-Oral Endoscopic Myotomy (POEM) for Esophageal Achalasia
07/19/2018	Added coverage language – In the absence of direction for CMS Kaiser Permanente criteria will be used
12/08/2022	Added new applicable CPT code to criteria
02/07/2023	MPC adopted new clinical criteria for Per-Oral Endoscopic Myotomy (POEM) for Esophageal Achalasia. Requires 60-Day notice. Effective 07/01/2023. Added October 2022 MTAC review.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Fecal DNA Testing

- Cologuard™
- Colorectal Neoplasm Detection
- PreGen-Plus Test

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Colorectal Cancer Screening Tests (210.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Colorectal cancer is the second leading cause of death from cancer in the United States. Most colorectal cancers begin with the development of benign adenomatous polyps. It is believed that cells acquire genetic changes as adenomatous polyps develop into an adenocarcinoma, a process that can take 10-20 years.

EXACT Sciences Corporation (Marlborough, MA) has developed tests that analyze patient stool samples to see whether they contain genetic markers associated with colorectal cancer. The PreGen-Plus, the topic of the current review, is a test for the early detection of colorectal cancer in an average-risk population. It uses a multitarget assay panel that incorporates 21-point mutations in K-*ras*, adenomatous polyposis coli (APC) and *p53* genes, a microsatellite instability marker (BAT-26) and a proprietary marker, the DNA Integrity Assay (Tagore, 2003). A similar test, PreGen-26, is intended to detect colorectal cancer in high-risk patients. The BAT-26 is the basis of the PreGen-26 test (manufacturer's website).

According to a review article on emerging technologies for colorectal cancer screening (Levin, 2003), it may be possible to identify cancer at an earlier stage with DNA tests such as the PreGen-Plus than with fecal occult blood test (FOBT), the standard non-invasive test. Other potential advantages of the PreGen-Plus test may be a reduced false-positive rate because the test targets mutations specific to colorectal cancer, and the need for only a single stool sample since DNA is shed continuously from colorectal cancer and precursor polyps. A potential disadvantage is that the most appropriate makers for DNA detection of colorectal cancer are not known and clinical evaluation of the tests is limited.

The FDA has determined that approval of the PreGen-Plus test is not required.

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Medical Technology Assessment Committee (MTAC)

Fecal DNA Testing

02/11/2004: MTAC REVIEW

Evidence Conclusion: The Tagore study provides preliminary data on the sensitivity of the PreGen-Plus test in a population with known colorectal neoplasia (47-85% depending on the stage of disease) and specificity in normal individuals (96%). This is not an accurate assessment of how the screening test would perform in a general population sample. Studies that include a blinded comparison of PreGen-Plus to a gold standard in a screening population are needed. In addition, head-to-head comparisons with the standard noninvasive test for colorectal cancer, fecal occult blood testing, would strengthen the evidence.

Articles: The manufacturer's website had an announcement dated October 2003 stating that a study comparing the sensitivity of the PreGen-Plus test and FOBT had been conducted and would be submitted to a peer-reviewed journal when data analysis was finished.

One was on the sensitivity and specificity of a multitarget assay panel labeled as PreGen Plus using colonoscopy as the gold standard (Tagore, 2003). The second article was on a plasma DNA test, not a stool test. The broader search on DNA testing for colorectal cancer yielded 49 articles. There was an empirical study demonstrating the successful extraction of DNA from the stool of colorectal cancer patients (Dong, 2001). Another empirical study extracted DNA from stool and evaluated the sensitivity and specificity of the DNA analysis compared to colonoscopy (Ahlquist, 2000). The PreGen-Plus test was not mentioned, although analysis for the Ahlquist study was done by Exact Laboratories. The Tagore study was critically appraised because it clearly used the PreGen-Plus test and had a larger sample size than the Ahlquist study (n=292 vs. n=61). The citation is as follows: Tagore KS, Lawson MJ, Yucaitis JA. et al. Sensitivity and specificity of a stool DNA multitarget assay panel for the detection of advanced colorectal neoplasia. *Clin Colorectal Cancer 2003*; 1: 47-53. See Evidence Table

The use of PreGen-Plus in screening of colorectal cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*

Fecal DNA Testing

10/20/2014: MTAC REVIEW

Evidence Conclusion: In an effort to establish the accuracy of the Cologuard™ test, Imperiale et al. compared the tests performance to the gold standard, colonoscopy. As a secondary endpoint, the investigators also compared the tests performance to the FIT. The cross-sectional study evaluated 9,989 asymptomatic averaged-risk adults between the ages of 50 and 84 years who were scheduled to undergo screening colonoscopy. All participants provided a stool specimen before routine bowel preparation for colonoscopy. Stool specimens were analyzed in three laboratories and colonoscopy results were evaluated by independent local pathologists and further confirmed and categorized by a central independent pathologist. The gold standard identified CRC in 65 participants and advanced adenomas (AA) in 757 participants. The Cologuard™ was able to accurately detect 60 cancers and 321 AA (sensitivities 92.3% and 42.4%, respectively) while the FIT identified 48 cancers and 180 AA (sensitivities 73.8% and 23.8%, respectively). The Cologuard™ had a lower specificity for detecting all nonadvanced adenomas or negative results when compared with FIT (86.6% vs. 94.9%, respectively) (Imperiale, Ransohoff et al. 2014). Risks of Diagnostic Test In terms of risk, the Cologuard™ test itself presents low risk to the patient as it is noninvasive, requires no bowel preparation or dietary restrictions and allows for collection during normal bowel movements in the toilet. The study reported four mild adverse events and one death. The death occurred prior to colonoscopy and was deemed to be unrelated to the study. Of particular concern, however, is the indirect risk as it relates to false positives and negatives. Although the Cologuard™ test yields a high sensitivity, that came at the cost of a lower specificity which could lead to additional colonoscopies as well as unnecessary stress and anxiety.

Table 1. Number Needed to Screen (NNS) to detect one CRC

	Colonoscopy	Cologuard	FIT
Any CRC	154 (120-200)	166 (130-217)	208 (156-286)
Stage I to III CRC	166 (130-217)	178 (140-238)	227 (169-313)
Advanced precancerous lesion	13 (12-24)	31 (28-35)	55 (48-65)

Conclusions from the last review of multitarget stool DNA testing in MTAC did not live up to genetic test evaluation criteria citing the need for additional research that includes blinded comparison with the gold standard in a screening population as well as, head-to-head comparison with the current standard noninvasive test. Since then, the Cologuard™ has undergone several evolutions reflected throughout the literature with the most current

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version validated by a large cross-sectional study including comparisons with the gold standard, colonoscopy, as well as the FIT. Generally speaking, the study, which was financially supported by the manufacturer Exact Sciences Inc., appears to be well-designed and well-conducted including almost 10,000 participants in 90 centers across the United States and parts of Canada. The investigators, who are also the developers of the device, fail to describe the baseline characteristics of the study population but do identify the significant differences between the participants whose results could be fully evaluated and those whose results could not. Further to this, recruitment was weighted towards the older age of the eligible age spectrum which might limit the generalizability of the results. The design of the study was the primary limiting factor. While it is typical to use a cross-sectional study design to compare diagnostic tests, the results provide only a snapshot of the situation at one given time, failing to provide adequate follow-up to demonstrate how the Cologuard™ might function in clinical practice. Further to this, the sensitivity and specificity is based on stool samples collected at one point in time limits the ability to provide an interval at which the Cologuard™ would be applied. Exact Sciences has provided the protocol for a longitudinal post-market approval study that will likely address these limitations. Conclusions: There is evidence to establish the analytic validity of the Cologuard™ test, that is, the test accurately identifies the particular gene variant.
There is evidence to establish the clinical validity of the Cologuard™ test, that is, how well the test is related to the presence, absence or risk of a disease. There is insufficient evidence to conclude that the test is not harmful to patients. There is insufficient evidence to establish the clinical utility of the Cologuard™ test, that is, the test is reasonably expected to lead to more appropriate patient management than if the test were not available.
Articles: The literature search for multitarget stool DNA testing for CRC screening yielded numerous publications. Among them were various editorials addressing the recent FDA approval, as well as commentary recognizing the Cologuard™ as the first product to be reviewed through the joint FDA-CMS parallel review pilot program. In addition, several publications that mirror the evolution of the device over the years were identified. The FDA's current approval relied on one clinical trial to establish the safety and effectiveness of the Cologuard™ test. This article was selected for review. See Evidence Table

The use of Stool DNA Testing for Colorectal Cancer Screening does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medical necessity review no longer required:

CPT® or HCPC Codes	Description
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
02/11/2004	02/11/2004, Instituted annual review because of Medicare criteria 04/05/2011 MDCRPC, 02/07/2012 MDCRPC,12/04/2012 MDCRPC, 04/02/2013 MDCRPC ,10/01/2013 MPC,08/05/2014 MPC, 05/15/2015 MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC , 10/02/2018MPC , 10/01/2019MPC, 10/06/2020MPC , 10/05/2021MPC , 10/04/2022MPC	05/11/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/11/2017	Cologuard was added to the covered services

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KAISER PERMANENTE®

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Clinical Review Criteria
Preimplantation Genetic Diagnosis (PGD)

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Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage)

Prevention and Invitae Corporation is the preferred lab for genetic testing when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae/prevention.*

PPO/POS members may use non-preferred labs at the out of network cost share.

Criteria

For Non-Medicare Members

Preimplantation genetic diagnosis (PGD) is performed on single cells removed from an embryo. Standard prenatal diagnosis is customarily performed on multiple cells obtained by chorionic villous sampling (CVS) or amniocentesis. PGD on single, embryonic cells is considered medically necessary only when there is a need to diagnose a specific, detectable single gene mutation in an embryo at risk due to an identified deleterious genetic mutation in one or both genetic parents, as defined below:

I. In order to meet medically necessary criteria for PGD, **both A and B must be met:**
   A. There must be documentation confirming that PGD is medically necessary to detect a single gene disorder or chromosomal abnormality whose expression in the fetus or child would be expected to have a significant adverse medical impact and that detection in the pre-implantation period would directly affect reproductive decisions.
   B. **One of the following** clinical circumstances must be documented:
      1. One genetic parent has a balanced, reciprocal translocation or Robertsonian translocation
      2. One genetic parent has a single gene autosomal dominant disorder
      3. Both genetic parents are known carriers of the same single gene autosomal recessive disorder
      4. The female genetic parent is a known carrier of a single gene X-linked recessive disorder

The procedure to obtain a cell sample from an embryo for PGD is covered when the above criteria for PGD are met. However, the procedures and services (such as IVF) required to create the embryos to be tested and the transfer of embryos to the uterus after testing, are covered only for members with advanced reproductive technology (ART) benefits and who meet medical necessity criteria for IVF (in vitro fertilization).

II. The following are *not* covered for preimplantation screening:
   A. Aneuploidy screening, including in the setting of recurrent miscarriage or repeated failure of IVF (e.g. screening for Down Syndrome, in women over the age of 35)

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B. Screening for chromosomal abnormalities in the absence of a known, clinically significant genetic or chromosomal defect in a genetic parent
C. Selecting against conditions or disorders in the absence of a known and identifiable genetic or chromosomal defect in a genetic parent
D. Gender selection of selection of nonmedical trait to determine an embryo's carrier status
E. Screening for autosomal recessive disorders when the embryos are created using donor egg or sperm
F. Detecting genetic or chromosomal abnormalities contributed by donor egg or sperm
G. Screening for adult-onset disorders or for genetic predisposition to adult-onset disease
H. HLA typing of an embryo to identify a future suitable stem cell, tissue or organ transplantation donor.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Historically, couples at high risk of transmission of a genetic disorder have had limited reproductive options, forced after prenatal diagnosis to choose between either termination of affected pregnancies or acceptance of the emotional and financial burden of having a child with severe disability and early mortality. Preimplantation genetic diagnosis (PGD) was introduced to enhance efficiency in assisted conception. It is a technique for reducing the burden of genetic disease performed on couples who are at risk of a specific inherited disorder and used to identify genetic defects present in embryos created through in vitro fertilization (IVF) before transferring them to the uterus.

PGD is performed in conjunction with IVF and is offered to both fertile and infertile couples. Introduced in 1990 as an experimental procedure, PGD has now become an established clinical option in reproductive medicine (Handyside, Kontogianni et al. 1990; Verlinsky, Ginsberg et al. 1990). Because only unaffected embryos are transferred to the uterus for implantation, PGD can provide an alternative to current post conception diagnostic procedures such as amniocentesis or chorionic villus sampling which are sometimes followed by pregnancy termination when results are unfavorable (Verlinsky, Cohen et al. 2004). PGD techniques are now also being utilized for preimplantation genetic screening (PGS) with the intent to identify potential genetic abnormalities in conjunction with IVF for couples without specific known inherited disorders.

With single gene disorders and inherited chromosomal abnormalities being the main indicators for PGD, the technique is available for most known genetic mutations. With that said, PGD can be considered a rapidly evolving technique. Put simply, PGD requires egg extraction, IVF, cell biopsy, genetic analysis and embryo transfer (Handyside, Kontogianni et al. 1990). At present, there are three different procedures utilized for cell biopsy, each with its own advantages and disadvantages, including polar body biopsy, cleavage-stage embryo biopsy and blastocyst biopsy. Depending on the whether the characteristic being tested for is associated with chromosomes or DNA, the sample can be analyzed in one of three ways including polymerase chain reaction (PCR), fluorescence in situ hybridization (FISH) and comparative genomic hybridization with new technologies emerging rapidly. Regardless of the methods, the results are used by parents and providers to select which embryos are transferred back to the uterus with the ultimate goal of establishing an unaffected pregnancy.

The accuracy and reliability of PGD are key issues and exploring these matters requires consideration of the technical challenges and risks inherent in the genetic test itself and in the IVF procedure that it entails. Any PGD strategy has to deal with the detection and avoidance of misdiagnosis from the onset with the risk and outcome relating directly to the type of genetic disorder for which testing is performed. Although PGD has been suggested as an alternative for current post conception diagnostic procedures, the amount of DNA available for testing is limited. Due to this risk, prenatal diagnosis by amniocentesis or chronic villus sampling testing is strongly recommended upon established pregnancy to confirm genetic health.

Applicable Codes

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Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
12/03/2013	12/03/2013 MPC, 10/07/2014MPC, 08/04/2015MPC, 06/07/2016MPC, 04/04/2017MPC, 02/06/2018MPC, 01/08/2019MPC, 01/07/2020MPC, 01/05/2021MPC, 03/01/2022MPC, 01/10/2023MPC	10/10/2022

MPC Medical Policy Committee

Revision History	Description
06/02/2020	Added section: “Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees.” Requires 60-day notice, effective date 10/01/2020.
10/10/2022	Noted Prevention lab as a preferred vendor for genetic testing.

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Clinical Review Criteria
Prolotherapy/Sclerotherapy

- Low Back Pain

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7) *This service is not covered per Medicare criteria.*
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Back pain is the most prevalent musculoskeletal condition encountered in primary care and is estimated to affect 65-80% of people during their life. The majority of back pain is benign, self-limiting and requires symptomatic therapy only. Back pain is often related to muscular, tendon or ligament strain or injury. Common treatments include physical therapy, steroidal and nonsteroidal anti-inflammatory drugs and chiropractic manipulation. One proposed treatment for chronic low back pain, which is resistant to other treatments, is the injection of sclerosing compounds into back tissue to produce scarring and potentially stabilize soft tissue in the area of the injury.

Prolotherapy, also called sclerotherapy and proliferative injection therapy, has been used as a treatment for chronic low-back pain since the 1950s (Dechow). Sclerosing agents are injected into the fibro-osseous junctions of the lower back. The rationale for using prolotherapy is that the injection of irritant solutions into a pain site will initiate local inflammation. The inflammation then begins a cascade of wound healing which results in the deposition of new collagen and stronger ligaments (Banks).

Medical Technology Assessment Committee (MTAC)

Prolotherapy/Sclerotherapy for Low Back Pain

06/09/1999: MTAC REVIEW

Evidence Conclusion: The published evidence consists of two randomized trials, one showing a 1.5-point improvement (7.5-point visual analogue scale) in pain and a 4.9 point improvement (33 item scale) in disability

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between the proliferant and placebo groups at 6 months. The experimental regimen also included injectable steroids, forceful spinal manipulation and different anesthetic volumes, therefore differences between experimental and placebo groups cannot be attributed only to proliferant. The second trial reports a less than 1-point difference in pain and disability scores between proliferant and placebo at 6 months. Overall, there is weak evidence that an intensive intervention (including proliferant) produces a statistically and clinically significant improvement in pain and disability. When proliferant and placebo are directly compared, there is weak evidence that proliferant provides no additional benefit compared to placebo.
Articles: Ongley, MJ, et al, A New Approach to the Treatment of Chronic Low Back Pain, 1987, *Lancet*, ii: 143-148. See Evidence Table. Klein, RG, et al, A Randomized Double-Blind Trial of Dextrose-Glycerine-Phenol Injections for Chronic Low Back Pain, *Journal of Spinal Disorders*, 1993, 6:23-33 See Evidence Table.

The use of prolo/sclerotherapy in the treatment of low back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/10/2002: MTAC REVIEW
Prolotherapy/Sclerotherapy for Low Back Pain
Evidence Conclusion: One new RCT was identified on prolotherapy/sclerotherapy for low back pain (Dechow). This was a valid RCT that compared three, once-weekly injections with sclerosing agents to placebo injections. The authors did not find statistically significant differences in pain, disability or spinal flexion between groups. There was clearly no effect of the intervention on disability, but it is possible that there could be smaller, yet clinically significant differences in pain or spinal flexion that this study was unable to detect.
Prolotherapy/sclerotherapy was previously reviewed by MTAC in April 1999. In the first MTAC review, two RCTs were critically appraised. Both were limited in that the treatment group received multiple interventions so the effectiveness of prolotherapy itself could not be determined. In summary, there is insufficient evidence that prolotherapy/sclerotherapy as a stand-alone intervention is effective for reducing low back pain. The results of one RCT powered to detect a 50% reduction in pain levels between groups suggest that it may be an ineffective intervention.
Articles: The search yielded six articles. There were two empirical studies, one of which was included in the initial MTAC review in 1999. The other study, an RCT, was evaluated. No additional empirical studies were identified from the appeal materials. The following article was critically appraised: Dechow E, Davies RK, Carr AJ, Thompson PW. A randomized, double-blind, placebo-controlled trial of sclerosing injections in patients with chronic low back pain. Rheumatology 1999; 38:1255-59. See Evidence Table.

The use of prolo/sclerotherapy in the treatment of low back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
M0076	Prolotherapy

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
04/1999	04/05/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 12/01/2013MPC, 08/05/2014MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC	04/05/2011

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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Proton Radiation Therapy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Proton Beam Therapy***, for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Proton Beam Therapy (KP-0389) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Most recent medical oncology notes
- Most recent radiation oncology notes
- Most recent imaging (i.e., CT/MRI)

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Background

Proton beam therapy (PBT) is a form of stereotactic radiosurgery that delivers a focused dose of radiation energy to the targeted area while surrounding normal tissue receives minimal radiation. PBT releases its highest percentage of energy at the end of its path (i.e., Bragg peak), depositing 100% of the dosage at the targeted tissue.

Prostate cancer is one of the most common cancers, and the second leading cause of cancer death in men in the US. The standard management options for a localized disease include surgery, radiotherapy, and watchful

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waiting. The optimal treatment, however, is not well defined; both surgery and radiation therapy are reported to have equivalent outcomes, and each approach has its advantages and side effects. Researchers have reported that for intermediate and high-risk disease, radical external beam treatment is the standard treatment, and that there is a dose response for biochemical relapse-free survival. The success of radiation therapy depends on the dose delivered to the tumor and the accuracy of delivery. However, dose escalation to >70 Gy is associated with an increase in genitourinary and gastrointestinal side effects. Several techniques have been developed to deliver high doses of radiation to the prostate while sparing surrounding normal tissue. Among these are the three-dimensional conformal radiotherapy external beam radiotherapy (EBRT), intensity modulated radiation therapy (IMRT), brachytherapy, and proton therapy (Vordermark 2006, Hoskin 2007, Rades 2007).

Proton therapy, like other forms of radiotherapy, works by aiming ionizing particles onto the target tumor. Theoretically proton radiation therapy has the benefit of more localized delivery of radiotherapy than that achieved with photons produced by a linear accelerator. Unlike X-ray beams, a single proton beam can be shaped to deliver a homogeneous radiation dose to irregular three-dimensional volumes. Due to their relatively large size, protons scatter less easily in the tissue with very little lateral dispersion. They follow a predetermined track and stop abruptly at any prescribed depth. The proton beam energy is at its minimum at entry to the body, and maximum, known as 'Bragg-peak', near the end of the range of the proton beam. Beyond the Bragg-peak, the dose falls practically to zero. By choosing appropriate proton beam energies, the depth of the Bragg-peak can be adjusted according to the depth and extent of the target volume. The improved dose distribution can potentially allow higher doses of radiotherapy to the tumor without increasing the normal tissue toxicity (Slater 1999, Brada 2007, Olsen 2007). There is a concern however, that proton beam radiotherapy exposes healthy tissue to stray radiation emitted from the treatment unit and secondary radiation produced within the patient. These exposures may potentially increase a patient's risk of developing a radiogenic second cancer (Taddei 2008).

Proton therapy was initially used for the treatment of choroidal malignant melanomas, and tumors of the skull base. Currently there is a growing interest in the use of proton therapy for the treatment of tumors where conventional radiation therapy would damage surrounding radiosensitive tissues to an unacceptable level as brain tumors, lung cancers, and other tumors in the neck, vicinity of the spinal cord, liver, upper abdomen and pelvis. Proton therapy is also favored for pediatric patients where long-term side effects, as occurrence of secondary tumors resulting from overall radiation dose to the body, are of concern.

Some investigators have questioned the ability of proton therapy to limit morbidity, and others have questioned its value relative to the cost. In addition, concerns have been raised about a potential risk for secondary malignancies.

National Cancer Institute Clinical Trials
Two Phase III trials are comparing photon versus carbon ion radiation therapy in patients with low and intermediate grade chondrosarcoma of the skull base (NCT01182753) and chordoma of the skull base (NCT01182779).

A Phase III trial is comparing hypo fractionated proton radiation versus standard dose for prostate cancer (NCT01230866).

National Comprehensive Cancer Network (NCCN) Guidelines
Prostate Cancer: NCCN guidelines for prostate cancer (v 3.2012) state that "proton beam therapy can be added as an alternative radiation sources. However, proton therapy is not recommended for routine use at this time since clinical trials have not yet yielded data that demonstrates superiority to, or equivalence of, proton beam and conventional external beam for the treatment of prostate cancer". (1)

Bone Cancer: NCCN guideline for bone cancer (v 2.2012) states that "proton and/or photon beam RT may be useful for patients with chondrosarcomas of the skull base and axial skeleton with tumors in unfavorable location not amenable to resection." (3)

The FDA cleared several medical devices designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Medical Technology Assessment Committee (MTAC)

Proton Radiation Therapy
12/01/2008: MTAC REVIEW

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Evidence Conclusion: No randomized clinical trials, to date, have directly compared the efficacy of protons and conventional radiation therapy using photons in the treatment of clinically localized prostate cancer. The only two published RCTs involving proton therapy were evaluating the effect of dose escalation on cancer control. Both studies used protons as a boost to photon irradiation and neither was intended to compare the efficacy of protons versus the conventional photon radiation therapy. Zietman et al's (2005) trial randomized 393 patients with early stage (T1B-T2B) prostate cancer to a proton dose of 19.8 GyE or 28.8 GyE followed by photon irradiation to 50.4 Gy. All patients in the two arms of the study received both photons and protons. The results showed no significant difference in 5-year survival (96% vs. 97%) between the two proton doses, but there was an improvement in 5-year biochemical total control rate from 61.4% for the low-dose group to 80.4% to the high dose group (p<.001). The higher radiation dose was however associated with an increase in acute and late grade 2 rectal toxicity. The largest published case series on proton therapy (Slater 2004) was retrospective, had selection bias, and no comparison or control group. Patients with localized prostate cancer who received proton therapy in the early 1990s were treated with a combination therapy of both protons and photons. Later, after the proton treatment capacity increased, the patients were selected to receive either proton therapy alone or in combination with photon therapy. Therapy was selected based on the patient's risk of lymph node micrometastases as calculated by Partin normogram. The study does not allow making any conclusion on the comparative efficacy of protons versus photon therapy. There is insufficient evidence to determine whether the use of protons for the treatment of patients with localized prostate cancer would improve survival and reduce biochemical failure rate compared with the highly conformal photon therapy currently used. There is insufficient evidence to determine whether the use of protons for treating patients with localized prostate would reduce acute or late rectal and urinary toxicity compared with the highly conformal photon therapy currently used.
Articles: The literature search revealed over 170 published articles on proton therapy for prostate cancer. The majority were review articles on the technical aspects of the therapy. No randomized controlled trials that directly compared proton therapy to any other conventional radiation therapy were identified. There were two published RCTs on dose escalation (Shipley 1995, and Zietman 2005) using a combination of photon and proton therapy for localized prostate cancer, and several case series with historical, or no controls. Shipley's trial (1995) used inadequate photon doses and techniques compared to the current standards. Zietman and colleagues' trial as well as the largest published case series on proton therapy were selected for critical appraisal. Zietman AL, Desilvio ML, Slater JD, et al. Comparison of conventional-dose vs. high-dose conformal radiation therapy in clinically localized adenocarcinoma of the prostate. A randomized controlled trial. JAMA 2005; 294:1233-1239. See Evidence Table. Slater JD, Rossi CJ, Yonemoto LT, et al. Proton therapy for prostate cancer.: The initial Loma Linda University experience Int J Radiat Oncol Biol Phys 2003;59:348-352. See Evidence Table.

The use of Proton radiation therapy for the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex
S8030	Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

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Date Created	Date Reviewed	Date Last Revised
06/04/2009	05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 03/05/2013MDCRPC,	09/01/2015

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	01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/01/2015	Added indication for pediatric central nervous
09/02/2015	Added new link for LCD
02/01/2022	Removed link to retired SRS/SBRT LCD L34151. Adopted KPWA policy for Medicare Advantage members.

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Clinical Review Criteria
LASIK (Laser Assisted In-situ Keratomileusis)
PTK (Phototherapeutic Keratectomy)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Refractive Keratoplasty (80.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Lasik is covered when **All of the following** conditions are met:

1. Astigmatism and/or anisometropia have been surgically induced.
2. Patient is unable to wear glasses or contact lenses after surgery due to anisometropia (eyes having unequal refractive power) and/or high astigmatism.
3. Documented attempts to correct the surgical error with historical means of refraction and/or contact lens fitting.
4. There must be 2.5 diopter or more increase in astigmatism and/or anisometropia from the pre to the postoperative state.
5. Patient must express some functional disability due to the increased astigmatism and the surgeon must have a reasonable expectation that the laser will improve the patient's function.
6. The patient's primary problem is not corneal graft rejection or multiple failures when comfort may be the goal, not vision improvement.
7. The equipment used is FDA approved and the procedure is performed by an ophthalmologist trained to use the equipment.
   Relative contraindications include:
   a. Poorly controlled autoimmune disease
   b. Immunosuppressive medications
   c. Keratoconus and other corneal ectasias
   d. History of keloid formation
   e. Coexisting ocular disease
   f. Unstable refractive error
   g. Underlying systemic disease affecting wound healing

Phototherapeutic keratectomy (PTK) is covered when the **ALL of the following** criteria are met:

1. It is being used to remove damaged and/or diseased tissue from the anterior surface of the cornea.
2. **ONE of the following** is true:
   a) The proposed treatment area is up to 300 microns thick or the cornea is at least 250 microns thick after ablation and other less invasive treatments are not possible or have failed (such as stromal puncture)
   b) The treatment of anterior corneal dystrophies, removal of scars and other opacities in the anterior third of the cornea and smoothing of irregular corneal surfaces to improve visual acuity and reduce pain

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associated with the corneal condition or improve the patient's ability to wear or tolerate spectacles or contact lenses.

3. And **None of the following** conditions exist:
   a) Active infections of the cornea
   b) Bullous keratopathy
   c) Deep pathology extending beyond the anterior third of the cornea
   d) Depressed scars
   e) Unstable keratometry
   f) Existing hyperopia

Photorefractive keratectomy (PRK) is considered cosmetic and is not covered.

Note: Phototherapeutic keratectomy (PTK) should not be confused with photorefractive keratectomy (PRK). Although technically the same procedure, PTK is used for the correction of particular corneal diseases; PRK involves use of the excimer laser for correction of refractive errors (e.g., myopia, hyperopia, astigmatism, and presbyopia) in persons with otherwise non-diseased corneas.

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Background

In 1995 the FDA approved the use of Excimer 193nm laser as an effective tool for performing phototherapeutic (PTK=correcting corneal pathology) and photorefractive (PRK=correcting visual abnormalities) keratectomy of PRK and PTK. In early 1996 Kaiser Permanente evaluated the use of this technology and its efficacy. Following that evaluation, it was recommended that Kaiser Permanente would provide PRK/LASIK as a non-covered service. However, in a few cases where traditional treatment options, including surgery, have failed and the only option available is PRK/LASIK.

Evidence and Source Documents

On March 13, 1996, The GHC Committee on Medically Emerging Technology (COMET) reviewed key articles and concluded that the recent FDA approved Excimer 193nm laser is an effective tool for performing phototherapeutic (PTK=correcting corneal pathology) and photorefractive (PRK=correcting visual abnormalities) keratectomy. In the case of photorefractive keratectomy, its use should be restricted to patients with low to moderate myopia (1 to 8 diopters of visual correction) until efficacy data becomes available for PRK in high myopes. For GHC patients, it was recommended that PTK for corneal pathology should be a covered service and that PRK for refractive errors should be a non-covered service.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
65765	Keratophakia
65767	Epikeratoplasty
65771	Radial keratotomy
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism
65760	Keratomileusis
S0800	Laser in situ keratomileusis (LASIK) ***S codes not covered by Medicare***
S0812	Phototherapeutic keratectomy (PTK) ***S codes not covered by Medicare***

Considered Cosmetic & Not Medically Necessary:

CPT® or HCPC Codes	Description

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S0810	Photorefractive keratectomy (PRK) ***S codes not covered by Medicare**

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Revision Dates	Date Last Revised
02/26/1998	08/03/2010[MDCRPC],06/7/2011[MDCRPC],04/03/2012[MDCRPC],05/01/2012[MDCRPC], 03/05/2013[MDCRPC],01/07/2014[MDCRPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/07/2023[MPC]	02/16/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/16/2016	Added additional keratoplasty codes
02/16/2022	Updated applicable codes

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Pulmonary Rehabilitation

- COPD
- Chronic Pulmonary Lung Disease
- Emphysema

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Clinical review is no longer required

For Non-Medicare Members

Clinical review is no longer required

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The American Thoracic Society and the European Respiratory Society define pulmonary rehabilitation as “an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease. Comprehensive pulmonary rehabilitation programs include patient assessment, exercise training, and psychosocial support”.

Individuals with chronic obstructive pulmonary disease (COPD) constitute the largest population of those referred for pulmonary rehabilitation. COPD is defined as a slowly progressive disease of the airways characterized by airflow limitation and loss of lung function that is not fully reversible. Pulmonary rehabilitation may also be of value for other patients who have respiratory symptoms associated with reduced functional capacity or health-related quality of life (Celli 2008; Nici 2006).

The American Academy of Chest Physicians and the American Association of Cardiovascular and Pulmonary Rehabilitation updated their guideline on pulmonary rehabilitation in 2007. The new guideline accepts the above definition of pulmonary rehabilitation. This guideline considers the three most important features of a successful pulmonary rehabilitation program to be: a multidisciplinary approach, individual assessment and goal-setting, and paying attention to physical functioning and social functioning. The guideline recommends at least 6 weeks of pulmonary rehabilitation; however, no specific combination of program components is recommended (Ries 2007).

Medical Technology Assessment Committee (MTAC)

Pulmonary Rehabilitation

05/01/2000: MTAC REVIEW

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Evidence Conclusion: Although there is some evidence that specific pulmonary rehabilitation programs have lasting benefits for selected patients (Guell et al., Griffiths et al.), conclusions cannot be drawn about the effectiveness of pulmonary rehabilitation in general for the following reasons: Each pulmonary rehabilitation program has different components (see attached table): study methodologies do not permit conclusions about which component or components affect outcomes. Each pulmonary rehabilitation program is a different length and has a different intensity (see attached table): it is not possible to draw conclusions about what length or intensity is necessary to improve outcomes. Study methodologies do not permit conclusions about whether the pulmonary rehabilitation program itself or other factors such as the social support provided by program participation affects outcomes. Most programs have small sample sizes and results may be unreliable. Replications of individual programs are not available. The results of programs are not necessarily generalizable to other populations. For example, the Guell et al. study was conducted only with men and results may not be generalizable to women. Most of the early studies examining the effectiveness of PR were of poor quality (as reported in the meta-analysis by Cambach et al.) The ideal evidence, which does not currently exist, would be well conducted RCTs that examine different combinations of PR program components (e.g. education alone, education+exercise, exercise alone, etc.). In addition, there needs to be sufficient numbers of participants and data for the entire population of interest (i.e. both men and women).
Articles: The literature search yielded 73 articles. There were 8 randomized controlled trials (RCTs) and 2 meta-analyses. Five RCTs were excluded because of one of the following reasons: The groups compared were not directly relevant to this review (in-patient vs. out-patient PR, PR vs. lung surgery); had a small sample size (total n 50); or were included in the meta-analysis that was selected for review.
Articles selected for critical appraisal include: The more recent meta-analysis: Cambach, W, Wagenaar, RC, Koelman, TW, van Keimpema, T, Kemper, HCG. The long-term effects of pulmonary rehabilitation in patients with asthma and chronic obstructive pulmonary disease: A research synthesis. Arch Phys Med Rehabil 1999; 80: 103-111. See Evidence Table. Griffiths, TL, Burr, ML, Campbell, IA et al. results at one year of outpatient multidisciplinary pulmonary rehabilitation: a randomized controlled trial. Lancet 2000; 355: 362-8. See Evidence Table. Guell, R, Casan, P, Belda, J et al. Long-term effects of outpatient rehabilitation of COPD: a randomized trial. Chest 2000; 117: 976-83. See Evidence Table. Wedzicha, JA, Bestall, JC, Garrod, R et al. Randomized controlled trial of pulmonary rehabilitation in severe chronic obstructive pulmonary disease patients, stratified with the MRC dyspnoea scale. Eur Respir J 1999; 12: 363-9. See Evidence Table.

The evidence failed MTAC evaluation criteria due to the lack of a standard definition of pulmonary rehabilitation and the paucity of rigorous studies.

Pulmonary Rehabilitation

12/01/2008: MTAC REVIEW

Evidence Conclusion: The best evidence on the efficacy of pulmonary rehabilitation for COPD is a Cochrane review of randomized controlled trials (Lacasse et al., 2006). PR was defined as a program of at least 4 weeks' duration that included exercise therapy, with the optional addition or education or psychosocial support. The meta-analysis did not specify whether programs included individualized assessment or a multidisciplinary team, so it is not clear how many programs met the criteria defined for this review. Pooled analyses in the Cochrane report found significantly better functional exercise capacity, maximal exercise capacity and quality of life in patients randomized to PR compared to usual care. Limitations of the evidence included in the Cochrane review include:
Most of the published RCTs were small, and of low-quality. None were rated by the Cochrane reviewers as high-quality. No data were reported on long-term effectiveness of PR. Most studies reported findings at the end of the active intervention. The outcomes reported were exercise capacity and quality of life. There are insufficient data on the impact of PR on the rate of exacerbations and hospitalizations. The comparison intervention in the Cochrane review was usual care, the content of which varied from study to study. Thus, we cannot draw conclusion on which components of PR might be effective. Another limitation of the body of evidence is that RCTs comparing PR to sham PR programs are not available. Therefore, we cannot determine whether PR programs per se are effective or whether there is a 'placebo effect' of participating in a program believed by patients to be beneficial. One RCT (Sewell et al., 2005) suggests that an individually tailored exercise program, a key feature of pulmonary rehabilitation, may not be any more effective than a general exercise program in which all participants perform the same exercise. The Sewell study did not find statistically significant differences in functional ability or exercise performance in patients with COPD randomly assigned to receive a 7-week PR program of education plus a general or individualized exercise program. The Sewell study is not conclusive—sample size calculations were not reported, and it may have been underpowered. In conclusion: The evidence on pulmonary rehabilitation for COPD has important limitations. RCTs were small and of low quality, outcome data are short-term and are only available for exercise capacity and quality of life, and a placebo effect of participating in a PR program cannot be ruled out. There are no RCTs comparing some PR program meeting criteria established for this review

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and a less-intensive intervention. It is important to know whether a comprehensive PR program that includes individualized assessment and involves a multi-disciplinary team is more effective than a less resource-intensive intervention such as an exercise program. There is insufficient evidence on the effectiveness of pulmonary rehabilitation for conditions other than COPD.

Articles: The ideal study is a double-blind randomized controlled trial comparing pulmonary rehabilitation to a sham rehabilitation program (i.e. a program of similar intensity without the therapeutic content under evaluation). No studies meeting these criteria were identified. However, there was one relatively large RCT (Sewell et al., 2005) that compared an individualized exercise program to a general exercise program for COPD. The general exercise program could be considered a type of sham and could allow for blinding of participants. Other than a sham-controlled trial, the next best design is a study comparing two PR programs with a different combination of components, especially if one of the PR programs met the definition for this review. One small RCT was identified that compared exercise only, exercise plus activity training and exercise plus didactic education (Norweg et al., 2005). This study, however, was excluded due to the small number of participants. A third type of comparison intervention is "usual care". Since the previous MTAC review, a Cochrane review of randomized controlled trials comparing pulmonary rehabilitation to usual care for patients with COPD has been published (Lacasse et al., 2006). No large, well-conducted RCT on PR versus any comparison intervention published after the Cochrane review was identified. The search did not yield any randomized controlled trials or meta-analyses that evaluated pulmonary rehabilitation for any lung condition other than COPD.The Cochrane review and one RCT were critically appraised: Lacasse Y, Goldstein R, Lasserson TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2006. Issue 4. See Evidence Table. Sewell L, Singh SJ, Williams JEA et al. Can individualized rehabilitation improve functional independence in elderly patients with COPD? Chest 2005; 128: 1194-1200. See Evidence Table.

The use of pulmonary rehabilitation in the treatment of COPD, chronic pulmonary lung disease and emphysema does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Pulmonary Rehabilitation

12/20/2010: MTAC REVIEW

Evidence Conclusion: A recent meta-analysis that evaluated the effectiveness of pulmonary rehabilitation after an acute exacerbation of COPD found that compared to usual care, subjects in the pulmonary rehabilitation intervention had fewer hospital admissions. However, only 3 studies with a total of 93 subjects were included in the meta-analysis (Puhan 2009).

Pulmonary Rehabilitation vs. Usual Care

Outcome	# of studies	# of subjects	Odds Ratio (95% CI)	NNT (95% CI)
Hospital admission	3	93	0.13 (0.04 to 0.35)	3* (2 to 4)

*NNT over 34 weeks

Conclusion: Evidence from a meta-analysis that included small studies of moderate quality suggests that pulmonary rehabilitation is effective at reducing hospital admissions in patients with an acute exacerbation of COPD.

Articles: Only randomized controlled trials, meta-analyses, and clinical trials were included in the review. Studies were excluded if they were: community based; if they did not have sufficient statistical power to detect a difference in one of the main outcomes; or if they did address one of the main outcome measures (hospitalizations or emergency department visits). The following study was critically appraised: Puhan M, Scharplatz M, Troosters T, Walters ED and Steurer J. Pulmonary rehabilitation following exacerbation of chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2009, Issue 1. Art No.: CD005305. DOI: 10.1002/14651858. CD005305.pub2. See Evidence Table.

The use of pulmonary rehabilitation in the treatment of COPD, chronic pulmonary lung disease and emphysema does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medically necessary review is no longer required:

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CPT® or HCPC Codes	Description
94625	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)
94626	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face-to-face, one-on-one, each 15 minutes (includes monitoring)
G0238	Therapeutic procedures to improve respiratory function, other than described by G0237, one-on-one, face-to-face, per 15 minutes (includes monitoring)
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring)
S9473	Pulmonary rehabilitation program, nonphysician provider, per diem ***S codes not covered by Medicare***

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Date Created	Review Date	Date Last Revised
01/16/2009	02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC] ,08/06/2013[MPC], 01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC] , 03/07/2023[MPC]	03/01/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/05/2016	Added NCD
09/03/2015	Changed Medicare link
11/17/2016	Added LCA A52770
09/07/2017	Clinical Review no longer required
03/01/2022	Updated applicable codes.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Facet Neurotomy

- Radiofrequency Neurotomy
- Neurolytic Agent

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Induced Lesions of Nerve Tracts (160.1)
Local Coverage Determinations (LCD)	Facet Joint Interventions for Pain Management (L38803)
Local Coverage Article (LCA)	Facet Joint Interventions for Pain Management (A58405)

For Non-Medicare Members

Effective until August 1, 2023

Kaiser Permanente has elected to use the Facet Neurotomy (KP-0218 09012021) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Effective August 1, 2023

Kaiser Permanente has elected to use the Facet Neurotomy (KP-0218 08012023) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Neurology, physiatrist, anesthesia, orthopedics)

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Background

Radiofrequency (RF) neurotomy is a treatment for various conditions, including certain types of back and neck pain. It is based on the premise that severing the nerve supply to a painful structure may reduce pain and allow a restoration of function. It was first described by Shealy in 1975 and the technique has been modified since that time (Niemisto, 2003). Generally, in order to use RF neurotomy, two criteria must be fulfilled: 1) the structure responsible for the pain must be at or near the spinal facet joints and 2) the painful structure must be identified with a diagnostic block of local anesthesia causing temporary relief of pain. Due to the high false-positive rate of

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single local anesthetic blocks, placebo-controlled blocks are recommended, particularly for the lumbar spine (Lord and Bogduk, 2002).

The RF neurotomy procedure consists of inserting a radiofrequency electrode percutaneously under fluoroscopy guidance to the targeted area. A small amount of electrical stimulation is initially used to identify the nerve position. A regional anesthetic is then injected. After that, RF current is applied to the tissue. RF current is low energy, high frequency alternating current. When applied to biological tissue, the current causes charged molecules to oscillate and the resulting friction produces heat. A RF lesion is made by raising the temperature of the electrode to 70-90°C for 60-90 seconds. The size of the lesion varies with the size of the electrode; the maximum width of the lesion is 3-4 times the width of the electrode tip. Since the lesions are small, accurate placement of the electrode requires knowledge of the topography of the target nerve tissues and surgical precision (Lord and Bogduk, 2002)

Documentation should include:

- Pre-procedural documentation must include a complete initial evaluation including history and an appropriately focused musculoskeletal and neurological physical examination. There should be a summary of pertinent diagnostic tests or procedures justifying the possible presence of facet joint pain.
- A procedure note must be legible and include sufficient detail to allow reconstruction of the procedure. Required elements of the note include a description of the techniques employed, nerves injected and sites(s) of injections, drugs and doses with volumes and concentrations as well as pre and post-procedural pain assessments. With RF neurotomy, electrode position, cannula size, lesion parameters, and electrical stimulation parameters and findings must be specified and documented.
- Facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance. Facet joint interventions performed under ultrasound guidance will not be reimbursed.
- A hard (plain radiograph with conventional film or specialized paper) or digital copy image or images which adequately document the needle position and contrast medium flow (excluding RF ablations and those cases in which using contrast is contra-indicated, such as patients with documented contrast allergies), must be retained and submitted if requested.
- In order to maintain target specificity, total IA injection volume must not exceed 1.0 mL per cervical joint or 2 mL per lumbar joint, including contrast. Larger volumes may be used only when performing a purposeful facet cyst rupture in the lumbar spine.
- Total MBB anesthetic volume shall be limited to a maximum of 0.5 mL per MB nerve for diagnostic purposes and 2ml for therapeutic. For a third occipital nerve block, up to 1.0 mL is allowed for diagnostic and 2ml for therapeutic purposes.
- In total, no more than 100 mg of triamcinolone or methylprednisolone or 15 mg of betamethasone or dexamethasone or equivalents shall be injected during any single injection session.
- Both diagnostic and therapeutic facet joint injections may be acceptably performed without steroids.

Medical Technology Assessment Committee (MTAC)

Back/Neck Pain

07/14/2004: MTAC REVIEW

Evidence Conclusion: Back Pain There is insufficient evidence to conclude that RF neurotomy improves health outcomes among patients with back pain. Two of the three RCTs on back pain that were reviewed (LeClaire; Barendse) did not find a significant benefit of RF neurotomy compared to a sham intervention in the primary analysis. Barendse may have been underpowered to detect a clinically significant difference between groups. The third study (van Kleef, 1999), which included patients with low back pain originating from the lumber zygapophysial joint, found significantly more clinical successes in the RF neurotomy group. The latter study (n=32), which included a multivariate analysis to adjust for baseline differences, had imprecise estimates with large confidence intervals and only an 8-week follow-up period. All of the studies were limited by small sample sizes. In addition, all of the studies used non-blinded diagnostic blocks and there may have been false positive findings of the location of pain. Long-term safety and efficacy of RF neurotomy for treating back pain was not evaluated.

Evidence Conclusion: Neck pain There is insufficient evidence to conclude that RF neurotomy improves health outcomes among patients with neck pain. One of the two RCTs reviewed (Lord) was well designed but had a biased presentation of study results. The authors did not report their primary outcomes, pain and impact of pain on activities of daily living, at the end of the double-blind follow-up period at 3 months. The results they did report were confounded by rescue treatment. The other RCT (van Kleef, 1996) found a significant benefit of RF neurotomy compared to sham intervention for patients with cervicobrachial pain. The study is limited by its short (8-week) follow-up period and small sample size (n=20), which can result in baseline differences between groups.

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Also, the van Kleef, 1996 study used non-blinded diagnostic blocks and some patients may have been falsely identified with cervicobrachial pain. Long-term safety and efficacy of RF neurotomy for treating neck pain was not evaluated.
Articles: The search yielded 23 articles. There was a Cochrane library review from 2003 that reviewed the randomized controlled trials on the topic but did not conduct a quantitative meta-analysis to evaluate the overall effectiveness of the treatment. Seven double-blind sham-controlled RCTs met the inclusion criteria for the Cochrane review. One additional small RCT published after the Cochrane review was identified in the Medline search, but this study was excluded because the patient population had already failed intradiscal electrothermal annuloplasty (IDET). The Cochrane investigators assigned a methodological quality score to each RCT they included. Studies that received a quality score of at least 7 out of 10 were selected for this review. The Leclaire and Barendse articles were by the same research groups but included different study populations. Back pain: There were four RCTs on the treatment of back pain. One RCT that had a low methodology score in the Cochrane review was not reviewed. The remaining three RCTs were critically appraised: Leclaire R, Fortin L, Lambert R et al. Radiofrequency facet joint denervation in the treatment of low back pain. *Spine* 2001; 26: 1411-1418. See Evidence Table van Kleef M, Barendse GAM, Kessels A et al. Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. *Spine* 1999; 24: 1937-1942. See Evidence Table Barendse GAM, van den Berg SGM, Kessels AHF et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain. *Spine* 2001; 26: 287-292. See Evidence Table Lord SM, Barnsley L, Wallis BJ et al. Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain. *N Engl J Med* 1996; 335: 1721-1726. See Evidence Table

The use of radiofrequency neurotomy in the treatment of chronic neck and back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/29/2005: MTAC REVIEW
Back Pain/Neck Pain
Evidence Conclusion: A PubMed search (2004 to present) yielded 6 articles. Four were review articles and one was a study of electrode placement, not effectiveness. There was one new RCT (Stovner et al. Cephalalgia 2004; 24: 821). The study was not worth critically appraising because it only included 12 patients. It did not find a significant benefit of radiofrequency neurotomy vs. sham treatment for next pain, but they almost certainly did not have sufficient statistical power.

This review was not taken to the Medical Technology Assessment Committee. The information was not sufficient to warrant a review by the committee.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)

Medicare: Considered Not Medically Necessary
Non-Medicare: Considered Not Medically Necessary - experimental, investigational, or unproven

CPT® or HCPCS Codes	Description

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Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure)
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary procedure)
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
07/14/2004	01/05/2010[MDCRPC], 05/04/2010[MDCRPC], 03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC] ,09/03/2013[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC] , 10/02/2018[MPC] , 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC],10/06/2022[MPC]	03/07/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD for Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy to L35178 and L34995
12/08/2016	Deleted LCD 35178 as it was retired, and LCD 34995 replaces it
07/11/2017	MPC approved criteria for repeat facet neurotomy
04/06/2021	MPC approved to adopt changes to facet neurotomy hybrid criteria. Requires 60-day notice, effective date September 1, 2021.
04/27/2021	Removed retired LCD L34995 and LCA A57728; Added replacement LCD L33803 and LCA A58405
10/04/2022	Revised criteria to clarify Facet Neurotomy for thoracic spine is not covered.
10/12/2022	Updated LCA A58405 link. Updated applicable codes.
03/06/2023	Update applicable codes.
03/07/2023	MPC approved to adopt changes to facet neurotomy hybrid criteria. Requires 60-day notice, effective date 08/01/2023.

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Clinical Review Criteria
Radioimmunoscintigraphy

- ProstaScint (Indium In 111 Capromab Pendetide, Capromab)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Radioimmunoscintigraphy"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Prostate cancer is the most frequently diagnosed malignancy in the US, and second leading cause of death in men. In the era of prostate specific antigen (PSA) testing, prostate cancer is detected at an earlier stage, and about 85% of newly diagnosed patients have a localized disease that may be treated with definitive radical prostatectomy or radiation therapy. Though these are considered definitive treatments, 15-40% of the patients will develop biochemical PSA relapse within 10 years. The disease may recur locally in the prostatic fossa, in the regional lymph nodes, or at distant sites (Nagda 2007, Raj 2001, Pukar 2008).

The appropriate management of prostate cancer is highly dependent on accurate information about the location and extent of the disease. Surgical resection of the prostate is not indicated for patients whose disease has spread outside the prostatic bed. Although a rising PSA level may be indicative of prostate cancer and a residual or recurrent disease after radical prostatectomy, it is not specific and cannot determine the stage of the disease or discriminate between local cancer and metastatic involvement. Normograms, or clinical algorithms (e.g. that developed by Partin and colleagues in the early 1990s), use a combination of serum PSA level, Gleason score, and clinical stage to predict the likelihood of extraprostatic disease in order to help with treatment decisions. The normograms offer a statistical probability of disease organ confinement for populations of patients with similar clinical variables, but sometimes do not apply to the individual patient, who may need to be evaluated further. Traditionally patients undergo transrectal ultrasound with biopsy to assess local tumor, chest x-ray to look for any

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lung metastases, bone scan to determine the presence of osseous metastases, and CT scan or MRI of the abdomen, and pelvis to evaluate lymph node for disease involvement. After definitive treatment of the cancer, patients are followed up with periodic measurement of PSA levels and digital rectal examination (DRE). Imaging is performed if there are suspicious findings on DRE, PSA relapse, or if the patients have symptoms such as bone pain. Distinguishing between local versus systemic extent of the disease in patients with a PSA relapse is crucial for determining the salvage treatment modality. Salvage radiation therapy is used for local recurrence in the prostatic fossa, and systemic therapy is considered for those with a disease outside the fossa.

Conventional CT scans and MRI may be helpful in evaluating patients who have advanced disease with adjacent organ invasion and distant lymph adenopathy but have limited clinical value in local staging or detecting early recurrence of the tumor. CT and MRI classify metastatic nodes strictly by size; they are classified as normal if they are one centimeter or less in diameter, and as abnormal if larger. The majority of patients presenting with clinically localized prostate carcinoma and occult lymph node metastases have either microscopic involvement or a disease volume less than 1 cm 3, which would go undetected. On the other hand, inflammatory or hyperplasic nodes grater than one centimeter in diameter might be erroneously classified as neoplastic (Polascik 1999, Raj 2002, Bander 2006, Nagda 2007).

In contrast to anatomic imaging, radioimmunoscintigraphy is a functional imaging modality which acquires images through the use of a radiolabeled antibody that selectively recognizes malignant tissue. One antigen of interest for prostate cancer is prostate-specific epithelial cell membrane antigen (PSMA) which is expressed at high levels in prostate cancers. The expression increases as the tumor grade increases, and in metastatic deposits. It increases further as the tumor becomes androgen independent.

Capromab pendetide (ProstaScint) is a murine monoclonal antibody that reacts with PSMA. Immunoscintigraphy is accomplished by labeling the antibody with indium 111. After infusion of the antibody, whole body planar and single-photon emission CT images are obtained. ProstaScint images can potentially aid in patient management by helping identify when the cancer has spread outside the prostatic bed to regional lymph nodes or to distant soft tissue sites. Capromab however, recognizes a molecular site that is masked in viable cells, and detects antigenic sites on the intracellular portion of PSMA, a site not accessible to circulating antibody. It thus cannot adequately image bone metastases, which are the most common and earliest site of metastatic spread in prostate cancer (Haseman 2007, Akin 2007).

Indium-capromab pendetide (ProstaScint, Cytogen, Princeton, NJ) was approved by the FDA in 1996 as an immunoscintigraphic diagnostic imaging agent for newly diagnosed patients with biopsy-proven prostate cancer, who are at high risk for pelvic lymph node metastases, and in patients with a rising PSA levels after prostatectomy.

Medical Technology Assessment Committee (MTAC)

Radioimmunoscintigraphy for the Diagnosis of Prostate Cancer

06/12/2009: MTAC REVIEW

Evidence Conclusion: As indicated earlier, 111Indium capromab pendetide (ProstaScint) scan was studied in two clinical settings. 1. Presurgical staging of prostate cancer, and 2. Post prostatectomy biochemical failure.
Presurgical staging of prostate cancer: Polascik and colleagues (1999) compared the accuracy and predictive values of ProstaScint with various algorithms/normograms used to predict lymph node involvement prior to surgery, and Manyak and colleagues (1999) compared it with CT scan and MRI results. The gold standard was pathological results of surgically resected lymph nodes. Bone metastases were not evaluated. These, as well as other published studies, included patients at high risk of extraprostatic disease. The overall results show that ProstaScint had sensitivity around 62%, specificity ranging from 72-80%, and a positive predictive value ranging from 62-66% in detecting lymph node involvement. The observed ProstaScint sensitivity in predicting lymph node metastases was higher than CT and MRI but lower than the various clinical algorithms based on a PSA level, biopsy Gleason score, and clinical stage. The predictive value of Partin's normogram was not improved when combined with ProstaScint scan. There are no published follow-up studies to indicate that high-risk patients with a negative capromab pendetide scan have a lower failure rate after surgery.
Biochemical failure after prostatectomy: There were no randomized controlled trials that compared outcomes of salvage radiation therapy in patients with and without ProstaScint imaging. The published studies retrospectively examined the association of negative and positive ProstaScint scans on PSA regression and/ or survival after salvage radiotherapy to the prostate fossa. The studies had their limitations, potential biases and confounding, and had conflicting results. Nagda and colleagues (2007), Wilkinson and Chodak (2004), and Thomas et al (2003) study results all indicated that ProstaScint scans has limited value in making clinical decisions.

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Nagda et al's study showed no significant difference in relapse free survival between patients who showed or did not show a positive capromab pendetide uptake. Wilkinson and Chodak 2004, found that less than half of the patients with a localized uptake of ProstaScint scan had a durable response after salvage radiation therapy. Thomas and colleagues 2003 found no statistically significant association between ProstaScint scan findings and the response to salvage radiotherapy. On the other hand, other the results of other studies (Haseman 2007, Proano 2006, Kahn 1998, and Levesque 1998) suggested that ProstaScint scan might be useful in selecting patients for salvage radiotherapy therapy. Haseman et al study (2007) showed that overall death, and prostate cancer specific death rates were significantly higher among patients with central abdominal ProstaScint uptake. Praono and colleagues 2006, found that patients with negative ProstaScint scans had significantly lower PSA progression rate after salvage radiotherapy than those with a positive scan. They however indicated that the finding might be dependent on the pre-radiotherapy PSA level. Kahn et al 1998, and Levesque and colleagues1998, also suggested that ProstaScint scan might be useful in selecting patients for salvage radiotherapy therapy. RCTs comparing salvage radiation therapy in patients with and without ProstaScint imaging would help determine the role of the scan in predicting success of salvage radiation therapy after failed definitive treatment. Conclusion: There is insufficient evidence to determine that ProstaScint would improve presurgical staging of prostate cancer, differentiate between local and distant spread in patients with biochemical failure after definitive treatment, or predict success of salvage radiation therapy.
Articles: The literature search revealed around 110 articles on Capromab pendetide (ProstaScint). The published studies examined the utility of ProstaScint/ radioimmunoscintigraphy in two settings: 1. Presurgical staging 2. PSA biochemical failure after prostatectomy. Presurgical staging: There were five studies that used surgical pathology results of resected lymph nodes as a gold standard. The three larger studies (N=195, N=152, and N= 51) were conducted by the same study group and most probably with overlapping populations. The other two were very small (N=19, and N=22). The study with the largest population size, as well as the study that compared the accuracy of ProstaScint vs. CT and MRI were selected for critical appraisal. PSA biochemical failure after prostatectomy: The utility of radioimmunoscintigraphy in patients with biochemical failure after definitive therapy was examined for: Its ability to differentiate between local and distant recurrence of the disease: There were 2 retrospective case series with no comparison group, and a very small study that compared the detection of metastatic disease by capromab vs. CT which have limited utility for detecting early recurrence of the disease. The search also revealed a small study on the impact of fusion of capromab pendetide data with those from MRI or CT in patients with recurrent prostate cancer. Due to the small size, design and quality of the studies, none was selected for critical appraisal. Its ability to predict response to salvage therapy: The literature search did not reveal any randomized controlled trials comparing outcome of salvage radiation therapy in patients with and without ProstaScint. There were seven retrospective studies; four examined the association between ProstaScint and PSA progression rate in patients after salvage radiotherapy, and three with survival/mortality outcomes. Two studies with mortality outcomes and one on PSA progression were selected for critical appraisal, based on methodology, size, and duration of follow-up. The following studies were critically appraised: Haseman MK, Rosenthal SA, Kipper SL, et al. Central abdominal uptake of indium-111 capromab pendetide (ProstaScint) predicts for poor prognosis in patients with prostate cancer. Urology 2007;70:303-308 See Evidence Table. Manyak MJ, Hinkle GH, Olsen JO, et al. Immunoscintigraphy with indium-111-capromab pendetide: evaluation before definitive therapy in patients with prostate cancer. Urology 1999;54:1058-1063 See Evidence Table. Nagda SN, Mohideen N, Lo SS, et al. Long-term follow-up of 111In-capromab pendetide (ProstaScint) scan as pretreatment assessment in patients who undergo salvage radiotherapy for rising prostate-specific antigen after radical prostatectomy for prostate cancer. Int J Radiation Oncol Biol Phys 2007; 67:834-840. See Evidence Table. Polascik TJ, Manyak MJ, Haseman MK, et al, Comparison of clinical staging algorithms and 111indium-capromab pendetide immunoscintigraphy in the prediction of lymph node involvement in high risk prostate carcinoma patients. Cancer 1999;85:1586-92 See Evidence Table. Proano JM, Sodee B, Resnik MI, et al. The impact of a negative (111) indium-capromab pendetide scan before salvage radiotherapy J of Urol.2006;175: 1668-1672. See Evidence Table.

The use of Radioimmunoscintigraphy for the diagnosis of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description

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78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day imaging
With diagnosis codes	
C61	Malignant neoplasm of prostate
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
D07.5	Carcinoma in situ of prostate
Z12.5	Encounter for screening for malignant neoplasm of prostate
Z80.42	Family history of malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate
Z90.721	Acquired absence of ovaries, unilateral
Z90.722	Acquired absence of ovaries, bilateral
Z90.79	Acquired absence of other genital organ(s)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/15/2009	04/04/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	07/15/2009

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Radiopharmaceuticals

- Dotatate (Lutathera) – used for neuroendocrine tumors
- Vipivotide Tetraxetan (Pluvicto™, formerly 177Lu-PSMA) – used for metastatic prostate cancer

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Vipivotide Tetraxetan (Pluvicto™, formerly 177Lu-PSMA)" and "Dotatate (Lutathera") ,*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Dotatate (Lutathera)	**Candidates must meet ALL of the following:** 1. Presence of metastasized or locally advanced, unresectable (with curative intent) gastroenteropancreatic neuroendocrine tumors (GEP-NET) **and** 2. Ki-67 protein ≤ 20% (patients with higher-grade disease need to be evaluated on case-by-case basis) **and** 3. Progressive disease under somatostatin analog therapy (SSA) **and** 4. At least 18 years of age **and** 5. Target lesions overexpressing somatostatin receptors as demonstrated on ^{68}Ga-DOTATATE PET/CT scan within last 3 months **and** 6. Monitoring labs must be conducted within the first 4 weeks of injection (baseline); 4-6 weeks after each Lutathera injection and 2 days prior to subsequent Lutathera injections **Contraindications:** 1. Women who are or may be pregnant, as this agent can cause fetal harm when administered to a pregnant woman (pregnancy category X) **or** 2. Women who are breast feeding **or** 3. Pediatric patients (<18 years of age)

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	4. Lutathera Therapy is not covered when: 5. Recent surgery, radioembolization, chemoembolization, radiofrequency ablation or chemotherapy within 4 weeks prior to initiation of Lutathera treatment. 6. Known brain metastases unless these metastases have been treated and stabilized. 7. Uncontrolled congestive heart failure (NYHA II, III, IV) 8. Treatment with *short-acting* somatostatin analog therapy (SSA) that cannot be interrupted for 24 hours before Lutathera administration, or treatment with *long-acting* (LAR) somatostatin analog therapy SSA that cannot be interrupted for at least 4 weeks before initiation of Lutathera a. Patient may go on short acting somatostatin analog therapy (SSA) as a bridge between LAR injection and Lutathera treatment, but this must be stopped 24 hrs. before Lutathera treatment. 9. Prior external beam radiation therapy to >25% of the bone marrow. 10. Current spontaneous urinary incontinence making it unsafe to administer Lutathera Please click here to view clinical criteria for PET Scan: Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)
Vipivotide Tetraxetan (Pluvicto™, *formerly* 177Lu-PSMA)	**Effective until June 1, 2023** Send all cases to MD for review **Effective June 1, 2023** Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto™, formerly 177Lu-PSMA) given every 6 weeks for 4-6 cycles is considered medically necessary for individuals with progressive metastatic castration-resistant prostate cancer who meet **ALL of the following** conditions: 1. Patient must be age 18 or older 2. Must be prescribed by Medical Oncology 3. Must have baseline CT/bone scan within the prior 2 months of chest/abdomen/pelvis with at least one visible lesion 4. Have been treated with 1 or more androgen-receptor pathway inhibitors (ie, enzalutamide and/or abiraterone) 5. Previously received at least 1 taxane-based chemotherapy regimens (docetaxel, cabazitaxel) for metastatic castration-resistant prostate cancer, for at least 2 cycles 6. Must have PSMA-positive mCRPC defined as having at least one tumor lesion with uptake greater than normal liver within the past 3 months 7. Does NOT have any PSMA-negative (defined as FDA approved PSMA tracer uptake less than or equal to uptake in normal liver) prostate cancer lesions exceeding the below size criteria: a. Visceral metastases ≥1cm b. Lymph node metastases ≥2.5cm c. Bone metastases ≥1cm 8. At least 30 days out from starting bisphosphonate or denosumab (if applicable) 9. No radium-223 within last 6 months 10. No chemotherapy, immunotherapy, or biologics within 28

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	days of treatment 11. No impending cord compression 12. Prior CNS metastases okay if stable; must not be on steroids for treatment of CNS metastases, OK if has received prior treatment for metastases (e.g., radiation, surgery), and must be neurologically intact 13. No NYHA 3-4 heart failure, active hep B/C, uncontrolled infection 14. Birth control if partner has child-bearing potential 15. Meets **ALL** of the following Diagnosis/Drug specific criteria below: a. WBC at least 2.5K/uL and/or ANC at least 1.5 K/uL b. Hgb > 9mg/dL (no transfusion within 30 days) c. Platelets > 100 K/uL d. T.bili < 1.5x ULN (3x for Gilbert's) e. AST/ALT < 3x ULN (5x if liver metastases) f. Serum creatinine < 1.5x ULN and creatinine clearance > 50 mL/min (using Cockcroft-Gault equation with actual body weight) g. Albumin > 3.0g/L h. ECOG* PS 0-2 (consider patients with PS2 very carefully; only 7% of patients on VISION had a PS of 2 so these patients were not well represented in the trial) If initial criteria are met, approve x4 doses. If initial criteria are not met, do not approve. **RENEWAL CRITERIA**: Must meet **ALL of the following**: *(Describe specific criteria that would warrant continuation of the drug)* 1. Patient has tolerated medication 2. Patient has shown evidence of response, defined as one of the following: a. PSA response b. Radiologic response c. Clinical benefit per treating physician If renewal criteria are met, approve x2 doses. If renewal criteria are not met, do not approve. **Pluvicto™ treatment greater than a total of 6 doses as per the Food and Drug Administration-approved regimen is considered investigational.**

Please click here to view clinical criteria for PET Scan: Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)

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Background

Neuroendocrine Tumors

Gastroenteropancreatic neuroendocrine tumors are rare. It is estimated that approximately one out of 27,000 people are diagnosed with gastroenteropancreatic neuroendocrine tumors (GEP-NETs) per year (Voelker, 2018). However, their incidence has increased in the last thirty years (Cives & Strosberg, 2018). Neuroendocrine tumors of the midgut represent the most common malignant gastrointestinal neuroendocrine tumors. Overall survival rate

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is less than 50% especially in patients with metastatic disease (Modlin, Lye, & Kidd, 2003; Yao et al., 2008). Initial therapy includes somatostatin analogue (Caplin, Pavel, & Ruszniewski, 2014). However, there exists a lack of second-line treatment for neuroendocrine tumors (except for everolimus for nonfunctional neuroendocrine tumors (Yao et al., 2016)) if first-line treatment fails. Radiolabeled somatostatin analogue, Lutetium-177, has been the center of attention and it may be promising for the management of advanced neuroendocrine tumors (NETs).

Lutathera or Lutetium Lu 177 dotatate is a radioactive targeted therapy. The medication binds to somatostatin receptors which are present on certain tumors. Once Lutathera binds to the receptor, it enters the cell and uses radiation to cause damage. However, it does not impact normal cells. Lutathera delivers beta- and gamma radionuclides to cancerous cells with a maximum particle range of 2 mm and a half-life of 160 hours (van der Zwan et al., 2015). It is administered as four infusions separated by eight weeks interval.

On January 29, 2018, the Food and Drug Administration approved lutetium Lu 177 dotatate (LUTATHERA, Advanced Accelerator Applications USA, Inc.) a radiolabeled somatostatin analog, for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Prostate Cancer
Source: Verbatim from Juzeniene A, Stenberg VY, Bruland ØS, Larsen RH. Preclinical and Clinical Status of PSMA-Targeted Alpha Therapy for Metastatic Castration-Resistant Prostate Cancer. Cancers (Basel). 2021 Feb 13;13(4):779. doi: 10.3390/cancers13040779. PMID: 33668474; PMCID: PMC7918517.)
"Prostate cancer is the second most common cancer in men worldwide, with an estimated 1.3 million new cases and 359,000 deaths in 2018 [1]. The tumors of 10–20% of prostate cancer patients become refractory to androgen deprivation therapy and progress as metastatic castration-resistant prostate cancer (mCRPC) [2,3]. Bone metastases dominate, but lymph node and visceral metastases are also frequent in mCRPC patients [4–6]."

Medical Technology Assessment Committee (MTAC)

Lutetium Lu 177 Dotatate (Lutathera) for Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
01/14/2019: MTAC Review
Evidence Conclusion:

- There is limited evidence comparing Lu-Dotatate and octreotide
  - Based on one RCT with moderate risk of bias, Lu-Dotatate may be more effective than octreotide LAR in adult population with predominantly low grade, higher level of expression of somatostatin receptors gastroenteropancreatic NETs who failed initial therapy.
  - However, Octreotide results in lower adverse events than Lu-Dotatate.
- In non-comparative studies, low evidence suggests that Lu-Dotatate may be effective and safe in patients with advanced gastroenteropancreatic neuroendocrine tumors.

Articles: PubMed was searched through October 19, 2018. Search terms include ((Lutathera OR lutetium Lu 177 dotatate OR lutetium 177 dotatate OR Lu-177 OR 177Lu-DOTATATE)) AND (Neuroendocrine tumors OR pancreatic neuroendocrine tumors OR gastrointestinal neuroendocrine tumors). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Several articles were identified but only one RCT (NETTER-1 trial) met the inclusion criteria. Clinicaltrial.gov was also searched on October 11, 2018 and identified several ongoing studies with no available results. See Evidence Table**.**

The use of Lutetium Lu 177 Dotatate (Lutathera) for Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostate-Specific Membrane Antigen Radioligand Therapy for the Treatment of Metastatic Castration-Resistant Prostate Cancer
07/14/2022: Medical Technology Assessment Team (MTAT)
Evidence Conclusion:
177-Lu PRLT
Overall Conclusion(s)
Efficacy

- Overall, moderate-certainty evidence from 3 RCTs with a total of 821 mCRPC patients, with

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disease progression after various therapies including androgen-receptor pathway inhibitors, taxane chemotherapy, and palliative radiotherapy, demonstrates that 177-Lu PRLT had a statistically significant decrease in PSA levels, increase in response rates (i.e., objective or overall response, disease control rate), prolonged OS and/or PFS, and/or improvement in quality of life outcomes compared to cabazitaxel, standard care, or docetaxel. An additional 2 RCTs (71 patients) investigated 177-Lu PRLT dosing and reported inconsistent data for PSA decline and disease control rates. The overall certainty in the RCT evidence was downgraded to reflect inconsistency, indirectness, imprecision, as well as risk of bias. With respect to the quality of individual studies, risk of bias is moderate due to heterogeneity in patient populations and/or treatment protocols, lack of masking, as well as loss to follow-up in control groups. Industry sponsorship of studies was also common, although this funding source is common in cancerrelated drug trials. There is moderate confidence that the reported effect estimate is likely to be close to the true effect, but there is a possibility that it is substantially different. Additional RCTs with large sample sizes, consistent patient selection and treatment regimen, would contribute to the overall certainty in evidence.

- In addition to the RCTs, there were 95 observational studies (3 retrospective comparative, 22 prospective non-comparative, 70 retrospective non-comparative) with 5,291 mCRPC patients demonstrating that, after treatment with 177-Lu PRLT, 55.5% to 84.7% patients experienced PSA decline, 0% to 73% had partial response, 8.4% to 46% had stable disease, 4% to 46% had progressive disease, with OS ranging from median 6 to 18 months and PFS ranging from median 3.8 to 11 months. The evidence from the observational studies is rated with lowcertainty given the retrospective and/or non-comparative study design in the majority of the included studies and the inherent biases associated with this design, as well as small sample sizes.

Safety

- Overall, low-certainty evidence from 5 RCTs with 1,142 mCRPC patients reported mortality rates ranging from 0% to 87% (5 RCTs; 1,142 patients) and serious (grade ≥3) anemia, bone marrow suppression, pain, and thrombocytopenia AEs occurring in greater than 10% of patients (4 RCTs; 985 patients). One RCT with 40 patients reported no statistically significant difference in treatment-emergent grade 3-to-5 AEs (30% vs 50%) among 177-Lu PRLT and docetaxel treated patients. The evidence certainty was downgraded for heterogeneity in patient populations and treatment protocols, lack of masking, and loss to follow-up in control groups. Furthermore, the lack of analyses in 4 out of the 5 RCTs, to determine the statistical significance of the between-group difference in mortality and/or AEs, warranted further downgrading of the evidence to low-certainty.
- In addition to the RCTs, there were 44 observational studies (2 retrospective comparative, 16 prospective non-comparative, 26 retrospective non-comparative) with 2,244 mCRPC patients reporting additional AEs including: increases in aspartate aminotransferase and alanine transaminase; chronic kidney disease (grade 1 to 2); hemoglobin toxicity; and renal toxicity (grade 1). The evidence from the observational studies was rated with low certainty given the majority of included studies had small sample sizes and used a retrospective and/or noncomparative study design.

225-Actinium (Ac) PRLT

Evidence Summary and Overall Conclusion(s)

- There is very-low-certainty evidence from 1 retrospective, non-comparative study with 40 mCRPC patients demonstrating 225-Ac PRLT decreased PSA levels, had an OS greater than 12 months, radiologic PFS of 6 months, and resulted in xerostomia and/or loss of taste events. There is very-low confidence that the reported effect estimate reflects the true effect due to the small, retrospective, non-comparative design from the single study that also lacked well-defined inclusion/exclusion criteria, long-term follow-up, and comparative evidence.

131-Iodine (I)-MIP-1095 PRLT

Evidence Summary and Overall Conclusion(s)

- There is very-low-certainty evidence from 1 retrospective non-comparative study with 34 mCRPC patients demonstrating 131-I-MIP-1095 PRLT decreased PSA levels, had a median time to PSA progression of 75 days, median OS of 17 months, with patients experiencing fatigue, leukopenia, thrombopenia, and xerostomia events. There is very-low confidence that the reported effect estimate reflects the true effect due to the small, retrospective, non-comparative design from the single study that also lacked well-defined inclusion/exclusion criteria, long-term follow-up, and comparative evidence.

References

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Abramaowitz, M., Li, T., Buyyounouski, M., Ross, E, Uzzo, R., Pollack, A. & Horwitz, E. (2007). The Phoenix definition of biochemical failure predicts for overall survival in patients with prostate cancer. *American Cancer Society, 112*(1), 55-60. Retrieved from Pubmed Database.

National Comprehensive Cancer Network (NCCN). 2022. *Prostate Cancer (Version 1.2023)*. Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A9513	Lutetium Lu 177, dotatate, therapeutic, 1 mCi
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
01/06/2023	01/10/2023[MPC]	1/23/2023

[MPC] Medical Policy Committee

Revision History	Description
1/10/2023	MPC approved coverage criteria for Pluvicto (Luteteium Lu 177 vipivotide tetraxetan) for Prostate Cancer. Requires 60-day notice; Effective June 01, 2023.
1/23/2023	Merged Lutetium Lu 177, dotatate (Lutathera) criteria to this Radiopharmaceuticals page with Lutetium Lu 177 vipivotide tetraxetan (Pluvicto). Archiving Lutathera criteria page.

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Breast Reduction (Mammaplasty) Surgery

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 16 120 Cosmetic Surgery.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Article	Billing and Coding: Plastic Surgery (A57222)

For Non-Medicare Members

Kaiser Permanente has elected to use the Reduction Mammaplasty (Mammoplasty) (KP-0274 v2) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (primary care physician)
- Physical Therapy notes if applicable
- Plastic surgery consultation
- Most recent height & weight

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Background

Reduction mammoplasty surgery is a covered benefit under Kaiser Permanente benefit packages when it is determined to be for medical rather than cosmetic reasons. This benefit was added by Kaiser Permanente on 11/1/83. Over the years several modifications have been made to the criteria. The main purpose of the criteria is to differentiate cosmetic from medical indications for the procedure.

Evidence and Source Documents

10/2012

Baasch M, Nielsen SF, Engholm G, Lund K Breast cancer incidence subsequent to surgical reduction of female breast. Br J Cancer April 1990; 73 (7): 961-961 1240 patients w surgical intervention for breast hypertrophy.

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Followed between 1943 and 1971. 32 cases of cancer identified by 1990. Expected number was 52.55 yielding a relative risk factor (RR) of 0.61. The greatest reduction was seen in women who had 600 or more grams or more of breast tissue. In the group who had the operation before the age of 20, 4 cases of breast cancer developed, compared to the expected 2.23, to give an RR of 1.79.
Dabbah A, Lehman J, Parker M, Tantri D, Wagner D Reduction Mammoplasty: An outcome analysis. Ann of P Surg October 1995; 35(4): 337-341
Survey of 285 consecutive female patients who had reduction mammoplasty between 1988 - 1993. Also, Chart reviews were conducted. Mean age was 40 and average follow-up was 37 months. 185 returned completed surveys and were included in the analysis. The most common complaints were: shoulder grooving (90%), back pain (82%), shoulder pain (78%), and neck pain (65%). The average amount of breast tissue removed was 855 gm from each breast (range 148 - 3,717 gm total). Most patients (97%) had improvement of symptoms. No statistically significant difference between obese and non-obese patients in outcomes or symptom relief and put into question the use of weight guidelines or bra-cup size reduction validation. The amount of breast tissue removed did not alter the outcome of surgery or relief of symptoms. The amount of breast tissue removed to relieve symptoms will vary with height, weight and bra-cup size for each patient. This puts into question the requirement of a maximum amount of breast tissue to be removed. Increase in complications when greater than 1,000 gm was removed from each breast. Overall patient satisfaction was high (95%, happy or very happy).
McMahan JD, Wolfe JA, Cromer BA, Ruberg RL. Lasting success in teenage reduction mammoplasty. Ann of P Surg September 1995; 35(3): 227-231 86 female patients less than 20 years of age. 48 contacted and returned questionnaire. Primary questions were: does the breast tissue grow back, what are the effects of future pregnancies and weight gain and do the potential consequences of surgery overshadow the early pain relief. Patient age range:15 - 19.9. Average range of follow-up was 5.9 yr (range 1.4-20.4). 72% reported regrowth of tissue. 11 patients had been pregnant since their surgery: 5 did not breast feed, 3 were unable to and 2 were still pregnant. The greatest improvements were seen in their presurgical symptoms, ability to increase their physical activity, and improvement in their self -esteem. None seemed to have problems with sexual pleasure from their breasts. Davis GM, Ringler SL, Short K, Sherrick d, Bengtson BP. Reduction Mammoplasty: Long-term efficacy, morbidity and patient satisfaction Plast Recon Surg 96: 1106-1110 780 female patients who had reduction mammoplasties between 1981 and 1992. 406 responded to a retrospective questionnaire. The mean age was 38yr. Follow-up average 4.7 yr. 60% of the study population was 5-10 kg over their ideal body weight as determined by the Metropolitan Life Insurance Company Statistical Bulletin (1985). Average reduction was 676 gram per breast (range 120-4200 gm). Conclusion was that women found that their preoperative symptoms were corrected by the surgery. Major complications are uncommon. Minor complications (50% of the women) are tolerated by the women. Thirty-seven women became pregnant following their operation. Of this population 68 % (25) successfully breast-fed their infants. Patients who lost nipple sensitivity were most likely to be dissatisfied with the procedure. Seitchik MW. Reduction Mammoplasty: Criteria for insurance coverage. Plast Recon Surg May 1995: 1029-1032The guidelines by which insurer determine eligibility for coverage of reduction mammoplasty must rely largely on subjective materials: reported patient symptoms, interpretation of photographs, determination of the amount of breast mass to be removed surgically. The author has attempted to find relationships between body weight and resected specimen weight that may be more objective.
100 consecutive reduction mammoplasties beginning 1991 recorded pre-op weight and height. The weight of resected breast tissue was obtained in the OR. Reduction planned for 46 to 70 kg body weight bra size of mid-B to small C. Above 70kg sizes ranged to a small D. Follow-up questionnaire 6 months postoperative. Based on his analysis he was unable to develop a model which would accurately predict preoperatively the amount of breast mass required to be removed to achieve the target bra size. He also felt that insurance company excise breast weight to determine eligibility for coverage was arbitrary.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19318	Breast reduction

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
09/26/1996	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 02/7/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	07/07//2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD Local Coverage Determination (LCD): Non-Covered Services L34886 and L35008
12/19/2017	Added LCD L37020
04/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare (KP-0274 MCG*): •**Added under 'Age 18* or greater'**: Younger patients can be approved on a case by case basis, with documentation from the surgeon as to the patient's appropriateness, including confirmation of full physical maturity and full understanding by the patient and her guardians as to the full nature of the surgery
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare (KP-0274 MCG*-see KP-0274 v2 eff 12/01/2020), including specificity for BMI parameters and the minimum amount of breast tissue to be removed. Added requirements for preoperative mammogram and smoking cessation for at least 30 days pre-op. Requires 60-day notice, effective date 12/01/2020.

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Clinical Review Criteria
Renal Sympathetic Nerve Ablation

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Renal Sympathetic Nerve Ablation***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Renal Sympathetic Nerve Ablation, Radiofrequency (A-1034) MCG* guideline for medical necessity determinations. This service is not covered per MCG* guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Renal sympathetic nerve ablation involves introduction of a catheter into the renal artery, with subsequent ablation of the sympathetic nerves of the artery and its branch vessels via use of a radiofrequency generator. Angiography is used to direct the procedure. Ablation of the sympathetic nerves is intended to reduce overall sympathetic drive and therefore improve blood pressure, especially in patients with resistant hypertension.

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Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
05/01/2021	05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved to adopt MCG A-1034 for Renal Sympathetic Nerve ablation. Requires 60-day notice, effective October 1, 2021.

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Clinical Review Criteria

Transcranial Magnetic Stimulation (TMS) for Treatment-Resistant Depression

- Medical Diagnoses
- Migraine Headaches
- Treatment Resistant Depression

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L37088)
Local Coverage Article (LCA)	Billing and Coding: Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (A57693)

For Non-Medicare Members

Service	Criteria Used
TMS	
Behavioral Health (treatment resistant depression)	MCG* B-KP-801-T For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Other diagnoses	Requires Medical Director Review

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Background

Repetitive Transcranial Magnetic Stimulation (rTMS)

Major depressive disorder is a common health condition, and is associated with substantial morbidity, mortality and health care costs. No single approach is uniformly effective at treating depression. Antidepressant treatment with SSRIs is currently a common first step. Approximately, two-thirds of patients respond to an initial course of antidepressants (O'Reardon et al., 2000). One alternative for non-responders is to switch to a different antidepressant, in the same or another class of medications. Findings from a recent RCT indicate that

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approximately 1 in 4 individuals who failed an initial course of SSRIs respond to a second one (Rush et al., 2006). Adding psychotherapy is another option for non-responders.

Interest in alternative treatment options, such as transcranial magnetic stimulation (TMS), has grown in recent years. TMS is a non-invasive method of modulating the brain's electrical environment by using magnetic fields. The technique involves applying alternating electrical currents through an insulated coil on the scalp which, ultimately, produces an electrical field in the brain, which in turn induces depolarization of nerve cells and results in the stimulation or disruption of brain activity. Changes in brain activity with TMS can be detected through various imaging techniques (PET, SPECT, or MRI). TMS can be delivered in either individual or repetitive pulses (the latter known as rTMS). Most studies of TMS for depression use repetitive pulses and target the left dorsal lateral prefrontal cortex (DLPFC). Reported side-effects of TMS are generally mild including headache, local discomfort, and transient change in auditory threshold, which can be prevented by the use of earplugs. Instances of mania and epileptic seizure, however, have been known to occur (Fitzgerald and Daskalakis 2008; George 2010; Shelton, Osuntokun et al. 2010; Slotema, Blom et al. 2010).

Several TMS devices, including the NeuroStar TMS system (Neuronetics, Atlanta, GA) and the Brainsway Deep TMS system (Brainsway Ltd., Jerusalem, Israel), have received 510(k) clearances by the United States Food and Drug Administration (FDA). The devices are indicated for the treatment of major depressive disorder (MDD) in adult patients who have failed one prior antidepressant medication at or above the minimal effective dose and duration. The medical technology and assessment committee (MTAC) previously reviewed TMS technology in 2009, and subsequently in 2011. In each case, the evidence failed to satisfy MTAC criteria due to inappropriate comparators and lack of established long-term efficacy.

Deep Transcranial Magnetic Stimulation (dTMS).

dTMS is a further development of the conventional rTMS. It uses a novel electromagnetic coil "the Hesel-coil or H-coil" which has a unique configuration designed to activate the brain tissue at a greater depth. the H-coil, comes in different variations and features, and unlike the conventional 8-figure coil, the H-coils that deliver the magnetic pulses are placed in a hood that is fitted to the head of the patient during treatment. The H-coils generate magnetic pulses that can penetrate 3-6 cm beneath the skull to stimulate deeper regions and neural pathways of the brain and produce antidepressant effects of greater magnitude compared to conventional rTMS. Each dTMS session includes a series of 2-second stimulations with a frequency of 18-20 Hz followed by a 20-second pause. One treatment session is thus equivalent to 40-55 stimulations, with a total of approximately 1700-2000 magnetic pulses delivered in 15-20 minutes. The acute treatment is administered 5 days a week for 4-5 weeks and is usually followed by maintenance phase in which treatment is delivered less often for up to 12 weeks (Roth 2007, Levkovitz 2015, Kedzoir 2016, Nordenskjold 2016).

Reported side effects include scalp discomfort, transient headache and dizziness, insomnia, perceiving an odd smell, numbness in the right cervical zone, and very rarely convulsions. The TMS machine produces loud snapping noises during stimulation and the patients are given earplugs for protection against hearing damage. However, some patients may still complain of hearing problems immediately following treatment (Bewernick 2015, Nordenskjold 2016).

An absolute contraindication to the use of any TMS is the presence of metallic or ferromagnetic objects in the head or eye, cochlear implants, implanted pacemakers, or other implants. Relative contraindications include history of previous epilepsy, skull trauma, cerebral damage of any etiology, severe headache or migraine, hearing loss, substance abuse, pregnancy, severe or recent heart disease, and systemic disease (Nordenskjold 2016, Valero Cabre 2017).

In 2013, the Brainsway Deep TMS system (Brainsway Ltd., (Har Hotzvim. Jerusalem, Israel), have received 510(k) clearances by the United States Food and Drug Administration (FDA) for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode. The Brainsway dTMS system is composed of an electromagnetic coil (H1 Coil), TMS neurostimulator, cooling system, a positioning device, and a cart.

Medical Technology Assessment Committee (MTAC)

Repetitive transcranial magnetic stimulation (rTMS)

06/01/2009: MTAC REVIEW

Evidence Conclusion: Active rTMS vs. sham treatment for treatment-resistant depression

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Efficacy: There is insufficient evidence on the long-term efficacy of rTMS for treatment-resistant depression. In the RCTs, patients were generally evaluated at the end of the treatment period, 4 weeks or less. A pooled analysis of the 4 studies that followed patients for an additional 1-2 weeks also found a significantly higher response rate with rTMS vs. sham treatment. There is sufficient evidence from a meta-analysis of 21 RCTs (Lam et al., 2008) that there is a higher short-term clinical response rate with rTMS compared to sham treatment (NNT=6). *Safety:* In the Lam meta-analysis, there was a low rate of withdrawals due to adverse effects overall, 2% of patients in the active rTMS group and 1.5% in the sham group. Janicak et al. (2008), in a study funded by Neuronetics, compiled safety data from one sham-controlled RCT and two unpublished open-label studies and found few treatment-related adverse effects. No deaths or seizures were reported among the 218 patients receiving active treatment A total of 41 serious adverse events were reported. 36 of the 41 were assessed by study investigators as unrelated to the study device. The 5 related events included 3 related to a manufacturing defect in a component of the study device, 1 was left-sided facial numbness and the fifth, deemed probably related, was not specified.
rTMS vs. other established treatment for treatment-resistant depression: There is insufficient evidence to draw conclusions about the safety and efficacy of rTMS for treatment-resistant depression compared to electroconvulsive therapy. One RCT comparing rTMS to ECT in this population was identified (Rosa et al., 2006). The study did not find a significant difference in the rate of clinical remission with rTMS compared to ECT. There were a relatively small number of patients enrolled, a relatively high drop-out rate and no analysis of statistical power, so conclusions cannot be made about equivalence of the treatments. There is insufficient evidence to draw conclusions about the safety and efficacy of rTMS for treatment-resistant depression compared to additional trials of antidepressants. No trials were identified comparing monotherapy with rTMS or antidepressants in this population. One RCT compared the combination of rTMS and escitalopram to escitalopram (plus sham rTMS) (Bretlau et al., 2008). The study, which included patients who failed at least one previous trial of antidepressants, used the difference in depression scores as the primary outcome, rather than the more clinically significant outcomes, clinical response or remission. With an appropriate statistical analysis, adjusting for multiple comparisons, there was a significant benefit of the combined active treatment group at the end of the three-week rTMS period, but no difference after an additional 9 weeks of medication treatment.
Articles: Active rTMS vs. sham treatment for treatment-resistant depression
The Pubmed searched yielded three meta-analyses of RCTs comparing rTMS for major depression to sham treatment. Only one of the three meta-analyses (Lam et al., 2008) focused on treatment-resistant depression, the FDA-approved indication and was critically appraised. No major sham-controlled RCTs were published after the meta-analysis literature search date (May 15, 2008). The search of the Cochrane database yielded a systematic review of rTMS for depression, but this review had not been updated since 2001 and was therefore excluded. A study that compiled safety data from several trials (Janicak et al., 2008) was reviewed, but an evidence table was not created. rTMS vs. other established treatment for treatment-resistant depression. One RCT comparing rTMS to ECT for patients with treatment-resistant depression (Rosa et al., 2006) was identified and critically appraised. Another RCT comparing rTMS and ECT had as its entry requirement, referral for ECT. The investigators did not specify that patients needed to have failed at least one treatment, so this study was excluded from further review. One RCT comparing rTMS to antidepressants for medication-resistant depression (Bretlau et al., 2008) was identified and critically appraised. Two other RCTs that evaluated the combination of rTMS and antidepressants as first-line treatment were excluded. The references for the studies that were reviewed are as follows: Bretlau LG, Lunde M, Unden M et al. Repetitive transcranial magnetic stimulation (rTMS) in combination with escitalopram in patients with treatment-resistant major depression. Pharmacopsychiatry 2008; 41: 41-47. See Evidence Table 1. Janicak PG, O'Rearson JP, Sampson SM et al. Transcranial magnetic stimulation in the treatment of major depressive disorder: A comprehensive summary of safety experience from acute exposure, extended exposure and during reintroduction treatment. J Clin Psychiat 2008; 69: 222-232. Lam RW, Chan P, Wilkins-Ho M et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: A systematic review and meta-analysis. Can J Psychiatr 2008; 53: 621-631. See Evidence Table 2. Rosa MA, Gattaz WF, Pascual-Leone A et al. Comparison of repetitive transcranial magnetic stimulation and electroconvulsive therapy in unipolar non-psychotic refractory depression: a randomized, single-blind study. Int J Neuropsychopharm 2006; 9: 667-676. See Evidence Table 1.

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of treatment-resistant major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/18/2011: MTAC REVIEW
Repetitive Transcranial Magnetic Stimulation (rTMS)
Evidence Conclusion: *rTMS vs. sham rTMS*: A recent RCT evaluated the safety and efficacy of daily left prefrontal cortex rTMS compared to sham rTMS for the treatment of antidepressant medication resistant depression in 190 patients with unipolar depression. The primary outcome was remission defined as a Hamilton Scale for Depression (HAM-D) score ≤3 or 2 consecutive HAM-D scored less than 10. Thirteen patients in the

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active rTMS group and five patients in the sham rTMS group experienced remission [Odds ratio 4.18, 95% CI (1.32-13.24), NNT=12]. There was no significant difference in adverse events by treatment arm. Results from this trial suggest that rTMS is more effective than placebo at treating medication resistant depression; however, this trial does not address the duration of the effect (George 2010). rTMS vs. venlafaxine ER the efficacy of rTMS over the right prefrontal dorsolateral cortex versus venlafaxine ER for the treatment of resistant depression was assessed in a recent RCT that followed 60 patients for 4-weeks. The primary outcome measure was change in Montgomery-Åsberg Depression Rating Scale (MADRS) score. Clinical response (more than a 50% reduction of the MADRS score) and remission (MADRS score ≤10 points) were also evaluated. There was no significant difference in mean change in MADRS score, clinical response, or remission rates between the two groups (Bares 2009).
Conclusion: There is insufficient evidence to determine the long-term safety and efficacy of rTMS for the treatment of depression in patients who have failed at least one prior antidepressant medication. Results from one RCT suggest that rTMS may be effective at treating medication resistant depression; however, this trial does not address the durability of the effect. Additionally, studies addressing the efficacy of rTMS differ with regards to the duration of treatment and treatment parameters. More research is necessary to identify the ideal duration of treatment and treatment parameters.
Articles: Studies were selected for review if they included at least 25 subjects and assessed either the safety or efficacy of transcranial magnetic stimulation for the treatment of depression. Studies were excluded if they addressed the safety or efficacy of TMS for the treatment of conditions other than depression; if they compared different TMS applications to each other; or if they lacked a valid comparison group. Two recent meta-analyses were also identified, but not selected for review. One meta-analysis that examined the efficacy of slow frequency (≤1 Hz) rTMS for the treatment of depression was not selected as the trials included were all published before the 2009 review (Schutter 2010). The other meta-analysis was not selected for review because of methodological limitations (Slotema 2010). Additionally, the majority of the articles included in these meta-analyses were also included in a previously reviewed meta-analysis. Two RCTs were selected for review. The following studies were critically appraised: Bares M, Kopecek M, Novak T, et al. Low frequency (1-Hz), right prefrontal repetitive transcranial magnetic stimulation (rTMS) compared with venlafaxine ER in the treatment of resistant depression: A double-blind, single-center, randomized study. *J Affect Disord 2009;* 118:94-100. See Evidence Table. George MS, Lisanby SH, Avery D, et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder: a sham-Controlled randomized trial. *Arch Gen Psychiatry 2010;* 67:507-516. See Evidence Table.

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of treatment-resistant major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/17/2015: MTAC REVIEW
Repetitive Transcranial Magnetic Stimulation (rTMS)
Evidence Conclusion: The BCBS TEC assessment, published in January of 2014, established that the available evidence on the use of TMS therapy for depression does not meet the TEC criteria. More specifically, the TEC assessment was not able to make conclusions with regard to the effect of TMS on health outcomes, net health outcomes, and, as a result, was unable demonstrate that the technology was as beneficial as any established alternative and that results were attainable outside the investigational setting (BCBS 2014). Subsequent to the TEC assessment, a group of European experts made a conflicting conclusion regarding the efficacy of TMS for the treatment of depression. In their analysis of the literature, the European experts made a level A recommendation establishing the efficacy of high frequency rTMS of the left DLPFC in depression (Lefaucheur, André-Obadia et al. 2014).
Effectiveness: In the first meta-analysis, Gaynes and colleagues pooled data from 18 trials with the overall aim to evaluate the efficacy of rTMS in patients with treatment resistant depression. In all three primary outcomes (severity of depression symptoms, response rate, and remission) the investigators reported that rTMS was superior to sham leading to the conclusion that rTMS is a reasonable, effective treatment option in patients with treatment-resistant depression (Gaynes, Lloyd et al. 2014). The second meta-analysis, carried out by Kedzior and colleagues, focused more on the durability of the antidepressant effect. In their analysis, data from 16 studies involving 495 patients demonstrated only a small antidepressant effect during follow up (Kedzior, Reitz et al. 2015). Safety: The literature reports several common events to be associated with TMS therapy including problems at the site of coil placement, tension like headaches and light-headedness with the most serious event reported being seizure. Overall, however, the technique appears to be relatively safe and reasonably well tolerated. Collectively, the body of published evidence relating to TMS therapy for depression is plagued with heterogeneity with a wide range of aims, outcomes and varying populations. To add to this, the technology is inherently limited by the lack of any established consensus regarding both the frequency and intensity of stimulation. Historically, TMS therapy for depression has failed MTAC criteria due to insufficient evidence. The

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current evidence remains conflicting and does not provide clear and convincing evidence that rTMS therapy is an effective and sustainable treatment option for depression. *Conclusion:* There is insufficient evidence to support the superiority of rTMS over antidepressants. There is evidence to support the short-term efficacy of rTMS over sham therapy. rTMS appears to be a relatively safe and well tolerated treatment.
Articles: The literature search identified an evidence-based guideline on the therapeutic use of rTMS in a variety of different conditions. (Lefaucheur, André-Obadia et al. 2014). In addition, a 2014 TEC (technology evaluation center) assessment produced by the Blue Cross and Blue Shield (BCBS) Association in association with Kaiser Permanente was identified (BCBS 2014). As a result, the literature search focused on updating the evidence base established by the guideline and TEC assessment (March 2014 through July 2015). The search yielded just over 200 publications including a variety of case series/reports, clinical trials, review articles, and meta-analyses. No studies were identified comparing rTMS as a monotherapy with antidepressants. The following studies were selected for critical appraisal: Gaynes BN, Lloyd S, Lux L, et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: a systematic review and meta-analysis. *J Clin Psychiatry*. 2014; 75(5):477-489. Kedzior KK, Reitz SK, Azorina V, et al. Durability of the antidepressant effect of the high-frequency repetitive transcranial magnetic stimulation (rTMS) in the absence of maintenance treatment in major depression: a systematic review and meta-analysis of 16 double-blind randomized, sham-controlled trials. *Depression and Anxiety*. 2015; 32:193-203.

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/09/2018: MTAC REVIEW
Deep Repetitive Transcranial Magnetic Stimulation (dTMS)
1. MTAC Discussion and Outcome

Randomized controlled trial (Levkovitz et al, 2015. Evidence table 1***)***

This was multicenter sham-controlled double-blind randomized trial that examined the safety and efficacy of dTMS using H-coil versus a sham therapy in adult patients with a first or recurrent depression episode fulfilling the DSM-IV criteria for MDD. The study enrolled 233 patients 22-68 years of age who had failed 1-4 adequate antidepressant treatments for the current episode. Symptom severity was equivalent to a score of at least 20 on the Hamilton Depression Rating Scale (HDRS) with 21 questions (HAMD-21).
The patients were randomly assigned to receive an active dTMS using the H-coil or a sham treatment that used a placebo coil placed next to the H1-coil. The coil was selected for each patient with a pre-programed card that was placed in a card reader attached to both-coils to maintain blinding of both the provide and the patient. All antidepressant medications were discontinued before the trial was begun.
Treatment was administered 5 days a week for 4 weeks, followed by twice-weekly treatment for up to 12 weeks. The treatment target was the dorsolateral prefrontal cortex on the left side with an intensity of 120% of the motor threshold with 2-s stimulations with 18 Hz followed by a 20-s pause, repeated 55 times over a total of ~20 minutes. The primary outcome was score change on the HAMD-21 after 4 weeks of therapy. Secondary outcomes were response and remission at 5 weeks, and adverse events. Response was defined as a reduction of ≥50% in the total HDRS-21 score compared to baseline; and remission was defined as a total HDRS-21 score <10.
233 patients were enrolled in the trial, N=212 were included in the ITT analysis, 181 (77%) in the per-protocol analysis. only 159 (68%) completed 5 weeks of the study and n=71 (30%) completed the 16 weeks.
Efficacy Levkovitz 2015 trial
The analysis showed that the treatment-group scored lower than the placebo group in the HDRS-21 from baseline to 5 weeks (primary outcome), The difference was not statistically significant according to the intention to treat analysis (ITT), but was statistically significant in the per-protocol analysis that included 77.7% of the patients enrolled (85% of those randomized to the treatment groups).
Validity of the trial
- The study was multicenter, randomized, controlled, double blinded, and had proper randomization and power analysis.
- dTMS was compared to sham therapy using an inactive coil, which is an important initial step to determine whether the treatment has a placebo effect. The trail, however, did not include a comparison arm with ECT or other alternative treatment to determine whether dTMS has a superior, inferior, or equivalent effect on TRD compared to other established therapies.
- The results showed no significant difference in the primary outcome between the active dTMS and sham therapy according to the ITT analysis. The difference, however, was significant in the PP analysis which does not consider the dropout due to insufficient improvement and/or compliance, or tolerance.

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- There were differences between the side effects and their rates reported to the FDA vs. those in the published article.
- Patients with psychosis, bipolar disorder, OCD, PTSD, any significant neurological disorder, increased risk of seizure or suicide were excluded from the study, which limits generalization of the results.
- The drop-out rate was high; only 68% of those initially enrolled completed the 5 weeks of treatment and less than one third completed the 16 weeks of the study, mainly due to insufficient improvement in the two study groups.
- The trial was supported by Brainsway the manufacturer of the dTMS H-coil; system, which is a potential source of reporting bias.

Meta-analysis: Kedzoir et al, 2015 (Evidence table 2***)***
Kedzoir and colleagues conducted a systematic review to investigate the acute antidepressant effect of dTMS using the H-coil in patients with MDD. The review included one RCT (Levkovitz, 2015) with 181 patients, and nine observational studies with a total of 162 patients. The observational studies very small (population sizes ranged from 6-29 participants); six were conducted in Israel, 2 in Italy and one in Canada. Most of the patients had treatment resistant unipolar depression and were on concurrent antidepressants (in only 2 studies dTMS was used as a monotherapy).
The authors pooled the results of the observational studies, and descriptively presented the results of the only one published RCT. The primary outcome was the change in standardized Hamilton Rating Scale for Depression scores, response rate, remission rate, and acceptability.
Validity of Kedzoir et al's meta-analysis
- The meta-analysis had generally valid methodology and analysis. However, due to the lack of published RCTs, the authors pooled the results of 9 small observational studies with a total of 162 patients. The observational studies did not include a control or comparison group that received a sham treatment, ECT or any alternative therapy and the results were based on pre-post comparisons.
- The calculated overall effect sizes may be inflated by the possible placebo effect of the TMS.
- The studies included in the meta-analysis used different definitions for remission rates, which as well as the response rates varied widely between the studies. Response rates tended to be higher among patients on concurrent antidepressants and to increase with time, while remission rates tended to decrease over time, but did not seem to be affected by the concurrent use of antidepressants.
- The small sample sizes of the studies included, the short follow-up duration, and lack of control or comparison group, do not allow making any conclusion on the efficacy of dTMS, the durability of the reported results, or comparative effectiveness to ECT or other alternative therapies.

Conclusion:
- There is insufficient evidence to determine the comparative efficacy and safety of dTMS to ECT or other alternative therapies.
- There is limited evidence from one RCT showing that dTMS may have a superior short-term benefit compared to sham therapy.

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
07/15/2009	06/01/2009, Reinstituted criteria annual review for Medicare 4/4/2011 MDCRPC, 5/3/2011 MDCRPC, 2/7/2012 MDCRPC, 12/4/2012 MDCRPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC, 03/07/2023MPC	03/03/2020

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
10/03/2017	MPC approved to adopt MCG hybrid criteria for rTMS
10/10/2017	Migraine Headaches removed from indication
09/20/2018	Added MTAC review and denial language for dTMS
11/06/2018	MPC approved coverage for deep TMS
03/05/2019	MPC approved the recommendation to add the indication to include 18 y/o and older
03/03/2020	MPC approved the amended criteria to the existing hybrid TMS criteria (B-KP-801-T) to include additional indications for Behavioral Health Exclusions, Continued Therapy and Extension Therapy.

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Retinal (Implant) Prosthesis System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Retinal (Implant) Prosthesis System*** for medical necessity determinations. Refer to the non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Retinitis pigmentosa (RP) comprises a group of hereditary eye diseases characterized by progressive degeneration of retinal photoreceptors; usually starting in the midperiphery of the fundus and advancing towards the macula and fovea. This field loss is progressive and usually does not reduce central vision until late in the disease resulting in severe visual loss that may lead to legal blindness. Like other areas of the mammalian central nervous system, neurons of the retina are not replaced following degeneration (Musarelle 2011, Petrs-Silva 2014, Rayapudi 2013)

Currently, there is no proven therapy for retinitis pigmentosa. However, there are worldwide efforts to develop new therapies for preserving or improving the retinal function. Therapeutic strategies that may potentially restore vision to patients who only retain light perception, or even no light perception vision, include optogenetics and retinal chip implants. Transcorneal electrostimulation is another technique that might help patients with retinitis pigmentosa who still have functional vision. Optogenetics uses light sensors to induce some cells to be reactive to light. The activated light sensor creates an electric current that can stimulate or inactivate a particular cell. Retinal chips on the other

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hand, use transducers to create electricity to replace the electrical stimulation that would normally be created by the photoreceptors. Eyes with retinitis pigmentosa respond to electrical stimulation from the retinal chip because the disease destroys the photoreceptors but leaves a significant percentage of inner retinal cells (ganglion and bipolar cells) intact and functional. The chip implants stimulate these remaining functional cells, thus bypassing the need for functioning photoreceptor cells. In order to restore visual function, chip implants have to detect light, convert light energy into electrical signal and deliver it to retinal neurons other than photoreceptors to elicit activity that is interpreted as vision (Garg 2013, Wieland 2011).

Retinal implants or prosthesis can be categorized according to the location of the stimulating electrodes. In clinical trials the electrodes were placed epiretinally, subretinally, suprachoroidally, or inside the optic nerve. In earlier feasibility studies the stimulating electrodes were placed temporarily (acute implantation). Chronic implantation on the other hand, refers to leaving the device in the subjects for a length of time. This requires considerable engineering to manufacture the device. Chronic retinal prosthesis can be divided into uncontrolled/passive stimulation devices or controlled /active stimulation devices, based on whether the electrical stimulation pattern can be controlled via software or just by light activation without the need for an external power source. Some of the major challenges for bioelectronic implants include long-term stable performance of the implanted electronics as well as a safe surgical impanation procedure (Weiland 2011).

Argus II retinal prosthesis system (Second Sight Medical Products Inc.) consists of an implantable device that is surgically implanted on and in the eye, and an external unit worn by the user. The implanted portion consists of a receiving and transmitting coil, a sealed electronic case fixed to the sclera outside the eye, and an electrode array (a 6 x 10 array of 60 electrodes) that is secured to the surface of the retina (epiretinal) inside the eye by a retinal tack. The electrode array is connected to the electronics by a metalized polymer cable that penetrates the sclera in the pars plana. The external unit consists of a small camera and transmitter mounted on a pair of sunglasses and a video processing unit (VPU) and battery that can be worn on a belt or shoulder strap. The camera captures a video and sends the information to the processor, which converts the image to electronic signals that are then sent to the transmitter on the glasses. The implanted receiver wirelessly receives these data and sends the signal to the electrode array via a small bus, where electric stimulation pulses are emitted. The controlled electrical stimulation of the retina induces cellular responses in retinal ganglion cells that travel through the optic nerve to the visual cortex and results in visual percepts. It is reported that positioning of the epiretinal array remains a challenge, since poor positioning was shown to lead to higher stimulus thresholds. In addition, object recognition including letter reading tasks generally requires head movement to move the camera. An implanted or an external camera coupled to eye movement may allow a more natural viewing experience for users (Weiland 2011, Lauritzen 2012, Dorn 2013).

Epiretinal implants have the advantage of their direct attachment to the ganglion cells which are the cells that need to be stimulated to generate a visual signal that is sent to the brain. A potential disadvantage of this however, is the unwanted stimulation for the retinal ganglion cells that can result in less distinct and /or wanted visual stimuli (Garg 2013).

Medical Technology Assessment Committee (MTAC)

Argus II Retinal Prosthesis System

04/21/2014: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of Argus II retinal prosthesis system in patients with profound visual loss due to retinitis pigmentosa. Argus II retinal prosthesis was evaluated in a small, multicenter, case series with no control group (evidence table1). The study enrolled 30 patients between June 2007 and August 2009. The primary performance endpoint was visual function as assessed by several visually guided tasks and orientation and mobility tasks. The primary safety endpoint was the number, severity, and relation of all adverse events. The study enrolled 30 blind patients 50 years or older (18 or older in some clinical sites) with a diagnosis of retinitis pigmentosa (or other outer retinal degeneration at some sites), with remaining vision of bare or no light perception in both eyes, and with a history of useful form vision. All participants received an Argus II implant and were regularly evaluated for a duration of 36 months. 28 of the 30 participants were available for testing. The results indicate that all 28 were able to perceive light during the postoperative stimulation of the implant. 57% were able to see the motion of a white bar moving across a black background, and many were able to identify some 3-4.5 cm letters on a high contrast background. The best vision was 20/1262. Adverse events associated with the Argus II system included conjunctival dehiscence or erosion over the extraocular implant in 16% of cases, endophalmitis (10%), and hypotony (10%). There was one intraoperative retinal tear, and two postprocedural retinal detachment. The adverse effects were treated in all patients except for one in whom the device had to be explanted.

Articles: The literature search revealed only one small observational study with no control or comparison group. The study was published in a number of journals articles and was critically appraised.

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Evidence Table. Ahuja AK, Dorn JD, Caspi A, et al. Blind subjects implanted with the Argus II retinal prosthesis are able to improve performance in a spatial-motor task. Br J Ophthalmol. 2011;95:539-543. da Cruz L, Coley BF, Dorn J, et al. The Argus II epiretinal prosthesis system allows letter and word reading and long-term function in patients with profound vision loss. Br J Ophthalmol. 2013;97:632-636. Dorn JD, Ahuja AK, Caspi A, et al. The Detection of Motion by Blind Subjects with the Epiretinal 60-Electrode (Argus II) Retinal Prosthesis. JAMA Ophthalmol. 2013;131:183-189. Parikh N, Itti L, Humayun M, et al. Performance of visually guided tasks using simulated prosthetic vision and saliency-based cues. J Neural Eng. 2013;10 (2):026017. doi: 10.1088/1741-2560/10/2/026017.

The use of Argus II Retinal Prosthesis System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy

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Date Created	Date Reviewed	Date Last Revised
05/06/2014	05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/06/2021

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
07/07/2020	Added Medicare LCA (A57642) for non-covered services
07/06/2021	Removed retired Medicare LCD (L35008) and LCA (A57642) for non-covered services. Added Kaiser Permanente Medical Policy statement for Medicare.

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Clinical Review Criteria
Radiofrequency Ablation

- Barrett's Esophagus
- Lung Cancer
- Renal Tumors
- Primary HCC and Metastatic Liver Cancer
- Uterine Fibroids

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Radiofrequency Ablation" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria Used
Barrett's Esophagus	Radiofrequency ablation is considered medically necessary for the treatment of members with Barrett's esophagus (BE) who have histological confirmation of low-grade dysplasia by two or more endoscopies three or more months apart.
Lung Cancer	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Renal Tumors Primary HCC and Metastatic Liver Cancer	Medical necessity review is no longer required for this service.
Transcervical Uterine Ablation of Leiomyomas	MCG* A-0782 This is not covered per MCG* For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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Evidence and Source Documents

Radiofrequency Ablation for the Treatment of Barrett's Esophagus
Radiofrequency Ablation in the Treatment of Lung Cancer
Radiofrequency Ablation of Renal Tumors
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
Radiofrequency Volumetric Thermal Ablation (RFVTA) of Uterine Fibroids Using the AcessaTM System

Medical Technology Assessment Committee (MTAC)

Radiofrequency Ablation for the Treatment of Barrett's Esophagus

BACKGROUND

Barrett's esophagus is a disease wherein the stratified squamous epithelium lining the esophagus gets replaced by metaplastic columnar epithelium. The disease affects more Caucasians than Blacks and is diagnosed around 55 years (Spechler & Goyal, 1996) and its prevalence varied widely from 0.4% to 20% (Gerson, Shetler, & Triadafilopoulos, 2002; Ormsby et al., 2000; Ward et al., 2006). Barrett's esophagus is caused by chronic gastro esophageal reflux disease (GERD). While Body mass index (BMI), is believed to be associated with increased risk of Barrett's esophagus (Kamat, Wen, Morris, & Anandasabapathy, 2009), studies have found that abdominal obesity is a risk factor for Barrett's esophagus (Corley et al., 2007; Edelstein, Farrow, Bronner, Rosen, & Vaughan, 2007; Kramer et al., 2013). It is not well known if germline mutations are associated with the disease.

Initially, Barrett's esophagus manifests with no symptoms or patients show signs of GERD. The most common symptoms of GERD are pyrosis (heart burn), regurgitation and dysphagia. Other manifestations of GERD are chronic cough, bronchospasm and laryngitis, chest pain resembling angina pectoris. GERD is complicated by erosive esophagitis, esophageal ulceration, stricture and hemorrhage (Spechler & Goyal, 1996), and Barrett's esophagus. The annual cancer incidence varied from 0.1 to 0.4% (Desai et al., 2012; Hvid-Jensen, Pedersen, Drewes, Sørensen, & Funch-Jensen, 2011; Rugge, Fassan, Cavallin, & Zaninotto, 2012; Shakhatreh et al., 2014). Studies have shown that the risk of developing cancer is proportional to dysplasia status and length of Barrett's esophagus (Pohl et al., 2016; Sikkema et al., 2011; Thota et al., 2015; Van der Veen, Dees, Blankensteijn, & Van Blankenstein, 1989). Patients with high-grade dysplasia have higher risk (4-8%) of progression to adenocarcinoma while patients with Barrett's esophagus, low-grade dysplasia and indefinite for dysplasia have a risk ranging from 0.2 to 1.2% (Singh et al., 2014; Verbeek et al., 2012). However, mortality due to esophageal adenocarcinoma is lower than that of other causes (Sikkema, De Jonge, Steyerberg, & Kuipers, 2010). Diagnostic is based on endoscopy and biopsy showing columnar epithelium and intestinal metaplasia respectively. Histology classification has described four types of Barrett's esophagus (BE); these include non-dysplastic (ND), low-grade for dysplasia (LGD), indefinite for dysplasia (ID), high-grade dysplastic (HGD).

General management includes proton pump inhibitor (PPI). Fundoplication may be an alternative for PPI resistance. Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) that inhibit cyclooxygenase (COX) have been described; however, these drugs have potential side effects. Surveillance has been promoted by many guidelines (Association, 2011; Fitzgerald et al., 2014; Shaheen, Falk, Iyer, & Gerson, 2016) but its benefit is not well documented. In addition, surveillance modality depends on the type of dysplasia. Treatment of dysplasia is of greatest importance. Several approaches have been described and include endoscopic ablative therapies, endoscopic resection or the combination of both, and esophagectomy. Endoscopic resection encompasses removal of both mucosa and submucosa (Pech, May, Gossner, Rabenstein, & Ell, 2004) and can lead to stricture. Endoscopic ablative therapies consist of radiofrequency ablation (RFA), photodynamic therapy, and endoscopic spray cryotherapy.

RFA uses radiofrequency energy and produces thermal injury to destroy the mucosa. Energy used comes from a balloon equipped with a series of electrodes to ablate the mucosa (Sharma et al., 2007). The radiofrequency energy can either be delivered circumferentially or focally. There are two different devices and accessories, both manufactured by BARRX. The balloon based HALO360 device is used to treat circumferential areas of BE. The system includes a high-power energy generator, a sizing balloon catheter and several balloon-based ablation catheters. There are 60 tightly spaced, bipolar independent electrodes encircling the balloon through which the energy is delivered. A preselected amount of energy is delivered in less than a second at 350 W. This allows for full thickness ablation of the epithelium without damage to the submucosa. The HALO [90] ablation system is used to treat more focal areas and uses a radiofrequency generator and an endoscope mounted electrode. Both procedures can be done on an outpatient basis. Barrx90 ULTRA, Barrx60, and Channel RFA device are alternative options for focal ablations.

02/01/2010: MTAC REVIEW
Radiofrequency ablation for the treatment of Barrett's Esophagus
Evidence Conclusion: The literature search revealed only one published randomized controlled trial (Shaheen et al, 2009) that compared radiofrequency ablation of Barrett's esophagus to a sham endoscopic procedure. The trial had valid design and analysis; it was multicenter, appropriately randomized, controlled, blinded, had sufficient statistical power, and with low dropout rate. However, radiofrequency ablation was compared to a sham procedure and not to another established alternative procedure with a curative intent for BE with dysplasia e.g. endoscopic resection, esophagectomy, or photodynamic therapy. Moreover, the trial had only one year of follow-up which is insufficient to determine the long-term efficacy, and safety of the procedure. Due to the short follow-up duration, the authors used neoplastic progression and eradication of dysplasia and metaplasia as surrogates for death from cancer. The trial randomized 127 patients (in a 2:1 ratio) with low- or high-grade dysplasia to undergo either radiofrequency ablation or sham endoscopic therapy. Randomization was stratified according to grade of dysplasia (LGD or HGD) and length of BE lesion (<4 or 4-8cm). Those in the ablation group underwent step-wise circumferential and focal ablation using HALO 360 and HALO 90 systems (BARRX Medical Inc, Sunnyvale, CA). Patients in the two groups underwent endoscopic surveillance for the study period; biopsies were obtained throughout the BE length every 3 months in patients with HGD or 6 months among those with LGD. After 12 months of follow-up, the results of the trial showed that more than three fourths of patients treated with radiofrequency ablation had complete eradication of intestinal metaplasia and dysplasia (77 % of all BE was completely reversed into normal epithelium among those who received RFA, vs. 2% in the control; 90% of patients with LGD, and 81.5% with HGD had complete eradication of the dysplasia vs. 23% and 19% of the controls respectively). The ablation therapy was also associated with a significant decrease in the risk of cancer but, as acknowledged by the authors this should be interpreted with caution due to the small number of cases. RFA therapy was not without risk as 5 (6%) cases developed esophageal stricture that required endoscopic dilatation, and 3 (3.5%) had other serious events as bleeding and chest pain.
Conclusion:

- There is fair evidence from one RCT with short-term follow-up that radiofrequency ablation using the HALO systems is superior to sham therapy (no therapy) in the treatment of BE with dysplasia.
- There is insufficient evidence to determine that RFA to has better outcomes and less harms than alternative therapies with curative intent for BE with dysplasia.
- There is insufficient evidence to determine the long-term efficacy, and safety of radiofrequency ablation therapy in the management of patients with Barrett's esophagus with dysplasia, and whether the risk of ablation is less than the risk of progression of BE.
- There is insufficient evidence to determine that radiofrequency ablation therapy eliminates the necessity for of further endoscopic surveillance of patients with Barrett's esophagus with dysplasia.
- There is insufficient evidence to determine that radiofrequency ablation therapy reduces or eliminates cancer risk in patients with Barrett's esophagus with dysplasia.

Articles: The search yielded around forty articles. Many were reviews, letters, and editorials. There was one randomized controlled trial and number of case series and reports. The RCT and the majority of the case series were conducted by the same group of investigators. The RCT with the following citation was critically appraised. Shaheen NJ, Sharma P, Overholt B, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. N Engl J Med 2009; 360:2277-2288. See Evidence Table

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The use of Radiofrequency ablation for the treatment of Barrett's esophagus with dysplasia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

09/19/2016: MTAC REVIEW
Radiofrequency ablation for the treatment of Barrett's Esophagus
Evidence Conclusion: RFA vs alternative treatment Systematic review comparing radiofrequency ablation and complete endoscopic resection in treating dysplastic Barrett's esophagus: a critical assessment of histologic outcomes and adverse events (Chadwick et al, 2014) (evidence table 1) The first study is a systematic review aiming to compare the efficacy and safety of complete endoscopic mucosal resection (EMR) and radiofrequency ablation (RFA) in the treatment of dysplastic BE. It was reported that dysplasia was eradicated in 95% and 92% of patients treated with EMR and RFA respectively. Intestinal metaplasia (IM) eradication was similar between both groups. After (23 and 21 months for EMR and RFA respectively) months of follow-up for patients, who were treated with EMR, dysplasia eradication was achieved in 85% of patients versus 79% among RFA group. In EMR group, additional treatments were reported in 7 studies. In EMR group, overall short-term adverse events were 12.5% and most frequently acute bleeding. In RFA group, overall short-term adverse events were 2.5% and most frequently acute bleeding (1%). In EMR group, overall long-term adverse events were 38% and most frequently stricture compared to 4% in RFA group. Buried BE was 3.8% in EMR group vs. 0% in RFA group (not reported in table). Progression to cancer appeared to be low in both groups. This indicates that both treatments are effective in the management of HGD BE but more events that are adverse are observed with EMR. However, the review is mostly based on observational studies. Ten studies were directly or indirectly industry funded; only 3 RCTs were represented in the review. Individual studies were small. Follow-ups periods were short (<1 year) and varied greatly limiting accurate assessment of cancer progression and incidence of recurrence. Fair evidence shows that both treatments are effective in managing HGD BE but RFA has less adverse events. **Radiofrequency ablation vs endoscopic surveillance for patients with Barrett's esophagus and low-grade dysplasia a randomized clinical trial (Phoa et al 2014)** (evidence table 2) This RCT investigated whether endoscopic radiofrequency ablation could decrease the rate of neoplastic progression. Compared to control group, patients who were treated with RFA, were less likely to progress to high grade dysplasia or cancer. At the end of endoscopic treatment, (After RFA), 92.6% and 88.2% of complete eradication of dysplasia and IM were observed respectively. During follow-up, patients who were treated with RFA were more likely to obtain complete eradication of dysplasia; the risk of complete eradication of dysplasia was increased by 70.5%. Complete eradication of intestinal metaplasia was maintained in 54of60patients (90.0%) receiving ablation compared with 0 of 68 patients receiving control (risk difference, 90% [95% CI, 82.4%-97.6%]; P < .001). Adverse events are represented by abdominal pain, bleeding, stricture, laceration, retrosternal pain while no adverse events were reported for endoscopic surveillance. The results indicate that in patients with low-grade dysplasia, RFA reduced the risk of progression to high-grade dysplasia or adenocarcinoma by 25% corresponding to an NNT of 4.0. Study had a valid methodology in general. However, it had some limitations: external validity is compromised (referral centers), study was underpowered for cancer-related death outcome which is the primary end point. Endoscopic rescue therapy was performed to decrease residual Barrett tissue. Based on the Cochrane collaboration's tool for risk of bias assessment, the overall risk of bias is low with unclear information on blinding. Fair evidence supports efficacy of RFA over endoscopic surveillance for low grade dysplasia. **Endotherapy versus surgery for early neoplasia in Barrett's esophagus: a meta-analysis (Wu et al., 2014)** (evidence table 5) This meta-analysis aimed to compare the efficacy and safety of endotherapy and surgery for early neoplasia in BE. A systematic literature search was performed up to December 2012 and included 870 patients. No significant difference between endotherapy and esophagectomy in the outcomes presented in the table below. However, endotherapy was associated with a higher neoplasia recurrence rate and fewer major adverse events. Limitations include: a small number of studies including retrospective studies; patients were not comparable in some studies leading to bias of the results. Different endotherapies including EMR, PDT, RFA and argon plasma coagulation were used. The type of surgery and the experiences of surgeons were different. Publication bias might also exist. Low evidence supports similar efficacy between endotherapy and surgery in the treatment of early Barrett's neoplasia with fewer adverse events. Efficacy of RFA (non-comparative studies. **Efficacy and durability of radiofrequency ablation for Barrett's esophagus: systematic review and meta-analysis** (Orman et al, 2013) (evidence table 3) This systematic review aimed to determine the efficacy and durability of RFA for patients with dysplastic and nondysplastic BE. The authors found 91% of patients achieved CE-IM while 78% achieved CE-D and that in 13% of cases, IM recurred after successful

treatment. Most common adverse events were stricture (5%) and pain (3%). Although the study has valid methodology, limitations included the poor quality of included studies and external validity. Settings include referral centers with capability in RFA. Heterogeneity was high. Adverse events may have been underestimated due to the retrospective design of a number of studies. Individual studies were small in size. Follow-ups periods were short. RFA was not compared to alternative treatment limiting accurate assessment. The results indicate that CE-IM and CE-D were achieved in most of the patients undergoing RFA with low IM recurrence and low adverse events.

Several prospective studies have assessed the efficacy of RFA. Their findings can be found in the following table. However, none of these studies compare RFA to alternative treatment.

Author, year	N	Intervention	Protocol	BE baseline	Median Follow-up (mos)	Findings	Adverse events
(Phoa et al., 2014)	132	ER combined with RFA	Visible lesions were removed with ER followed by serial RFA every 3 months. Follow-up endoscopy was scheduled at 6 months after the first negative post-treatment endoscopic control and annually thereafter	BE≤12 cm with HGD and/or EC	27	CE-neo:92% CE-IM: 87% Recurrence: neo and IM 4% & 8% respectively	Mucosal lacerations (8%) and stenosis (6%).
(He et al., 2015)	96	RFA	RFA was used at baseline to treat all unstained lesions (USL), and then biopsy (and focal RFA if USL persisted) was performed every 3 months until all biopsies were negative for MGIN, HGIN, and ESCC	moderate/high grade intraepithelial neoplasia [MGIN/HGIN] and early flat-type esophageal squamous cell carcinoma [ESCC]	12	73% & 84% of complete response at 3 and 12 months respectively. Progression in 2%	Stricture (21%)
(Haidry et al., 2014)	508	RFA/EMR	Visible lesions were removed by EMR. Thereafter, patients had RFA 3-monthly until all BE was ablated or cancer developed	HGD or IMC	6 years	CE-D: 77% to 92% CE-IM:56% to 83% (p<0.0001) Progression to OAC at 12 months (3.6% vs. 2.1%, p=0.51) Risk of IM recurrence at 5 years: 32%	
(Small et al., 2015)	246	EMR and/or ablation therapy		HGD/IMC		83.7% with HGD 75.7% with IMC	

BE, Barrett's esophagus; ER, endoscopic resection; EMR, endoscopic mucosal resection

Low grade dysplasia **Meta-analysis of endoscopic therapy for low-grade dysplasia in Barrett's oesophagus (Almond et al 2014)** (evidence table 4) This systematic review aimed to identify systematically all reports of endoscopic treatment of LGD, and to assess outcomes in terms of disease progression, eradication of dysplasia and intestinal metaplasia, and complication rates. The search was performed from January 1988 to January 2013. 37 studies reporting outcomes of endoscopic therapy for 521 patients with LGD. Study quality was assessed using Jadad scale for controlled trials and the Newcastle–Ottawa scale for uncontrolled trials. The results indicated that 67.8% and 88.9% achieved CE-IM and CE-D respectively. The overall incidence of progression to cancer is 3.90. The authors concluded that RFA does not eradicate the risk of progression to cancer, but it appears to be safe and effective at eliminating LGD. Fair evidence supports the efficacy and safety of RFA in the treatment of low-grade dysplastic BE. However, studies with longer follow-up are needed.

Conclusion:

- Fair evidence shows that Radio frequency ablation (RFA) and endoscopic mucosal resection are both effective in managing HGD BE but RFA has less adverse events.

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- Fair evidence supports efficacy of RFA over endoscopic surveillance for low grade dysplasia.
- Low evidence supports similar efficacy between endotherapy and surgery in the treatment of early Barrett's neoplasia
- There is fair evidence that RFA is effective and safe for the treatment of low-grade dysplasia; however, studies with long follow-up are needed.
- There is sufficient evidence to determine whether RFA is effective and safe for the treatment of high-grade dysplastic Barrett's esophagus.

Articles: The literature revealed a number of articles, but the following articles were selected for critical appraisal: Systematic review comparing radiofrequency ablation and complete endoscopic resection in treating dysplastic Barrett's esophagus: a critical assessment of histologic outcomes and adverse events (Chadwick et al, 2014) See Evidence Table 1. Radiofrequency ablation vs endoscopic surveillance for patients with Barrett's esophagus and low-grade dysplasia a randomized clinical trial (Phoa et al 2014) See Evidence Table 2. Efficacy and durability of radiofrequency ablation for Barrett's esophagus: systematic review and meta-analysis (Orman et al, 2013) See Evidence Table 3. Meta-analysis of endoscopic therapy for low-grade dysplasia in Barrett's oesophagus (Almond et al 2014) See Evidence Table 4. Endotherapy versus surgery for early neoplasia in Barrett's esophagus: a meta-analysis (Wu, Pan, Wang, Gao, & Hu, 2014) See Evidence Table 5.

The use of Radiofrequency ablation for the treatment of Barrett's esophagus with dysplasia does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Ablation in the Treatment of Lung Cancer

BACKGROUND

Lung cancer is the leading cause of cancer related mortality in the United States. It has two main types; the non-small cell lung cancer (NSCLC) which accounts for approximately 80-85% of cases, and the small cell lung cancer (SCLC). After the initial diagnosis of the disease is made, it is essential to have an accurate TNM staging in order to determine the appropriate therapy. The standard treatment of patients with stage I or II NSCLC is surgical resection, and in order to achieve a potential cure from the disease, the cancer must be completely resectable through pneumonectomy or lobectomy, and the patient should be able to tolerate the surgery and have adequate pulmonary function. Patients with more advanced or metastatic lung disease, or who cannot tolerate surgery, due to age or the presence of other co-morbidities, are poor surgical candidates. They are traditionally offered treatment with conventional external beam radiotherapy which is considered the most reasonable alternative. However, its results have not been satisfactory, and it has lower overall long-term survival than complete surgical resection. This radiation therapy may also be associated with regional complications as radiation pneumonitis, fibrosis, and esophagitis, and is not indicated for pulmonary metastases. Chemotherapy was found to have only a modest therapeutic effect and is usually used as palliative therapy. This has led the researchers to develop minimally invasive techniques as stereotactic radiotherapy, brachytherapy, photodynamic therapy, bronchial artery infusion of chemotherapy, cryotherapy and radiofrequency ablation (RFA) (D'Amico 2003, Qiao 2003, Pennathur 2007). Radiofrequency ablation is a relatively new minimally invasive therapy that potentially leads to localized tissue destruction. It works by transferring radiofrequency (RF) energy from a generator through an electrode, to the target tissues. The waves are converted into heat, resulting in thermal damage, and coagulative necrosis of the tissues. For solid organ tumor ablation, thin RF electrodes are introduced laparoscopically or percutaneously to the target lesion under ultrasound, CT, or MRI guidance. A power of 5-120W is delivered to the electrodes, and an alternating current of 450-1,200 kHz passes from the tip to the surrounding tissue. When the temperature of the tumor cells is raised above 70oC cell destruction occurs. Several radiofrequency ablation devices were cleared by the FDA as tools for general ablation of soft tissue by thermal necrosis. The devices were also cleared for ablation of liver lesions, and bone metastases. According to the FDA, they have not been cleared for lung tumor ablation as their safety and effectiveness have not been fully established. In December 2007, the FDA issued a public health notification to alert the health practitioners of the deaths associated with lung tumor ablation using the radiofrequency devices (FDA Web site).

06/04/2008: MTAC REVIEW

Radiofrequency Ablation in the Treatment of Lung Cancer

Evidence Conclusion: There is limited evidence on the efficacy and safety of radiofrequency ablation for the treatment of lung cancer in patients who are not candidates for surgical resection. The body of evidence

consists of small observational case series with no control or comparison groups that compare the RF ablation with conventional or other noninvasive techniques used for the treatments of patients with non-operable lung cancer, or those who cannot tolerate surgery. The published studies were heterogeneous; there were differences in the eligibility criteria of the studies, patient characteristics, stage of the disease, cancer type, number and sizes of the lesions, as well as other tumor characteristics. There were also variations in the ablation approaches, types of devices used to deliver the therapy, follow-up, endpoints, and outcome measures. Moreover, the follow-up duration in the majority of the studies was too short to determine the long-term safety and effectiveness of the therapy. Overall, the results of the published studies indicate that the median survival of patients receiving the therapy ranged from 8.6 months to 33 months. The one-year survival rate ranged from 63-85%, the two-year survival was 55-65% and the three-year survival rate was 15-46%. Complete tumor necrosis ranged from 38% to 95%, and local disease recurrence varied from 3% to 38.1%. The studies indicate the RF ablation has better outcomes with tumors smaller than 3 cm in diameter vs. those >3cm in diameter, as this would allow oversizing of the ablation areas. The adverse effects associated with FR ablation included pneumothorax that often-needed aspiration, pleural effusion, hemoptysis, pain, as well as other complications some of which required hospitalization of the patients. The authors of the published studies presented the results for all patients combined, with no adjustments for confounding factors as age of the patients, presence of other co-morbidities and/or malignancies, or the use of other adjuvant therapy. Moreover, in the absence of comparison groups, it is hard to determine whether radiofrequency ablation leads to better local control or improved survival outcomes than external beam radiation therapy or any other noninvasive treatment. In conclusion there is insufficient published evidence to determine the efficacy and safety of radiofrequency ablation for the treatment of lung cancer.
Articles: The search yielded over 300 articles. Many were review articles or publications not related to the current review. No meta-analyses of empirical studies randomized, or non-randomized controlled studies were identified. The majority were observational prospective case series with population sizes ranging from <10 to 60 patients. There was a larger (N=153) retrospective observational study that evaluated the long-term efficacy and safety of the therapy. Prospective series with at least 50 patients, and/or with longer-term follow-up, as well as the larger retrospective series were selected for critical appraisal. *The following studies were critically appraised:* DE Baire T, Palussiere J, Auperin A, et al. Midterm local efficacy and survival after radiofrequency ablation of lung tumors with minimum follow-up of 1 year. Prospective evaluation. Radiology 2006.240:587-596. See Evidence Table. Ambrogi MC, Lucchi M, Dini P, et al. Percutaneous radiofrequency ablation of lung tumors: results in mid-term. Eur J Cardiothorac Surg. 2006. 30:177-183. See Evidence Table. Gadaleta C, Catino A, Mattioli V. Radiofrequency thermal ablation in the treatment of lung metastases. In Vivo. 2006; 20:765-768. See Evidence Table. Simon CJ, Dupuy DE, DiPetrillo TA, et al. Pulmonary radiofrequency ablation: Long-term safety and efficacy. Radiology 2007.243:268-275. See Evidence Table.

The use of Radiofrequency ablation in the treatment of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Ablation of Renal Tumors
BACKGROUND
With the widespread use of body imaging techniques as magnetic resonance imaging (MRI), computed tomography (CT), there is an increasing number of pre-symptomatic, incidentally detected small renal masses or lesions with unclear clinical significance. The standard treatment for renal masses is radical nephrectomy. Other available treatment options for these small, incidentally discovered masses include watchful waiting or partial nephrectomy. Recently, with the current trend of minimally invasive surgery, nephron-sparing approaches have gained more acceptance. Among these are radiofrequency (RF) ablation, cryoablation, microwaves, and high intensity focused ultrasonography (HIFU). These techniques are still under development and only target selected, small renal tumors with a diameter of 4 cm or less. RF ablation works by transferring RF energy from a generator through an electrode, to the target tissues. The waves are converted into heat, resulting in thermal damage, and coagulative necrosis of the tissues. For solid organ tumor ablation, thin RF electrodes are introduced laparoscopically, or percutaneously to the target lesion under ultrasound, CT, or MRI guidance. A power of 5-120W is delivered to the electrodes, and an alternating current of 450-1,200 kHz passes from the tip to the surrounding tissue. When the temperature of the tumor cells is raised above 70°C cell destruction occurs. The size of the lesion depends on the thermal properties of the tissue, the time, and the amount of the energy delivered. Radiofrequency ablation has been used for selected liver and bone tumors. It is approved by the FDA for ablation of aberrant atrioventricular conduction

pathways in patients with Wolf-Parkinson-White syndrome, and for treating soft-tissue lesions in the liver. Its use for human renal tumors is still under investigation, and its efficacy and safety as well as its dosimetry have not been fully established.

12/11/2002: MTAC REVIEW
Radiofrequency Ablation of Renal Tumors
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of radiofrequency ablation for the treatment of renal tumors.
Articles: The search yielded one review article, two case reports and three case series with 10-15 patients each. There were no meta-analyses or randomized controlled studies.

> The use of radiofrequency ablation in the treatment of renal tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
BACKGROUND
The liver is a common site for primary and secondary malignancies. Hepatocellular carcinoma (HCC), the most common primary tumor is the fifth most common cancer in the world, and the third most common cause of cancer-related mortality. It is responsible for more than half a million deaths across the globe each year. Treatment options for patients diagnosed with primary and secondary malignancies are limited. Less than 15% are candidates for surgical resection at presentation because of inadequate liver functional reserve, extrahepatic disease, anatomic constraints of the tumor, or medical comorbidities. The use of external beam radiation is limited due to the intolerance of normal liver parenchyma to tumoricidal radiation doses (the dose required to destroy solid tumors (>70 Gy) is much higher than the liver tolerance dose of 35 GY). In addition, systematic chemotherapy was found to have little impact on survival, and negative impact on the health-related quality of life due to the toxicity to other organs and systems. These limitations have led to the emergence of other therapies, such as radiofrequency ablation (RFA), cryosurgical ablation (CSA), percutaneous ethanol injections (PEI), hepatic arterial infusion chemotherapy, transarterial chemo-embolization (TACE), and selective intrarterial radioembolization therapy (Steel 2003, Salem 2005, Ibrahim 2008, Bult 2009, Riaz 2009, Bhardwaj 2010). Ablative techniques improve the ability to treat patients with unresectable hepatic tumors. Thermal ablative techniques, such as RFA, destroy tumors via a source that changes temperature to levels that are associated with cell death while causing minimal damage to adjacent, normal tissue. Chemical ablative techniques, such as PEI, involve the injection of cancer killing chemicals such as pure alcohol (ethanol) or acetic acid directly into the tumor. The choice of technique depends on equipment availability and physician preference. PEI is a chemical ablative technique where absolute or 95% ethanol is injected into tumor tissue resulting in coagulative necrosis through cytoplasmic dehydration, denaturation of cellular proteins, and small vessel thrombosis. When the consistency of the tumor is ‘soft’ within a ‘hard’ cirrhotic liver (most HCCs), the distribution of ethanol is relatively uniform; however, when the tumor is ‘hard’ within a ‘soft’ normal liver (most metastases), the distribution is not as uniform. For this reason, PEI works better for HCC than for metastases. Complications of PEI include: hyperthermia, pain, elevated serum liver function tests, needle-tract seeding, pleural effusion, biliary stricture, portal vein thrombosis, and bleeding in the biliary tract (Clark 2007, Yamane 2009). The most commonly used ablative technique in the United Stated is RFA. RFA causes tumor destruction through the use of alternating high-frequency electric current in the radiofrequency range (460-500 kHz). This current is delivered through an electrode placed in the center of a lesion. Ions within the cell follow the alternating current creating frictional heat producing local tissue temperatures that can exceed 100°C. This ionic agitation leads to tissue destruction via tissue boiling and creation of water vapors. Once temperatures greater than 60°^{C} are reached, protein denaturation, tissue coagulation, and vascular thrombosis result in a zone of complete ablation. Partial tissue destruction can occur up to 8 mm in diameter from the zone of complete ablation. RFA can be delivered either percutaneously, laparoscopically, or through open approaches (laparotomy). Complications from RFA include pleural effusion, hepatic abscess, biliary injury, liver failure, intra-abdominal hemorrhage, pneumothorax, and hypoxemia. The most troubling complications arise when a probe is placed too close to the diaphragm or intra-abdominal organ, resulting in ablation of the surrounding viscera with the accompanying complications of perforation, diaphragmatic injury, or pulmonary damage. Limitations of RFA include: treating lesions in perihilar areas or near large vascular structures, and real time monitoring of the ablative zone is difficult due

to air released during heating (Yamane 2009, Arciero 2006). RFA has received FDA approval for generic tissue ablation and the ablation of unresectable colorectal cancer metastases.

08/11/1999: MTAC REVIEW
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
Evidence Conclusion: The best published scientific evidence evaluating percutaneous radiofrequency (RF) ablation of liver cancer consists of one case series of 39 patients with primary hepatocellular carcinoma and 11 patients with other primary tumors who had liver metastases. The majority of patients had 3-4 treatments with one or more nodules being ablated at each session. Five patients experienced mild pain during the procedure; no other complications were reported. The 5-year survival rate among those with primary hepatocellular carcinoma was 40%; the period of follow-up for persons with liver metastases was too short for the calculation of a 5-year survival rate. Because the survival rate of patients treated with RF ablation was not directly compared to that of a control group, it is not possible to determine whether this treatment improves survival among patients with liver cancer.
Articles: Rossi S, DiStasi M, Buscarini E, Quartetti P, Garbagnati F, Squassante L, Paties CT, Silverman DE, Buscarini L. Percutaneous RF interstitial thermal ablation in the treatment of hepatic cancer. AJR Am J Roentgenol 1996; 167: 759-68. See Evidence Table.

The use of radiofrequency ablation in the treatment of primary HCC does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/08/2001: MTAC REVIEW
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
Evidence Conclusion: Only one study on radiofrequency ablation was a controlled trial. The remainder were case series. The trial reported on a clinically intermediate outcome, liver necrosis, not survival. The case series reports had survival information, but this was not presented in a standardized format (e.g. 1-year survival, 3-year survival). Instead, they reported on survival after a certain mean or median follow-up time (patients had different amounts of follow-up time) which is more difficult to interpret. For primary HCC, in the one trial comparing RF ablation to an alternative technique, PEI, both techniques resulted in high rates of complete necrosis and the difference in rates was not statistically significant (Livraghi). PEI required more sessions and RF ablation had more adverse effects (there was 1 major and 4 minor complications with RF ablation, none with PEI). In the case series reviewed (Curley), there was a 72% survival rate after a median of 19 months of follow-up (all patients had at least 12 months follow-up). Livraghi (2001) (not critically appraised for this review) reported on a case series of patients with HCC treated with PEI. The 1-year survival rate for patients with a single HCC 5 cm or smaller was 98, 93 and 64%, respectively for Child's A, B and C cirrhosis. For metastatic hepatic cancer, de Barre found that 81% patients survived after a mean follow-up of 14 months; 62% of these who survived had hepatic disease or distant metastases. 2-year or longer follow-up data were not available. This does not appear to be a dramatic increase in survival compared to untreated metastatic liver cancer (mean survival 6 to 21 months), but there is not strong evidence to support this claim. No studies compared RF ablation treatment to another treatment for metastatic liver cancer such as cryosurgery. In a case series on cryosurgery for hepatic colorectal metastases (Ruers, 2001) (not critically appraised for this review), the 1-year survival was 76% and the 2-year survival was 61%. The effectiveness of RF ablation may differ depending on the type of metastatic tumor.
Articles: The search yielded 85 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were no randomized controlled trials or meta-analysis. There was one non-randomized controlled trial and the rest of the empirical articles were case series. Articles on HCC and metastatic liver cancer were analyzed separately. Two studies on primary hepatocellular carcinoma were reviewed (the non-randomized trial and a recent case series with a moderate sample size by a different research group): Livraghi T, Goldberg SN, Lazzaroni S, Meloni F, Solbiati L, Gazelle GS. Small hepatocellular carcinoma: Treatment with radiofrequency ablation versus ethanol injection. Radiology 1999; 210: 655-661. See Evidence Table. Curley SA, Izzo F, Ellis LM, Vauthey JN, Vallone P. Radiofrequency ablation of hepatocellular cancer in 110 patients with cirrhosis. Ann Surg 2000; 232: 381-91. *One study on metastatic liver cancer was reviewed (the largest case series with the longest follow-up):* de Barre T, Ellas D, Dromain C, El Din MG, Kuoch V, Ducreux M. et al. Radiofrequency ablation of 100 hepatic metastases with a mean follow-up of more than 1 year. AJR 2000; 175: 1619-25. See Evidence Table.

The use of radiofrequency ablation in the treatment of primary HCC does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/21/2010: MTAC REVIEW
Radiofrequency Ablation of Primary HCC and Metastatic Liver Cancer
Evidence Conclusion: While there are many studies comparing RFA with resection and other ablative techniques, such as PEI, for the treatment of liver cancer, the data are difficult to compare since the studies are heterogeneous in study design, patient selection, data collection, tumor characteristics, primary cause of liver disease, route of access, electrode types used, and periinterventional systemic treatment. **Primary Liver Cancer** *RFA vs. Resection* The study selected for critical appraisal was a randomized controlled trial that compared the results of RFA with resection for the treatment of solitary and small HCC. Overall and disease-free survival rates were not statistically different for patients with solitary HCC < 5 cm in diameter treated with either RFA or resection. Additionally, patients treated with RFA had fewer major complications than patients treated with resection (0.04% vs. 56%, p<0.05). Treatment groups were comparable at baseline for all characteristic measured with the exception of serum alanine aminotransferase (ALT). Patients in the RFA group had higher serum ALT concentrations compared to patients in the resection group. Factors that limit the validity of the study include: uneven dropout rates, use of additional techniques, and lack of generalizability (Chen 2006). Another nonrandomized study comparing RFA with resection demonstrated similar survival outcomes between RFA and resection for tumors <5 cm (Montorsi 2005). One recent retrospective study suggested that overall and disease-free survival was higher for patients treated with resection compared to patients treated with RFA. However, in a subgroup analysis by tumor size, there was no significant difference in survival between RFA and resection for patients with tumors ≤3 cm. Results from this study should be interpreted with caution as this study contained significant selection bias; most patients who underwent RFA had more advanced tumors and worse liver function than those who received resection (Guglielmi 2008). *RFA vs. PEI There* are several published randomized controlled trials and meta-analyses comparing the efficacy of RFA versus PEI. Two of the most recent meta-analyses were selected for appraisal (Germani 2010, Bouza 2009). Results were consistent across the two analyses. Compared to patients treated with PEI, patients treated with RFA had higher three-year overall survival rates (73% RFA vs. 58% PEI, p<0.001) and lower rates of local recurrence (7% RFA vs. 22% PEI, p<0.001). Patients treated with RFA experienced more complications (19% RFA vs. 11% PEI, p<0.001) than those treated with PEI; however, there was no difference in the rate of major complications (4% RFA vs. 3% PEI, p=0.22).The most frequent complication reported in both groups was severe pain. All studies included in the analysis were classified to be trials with high-risk of bias. *RFA + PEI vs. RFA alone* There have been several published studies comparing PEI + RFA versus RFA alone. A randomized controlled trial was selected for review (Zhang 2007). Results from this trial suggest that overall survival is higher for patients with HCC treated with PEI + RFA versus RFA only (p=0.04). In a subgroup analysis by tumor size, survival was significantly better for those treated with PEI + RFA who had tumors between 3.1 and 5.0 cm compared to those treated with RFA only (p=0.03). There was no significant difference in survival for patients with tumors ≤3 cm or tumors 5.1-7.0 cm. The local recurrence rate was higher for those treated with RFA alone compared to those treated with PEI + RFA (p=0.01). There was no significant difference in overall, intrahepatic, or extrahepatic recurrence rates. There were no procedure related mortalities or major complications. Pain and fever were the most commonly seen minor complications. Data after 2-years should be interpreted with caution as less than 45% of patients were followed for 3-years. Results are not generalizable to women as less than 15% of the patients enrolled in the study were women. Additionally, the predominant cause of HCC in the study was hepatitis B while the predominant cause of HCC in Japan, Europe, and the United States is hepatitis C and alcohol abuse. *Secondary Liver Cancer RFA vs. Resection* No randomized controlled trials evaluating RFA compared to resection for unresectable liver metastases from colorectal cancer were identified. Results from a retrospective cohort study indicate that patients treated with resection had the highest overall and disease-free survival rates and the lowest rates of recurrence compared to patients treated with RFA alone or RFA + resection. Results from this study should be interpreted with caution as this study contained significant selection bias. Patients who were treated with RFA were not eligible for resection (Abdalla 2004). The majority of other studies (Park 2007, Aloia 2006, Hur 2009) comparing RFA and resection reached similar conclusions regarding survival and recurrence rates; however, a few studies have found that survival rates were comparable (Oshowo 2003). It is hard to compare results across studies as the primary cause of the disease differs, techniques differ, and disease characteristics differ. Additionally, none of the treatment groups

were comparable at baseline. Patients treated with RFA were not eligible for resection. *Conclusion:* There is fair evidence that overall and disease-free survival rates were not statistically different for patient with solitary HCC <5 cm in diameter treated with either RFA or surgical resection. There is fair evidence that patients with HCC treated with RFA have better survival and lower recurrence rates than patients treated with PEI. There is fair evidence that for patients with HCC and tumors between 3.1 and 5.0 cm in diameter the combined treatment of PEI plus RFA versus RFA alone increases survival; however, long term follow-up is needed. There is insufficient evidence to determine the efficacy of RFA compared to surgical resection for patients with liver metastases. **Articles:** The literature search yielded around 250 articles pertaining to the use of RFA. The majority of these articles were case series and cohort studies. Only one randomized controlled trial (Chen 2006) was identified that compared RFA with resection for small HCC. There were several RCTs and meta-analyses comparing RFA with PEI. The two most recent meta-analyses (Bouza 2009, Germani 2010) were selected for review. There were several studies comparing the combined use of PEI and RFA. Many of these studies did not have a control group or did not assess survival as an outcome. An RCT that compared PEI + RFA with RFA alone was selected for review (Zhang 2007). No randomized controlled trials or meta-analyses were found pertaining to the use of RFA for metastatic liver cancer. The literature consisted mainly of case series and cohort studies. A retrospective cohort study (Abdalla 2004) that compared resection to RFA was selected for review. The following studies were critically appraised. Chen MS, Li JQ, Zheng Y et al. A prospective randomized trial comparing percutaneous local ablative therapy and partial hepatectomy for small hepatocellular carcinoma. *Ann Surg 2006;* 243:321-328. See Evidence Table. Bhardwaj N, Strickland AD, Ahmad F et al. Liver ablation techniques: a review. *Surg Endosc 2010;* 24:254-265. Bouza C, López-Cuadrado T, Alcázar R et al. Meta-analysis of percutaneous radiofrequency ablation versus ethanol injection in hepatocellular carcinoma. *BMC Gastroenterol 2009;* 9:31-39. See Evidence Table. Germani G, Pleguezuelo M, Gurusamy K et al. Clinical outcomes of radiofrequency ablation, percutaneous alcohol ablation and acetic acid injection for hepatocellular carcinoma: A meta-analysis. *J Hepatol 2010;* 52:380-388. See Evidence Table. Zhang YJ, Liang HH, Chen MS et al. Hepatocellular carcinoma treated with radiofrequency ablation with or without ethanol injection: A prospective randomized controlled trial. *Radiology 2007;* 244:599-607. See Evidence Table. Abdalla EK, Vauthey JN, Ellis LM et al. Recurrence and outcomes following hepatic resection, radiofrequency ablation, and combined resection/ablation for colorectal liver metastases. *Ann Surg 2004;* 239:818-827. See Evidence Table.

The use of radiofrequency ablation in the treatment of primary HCC does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Laparoscopic Radiofrequency Volumetric Thermal Ablation (RFVTA) of Uterine Fibroids Using the AcessaTM System

BACKGROUND

Uterine fibroids, also known as uterine myomas or leiomyomas, are non-cancerous tumors that grow within the wall of the uterus. They are the most common pelvic neoplasms in women, occurring among 20-40% of those in the reproductive age and 70%-80% by the age of 50. Uterine myomas are commonly classified into 3 subgroups according to their location: subserosal (projecting outside the uterus), intramural (within the myometrium) and submucosal (projecting into the cavity of the uterus. (A more recent classification was developed by International Federation of Gynecology and Obstetrics [FIGO]). Uterine fibroids also vary in size and number ranging from one tiny seedling to multiple bulky mases that can significantly enlarge the uterus. The majority of uterine leiomyomas are asymptomatic and can go unnoticed or are incidentally detected on clinical examination or imaging. However, 20-50% are symptomatic causing abnormal uterine bleeding (AUB) including menorrhagia, dysmenorrhea, pelvic pressure, back pain, and fertility issues (Brucker 2014, Chittawar 2015, Vilos 2015, Lee 2016).

Uterine fibroids are currently the leading indication of hysterectomy worldwide. Hysterectomy is the most effective and definitive treatment for symptomatic fibroids, however, many women desire to preserve their fertility and/or conserve their uterus. Myomectomy is the alternative procedure for these women; it can be performed by conventional laparotomy or by minimal access techniques such as laparoscopy, robotic-assisted laparoscopy, hysteroscopy, or other modified techniques depending on the number, size, and location of the fibroids. Each technique has its benefits and associated harms, but myomectomy in general carries the risk of fibroid recurrence and potential need for future hysterectomy. The recurrence rate ranges from 10-50% depending on age, number of fibroids, uterine size, and childbirth after myomectomy.

Conventional laparotomy has been the approach of choice for many surgeons, but it is associated with intra- and post-operative blood loss requiring blood transfusion in approximately 20% of cases. Laparoscopic myomectomy performed by a highly skilled laparoscopic surgeon is associated with less blood loss, diminished postoperative pain, faster recovery, and shorter hospital stay compared to abdominal myomectomy. However, the multilayer suturing may be challenging, and the procedure takes longer to perform and requires surgical expertise and specialized equipment. In addition, there may be a limit to the size and number of lesions removed laparoscopically. There is also a concern about the risk of uterine rupture occurring in the second or third trimester of pregnancy after laparoscopic myomectomy. A recently raised concern is the risk of power morcellation in cases of undiagnosed uterine malignancy while removing the fibroids laparoscopically as this may result in disruption and wide dissemination of an unrecognized sarcoma (Brucker 2014, Chittawar 2015, Vilos 2015 Kramer 2016).
Alternative non-surgical or minimally invasive management options for uterine fibroids include medical treatment (hormonal and non-hormonal); magnetic resonance guided focused ultrasound surgery (MRgFUSD), uterine artery embolization (UAE), laparoscopic occlusion of uterine arteries, and radiofrequency (RF) myolysis or ablation of the myomas (Chittawar 2015, Vilos 2015).

Myolysis was introduced in the 1980s as a conservative option for treating myomas. It uses a focused energy to cause tissue destruction. Energy sources include laser, bipolar, monopolar, cryoprobe, or thermal radiofrequency ablation (RFA). In general, a radiofrequency system consists of a generator, an electrode, electrode return pads, and cables connecting these elements. The generator produces high frequency, low voltage, alternating current that is transmitted via an electrode with an insulated shaft. Placing the electrode into the target tissue results in transmission of the current through the tissue. The current then travels to the electrode return pads and back to the generator completing the circuit. The heat produced by ionic movement within the cells adjacent to the exposed portion of the electrode, spreads and produces volumetric ablation through coagulative necrosis (Lee 2016)

In 2002 Lee BB, first reported on the use of RF ablation under laparoscopic intraabdominal ultrasound guidance to treat patients with symptomatic myomas. A number of observational small feasibility studies using different systems were published along the years (Chudnoff 2013, Chittawar 2015, Kramer 2016, and FDA website accessed April 2017). The Acessa™ System (Halt Medical, Inc., Brentwood, CA) is an ultrasound guided system for performing radiofrequency volumetric thermal ablation (RFVTA) of fibroids in the outpatient setting. The system consists of several components including a dual function RF generator, a disposable 3.4 mm diameter hand piece with a deployable 7-needle electrode array, a handpiece cable, two disposable dispersive electrode pads, pad cable, power cord, and a foot pedal. It is designed to deliver up to 200W of RF power in 3 operational modes: Temperature Control, Manual Control, and Coagulation Mode. Additional equipment needed for the RFA procedure using the Acessa™ system include a standard laparoscopic tower (insufflator, camera box, light source and printer), laparoscope 5 or 10 mm, ultrasound machine with laparoscopic transducer, and two video monitors one for the laparoscopic image and one for the ultrasound image (Chudnoff 2013, lee 2016 and Acessa website accessed April 2017).

The procedure is performed under general anesthesia and laparoscopic intra-abdominal ultrasound guidance. The laparoscopic ultrasound probe is used to determine the location and size of all fibroids present. The RFA handpiece tip is then inserted percutaneously through a 2-mm skin incision and directed into each myoma with laparoscopic and ultrasound guidance to verify the appropriate placement of the device within each myoma. The electrode array is then deployed, the appropriate duration of ablation is determined, and the treatment applied. Once the ablation is completed, the generator is switched to coagulation mode to seal the tract during withdrawal of the handpiece and provide hemostasis. Irregular myomas and those ≥ 4 cm in diameter require multiple overlapping ablations to ensure adequate ablation of the myoma periphery. After ablation, the myomas are not replaced by fibrous tissue, but are gradually reabsorbed by the surrounding myometrium. Complete reabsorption depends on the completeness of ablation, location of the myoma and weal as its size (Vilos 2015, Lee 2016).

More recently a transvaginal approach was introduced for delivering the energy without the need for general anesthesia. The procedure was examined in an observational study in China and used a different radiofrequency generator (Jiang 2014).

06/21/2017: MTAC REVIEW

Evidence Conclusion: **Comparative studies** the only randomized controlled trial identified by the literature search was a single center study that compared the laparoscopic ultrasound guided radiofrequency volumetric thermal ablation (RFVTA) of uterine fibroids versus laparoscopic myomectomy (LM). It is an industry sponsored ongoing post-market RCT trial with a 5-year follow-up plan. The perioperative results of the trial as well as follow-up data at 12 and 24 months were reported in three publications (Brucker 2014, Hahn 2015, and Kramer 2016) (Evidence Table 1). The trial compared RFVTA to LM which is more invasive treatment, rather than to a minimally invasive procedure such as uterine artery embolization (UAE). The primary outcome was the mean time to hospital discharge which may not be the ideal primary outcome as patients undergoing LM may require one day stay in the hospital. In this trial all 25 patients in the LM group were hospitalized overnight to monitor for potential post-procedure bleeding. Patient symptoms and safety of the procedure were secondary outcomes based on subjective responses to validated questionnaire. The study was not blinded, which is a potential source of bias, and it was only powered to detect significant differences between the two treatments for the primary outcome and not for the patient outcomes that matter. The perioperative results show significantly less time spent in hospital and less bleeding with RFVTA compared to LM (Brucker 2014 Evidence Table 1).

Outcons in the two intervention groups (Brucker 2014)

Outcomes	LM group* N=25	RFVTA N=25	P value
Time to hospital discharge in hours, Mean	29.9 ± 14.2	10.0 ± 5.5	<0.001
Median	22.6	7.8	
Range	16.1-68.1	4.2-25.5	
Intraoperative blood loss in ml, Mean	51 ± 57	16 ± 9	Not provided
Median	35	20	
Range	10-300	0-30	

Patients were kept overnight in the hospital for observation

At 12-months women in the two treatment groups reported significant reduction in their symptom severity and improvement health related quality of life (HR-QoL) compared to baseline. The reported improvements were better with LM compared to RFVTA, but the differences between the two groups were not statistically significant. The only statistically significant difference between the two groups was the degree of patient satisfaction (very vs. moderately satisfied) favoring the myomectomy group. Two women in the ablation group underwent hysterectomy and one underwent myomectomy (Hahn 2015). The interim analysis at 24 months also showed significant improvement in the patient-reported symptom severity for both interventions compared to baseline. However, the improvement reported in health-related quality of life reached a statistically significant level only among patients in the LM group (Kramer 2016). The authors concluded that both interventions have similar clinical benefits, and that 12-and 24-months data suggest equivalence in safety and patient-reported efficacy of RFVTA and LM. However, the study was not designed nor powered as an equivalent trial and the numbers were too small to provide sufficient statistical power to detect significant differences. A lack of significant statistical difference does not necessarily indicate equivalence. The trial was randomized and controlled, but not without limitations. It was a single-center, relatively small, and unblinded trial. 14% of the study population was not included in the 12- and 24-months analysis which was based on per-protocol rather than on intention to treat (ITT) analysis, and on patient-reported outcomes. The study was conducted in Germany among 100% white women, with symptomatic fibroids <10 cm diameter, and other strict inclusion/exclusion criteria, that may limit generalization of the results. In addition, there were some baseline differences between the two study groups as regard age, number, size, and location of fibroids. The authors indicated that randomization occurred intraoperatively after laparoscopic ultrasound mapping of the uterus to classify the fibroid and define its size and location, and did not indicate whether any patient was excluded from randomization based on the ultrasound results, which may be a potential source of selection bias. **Non-comparative studies** the literature search identified two small low-quality feasibility studies and a one non-comparative observational study (Halt trial), the pivotal study that led to the FDA clearance of the

Acessa System in 2012. Halt trial (Chudnoff 2013, Guido 2013, Berman 2014). (See Evidence Table 2) was a prospective multicenter study that examined the efficacy and safety of laparoscopic ultrasound-guided RFVTA of uterine myomas in symptomatic women. The study enrolled 137 women with documented fibroids and menstrual blood loss between 150 and 500mL from 11 centers in the US and Latin America (additional inclusion /exclusion criteria are provided in the evidence table). The primary outcomes were the volume of menstrual bleeding compared to baseline, surgical re-intervention and device related adverse events at 12 months, Secondary outcomes included uterine volume measurements, patient-reported Uterine Fibroid Symptom and Health Related Quality of Life (QoL) scores and general health outcome scores at 3-6 and 12 months. Guido, 2013 and Berman, 2014 reported on the effect of the RFVTA on symptom severity qualitative clinical outcomes at 2- and 3 years after the intervention based on the patients' responses to validated questionnaires.

Rate of reduction in menstrual blood from baseline to 12 months

Outcome	
Decrease of menstrual blood from baseline to 12 months	n/N 104/127 81.9%
% women with ≥ 50% reduction in menstrual flow from baseline to 12 m	42% (95% CI, 31.6-48.7%)
% women with ≥ 40% reduction in menstrual flow from baseline to 12 m.	48.8% (95% CI, 40.1-57.5%)
% women with ≥ 30% reduction in menstrual flow from baseline to 12m.	59.1% (95% CI, 50.5-67.6%)
% women with ≥ 22% reduction in menstrual flow from baseline to 12 m.	67.7% (95% CI, 59.6-75.8%)

The results suggest that menstrual blood loss was significantly reduced from baseline to 12 months post-procedure. By the end of 12 months after the procedure there was one surgical intervention for persistent bleeding and one serious adverse event. Between 12 and 24 months 6 more women underwent surgical intervention for fibroid-related bleeding and one experienced severe adverse event during and after a Cesarean section delivery. By 36 months a total of 14 women (11.0%) had repeat surgical re-interventions for fibroid symptoms (11 hysterectomies, 2 myomectomies, and 1 uterine artery embolization). The results also show significant improvement in patient-reported symptom severity and health related QoL at 3 months compared to baseline, and that all quality of life and health state scores remained stable over 12, 24, and 36 months of follow-up. 5 patients (4%) experienced treatment-related adverse events including pelvic abscess, laceration in sigmoid colon, vaginal bleeding, severe lower abdominal pain and superficial uterine serosal burn. One woman got pregnant and delivered a healthy full-term baby by C-section, but experienced severe bleeding during the surgery and 48 hours later. Halt trial was sponsored by Halt Medical, the manufacturer of Acessa™ System. It was not a comparative trial and only aimed at examining the safety and efficacy of the procedure. The study was multicenter and included a diverse population, but had strict inclusion /exclusion criteria as regards the size of the leiomyomas, size of the uterus, minimum preoperative hemoglobin and other variables including limiting the procedure to women who did not desire future childbearing, all of which may limit generalization of the results.

Conclusion

- There is insufficient published evidence to determine that laparoscopic ultrasound guided radiofrequency volumetric thermal ablation (RFVTA) of symptomatic uterine myoma has superior or equivalent results as other therapies/interventions used among women with symptomatic fibroids who desire to conserve their uterus. The only comparative study published to date, was small, unblinded, and only powered to detect significant difference in the length of post procedural hospital stay with RFVTA versus laparoscopic myomectomy. It was not powered to detect differences in the clinical outcomes or quality of life. A lack of significant differences does not necessarily indicate equivalence.
- There is insufficient evidence to determine the safety of the laparoscopic ultrasound RFVTA or the durability of the observed benefit over the years. The comparative study was too small and with insufficient follow-up period. The other studies examining the safety of the procedure were all observational; the largest and longest of which was the pivotal Halt trial which reported significant benefit and durability of the effect of the intervention for up to three years. However, similar to the other published

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observational studies on this technology, it had its limitations; had no control or comparison group, and the majority of outcomes were subjective. The three-year follow-up of Halt trial shows an increasing rate of repeat surgeries along the years. By the end of the third year, 14 (12%) of the women who entered the 3-year follow-up had repeat surgeries 11 (79%) of which were hysterectomies

Articles: The literature search for studies on laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids identified 4 studies with population sizes ranging from 31 to135, reported in 9 publications. Only one study was randomized and controlled with its results were published in three articles (Brucker 2014, Hahn 2015, and Kramer 2016). The others were observational, non-comparative studies including a very small short feasibility study (Garza 2011), a small study (N-35) with 12 months follow-up (Robles 2013) and the pivotal Halt trial (published in 4 articles (Chudnoff 2013, Guido 2013, Galen 2013, and Berman 2014). The RCT and the HALT trial were selected for critical appraisal. Berman JM, Guido RS, Garza Leal JG, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *J Minim Invasive Gynecol*. 2014 Sep-Oct; 21(5):767-774. Brucker SY, Hahn M, Kraemer D, et al. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *Int J Gynaecol Obstet*. 2014 Jun; 125(3):261-265.Chudnoff SG, Berman JM, Levine DJ, et al. Outpatient procedure for the treatment and relief of symptomatic uterine myomas. *Obstet Gynecol*. 2013 May; 121(5):1075-1082. Galen DI, Isaacson KB, Lee BB. Does menstrual bleeding decrease after ablation of intramural myomas? A retrospective study. *J Minim Invasive Gynecol*. 2013 Nov-Dec; 20(6):830-835. Guido RS, Macer JA, Abbott K, et al. Radiofrequency volumetric thermal ablation of fibroids: a prospective, clinical analysis of two years' outcome from the Halt trial. *Health Qual Life Outcomes*. 2013 Aug 13; 11:139. Hahn M, Brucker S, Kraemer D, et al. Radiofrequency Volumetric Thermal Ablation of Fibroids and Laparoscopic Myomectomy: Long-Term Follow-up from a Randomized Trial. *Geburtshilfe Frauenheilkd.* 2015 May; 75(5):442-449. Krämer B, Hahn M, Taran FA, et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. *Int J Gynaecol Obstet*. 2016 May; 133(2):206-211.

The use of Laparoscopic Radiofrequency Volumetric Thermal Ablation (RFVTA) of Uterine Fibroids Using the AcessaTM System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Barrett's Esophagus- Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
With Diagnosis Codes	
K22.70	Barrett's esophagus without dysplasia
K22.710	Barrett's esophagus with low grade dysplasia
K22.711	Barrett's esophagus with high grade dysplasia
K22.719	Barrett's esophagus with dysplasia, unspecified

Lung Cancer - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency

Transcervical Uterine Ablation of Leiomyomas - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Dates Reviewed	Date Last Revised
07/17/2008	Added to annual review on 04/04/2011 MDCRPC, 02/07/2012 MDCRPC,12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC ,11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC	04/05/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
05/03/2016	Combined RFA Barrett's Esophagus and Lung Cancer into one policy
10/04/2016	Added MTAC Review
11/01/2016	MPC approved criteria of medical necessity for Barrett's Esophagus
08/01/2017	Added MTAC Review for RFVTA
12/05/2017	Adopted KPWA Policy for Barrett's Esophagus and Uterine Fibroids for Medicare
08/28/2018	Removed non-covered LCD for lung cancer
11/17/2020	Removed references to vertebral augmentation for painful spinal metastases as there is already separate criteria for vertebroplasty
04/05/2022	MPC approved to adopt MCG* A-1039 Transcervical Uterine Ablation of Leiomyomas. This service continues to be considered not medically necessary.

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Clinical Review Criteria
Rhinoplasty

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Article	Billing and Coding: Plastic Surgery (A57222) Cosmetic vs. Reconstructive Surgery (A52729) Medicare retired Article for Cosmetic vs. Reconstructive Surgery (A52729). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCAs are not retired because they are incorrect. Therefore, continue to use LCA A52729 for determining medical necessity.

For Non-Medicare Members

Kaiser Permanente has elected to use the (MCG)* Rhinoplasty (KP-0184) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The nose is responsible for almost 2/3 of the resistance to airflow during breathing, with most of the resistance occurring in the anterior part of the nose, called the nasal valve, comprised of the external and internal valves. External valve collapse may be idiopathic or associated with a history of trauma or previous surgery; common causes of internal valve collapse are septal deviation and previous surgery. Restoration of the normal aperture of the internal and external components of the nasal valve are important treatment strategies for the correction of

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nasal obstruction.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
06/04/2013	06/04/2013[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/2/2015	Added LCA
12/19/2017	Added the Plastic Surgery LCD
08/04/2020	Added Medicare LCA A57222

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KAISER PERMANENTE®

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Clinical Review Criteria
Robotic Assisted Surgeries (RAS)

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Criteria

For Medicare Members

This policy does not apply to Medicare members.

For Non-Medicare Members

Kaiser Permanente will not separately reimburse for the use of robotic surgical systems, including but not limited to the CPT/HCPCS codes listed in this document.

Please refer to Kaiser Permanente payment policy for reimbursement clarifications.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Robotic assisted surgery involves use of a computerized system operated by a surgeon at a computer console connected with robotic arms. The system is used to assist in laparoscopic surgical procedures. Robotic assisted surgery may allow for finer more precise control of the instruments by the surgeon, though surgery may take longer. Laparoscopic surgery is associated with improved postsurgical pain and recovery and with lower risk of infection and blood loss for some procedures compared with open surgery.

In 2000, the da Vinci robot was approved by the Food and Drug Administration (FDA) for general laparoscopic surgery. Numerous other indications for the da Vinci system have since been approved by the FDA, including urological procedures, gynecologic laparoscopic procedures, general thoracoscopic procedures, and others. In 2007, the American Medical Association determined that an additional CPT code for robotic-assisted procedures was not necessary.

Robotic assisted surgery has been used in the following procedures:
Prostatectomy; Hysterectomy; Nephrectomy; Cardiac Surgery; Adjustable Gastric Band; Adnexectomy; Adrenalectomy; Cholecystectomy; Colorectal Surgery (Colorectal Resection, Colectomy, Mesorectal Excision); Cystectomy; Esophagectomy; Fallopian Tube Reanastomosis; Fundoplication; Gastrectomy; Heller Myotomy; Ileovesicostomy; Liver Resection; Lung Surgery; Myomectomy; Oropharyngeal Surgery; Pancreatectomy; Pyeloplasty; Rectopexy; Roux-en-Y Gastric Bypass; Sacrocolpopexy; Splenectomy; Thymectomy; Thyroidectomy; Trachelectomy; and Vesico-vaginal Fistula.

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In March 2013, the American Congress of Obstetricians and Gynecologists released a statement that said in part, "There is no good data proving that robotic hysterectomy is even as good as—let alone better—than existing, and far less costly, minimally invasive alternatives."

The Health Care Authority in Washington State conducted an evidence review for each procedure listed above and found the evidence to be minimal in most cases. The outcome of their review was to not pay additionally for the use of the robotic device use.

Applicable Codes

Not separately reimbursed:

CPT® Codes	Description
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
03/04/2014	03/04/2014[MPC], 04/01/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/06/2021

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD Non-Covered Services L34886
05/04/2020	Updated the Non-Medicare statement to match the Kaiser Permanente Payment Policy for Robotic Assisted Surgery
07/07/2020	Added Medicare LCA (A57642)
07/06/2021	Removed retired Medicare LCD (L35008) and LCA (A57642) for non-covered services. Added statement that policy does not apply to Medicare members.

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Clinical Review Criteria
Sacral Nerve Stimulator for Fecal and Urinary Incontinence

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Sacral Nerve Stimulator for Urinary Incontinence (230.18)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017)

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Implanted Electrical Stimulator, Sacral Nerve (A-0645) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG* are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

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The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Fecal incontinence is the inability to control the loss of fecal matter from the bowel. Management of fecal incontinence includes conservative therapy, such as dietary and lifestyle changes, antidiarrheal medications, biofeedback therapy, absorbent pads, and anal plugs, as well as surgical interventions, such as direct sphincter repair and implantation of an artificial sphincter (Mowatt 2007, Tan 2011).

Sacral nerve stimulation is a treatment option for patients who have failed or could not tolerate conservative therapy. It involves applying electrical stimulation to a sacral nerve via an electrode that is placed through the corresponding sacral foramen. In order to be a candidate for sacral nerve stimulation, patients must undergo a testing phase known as peripheral nerve evaluation to determine if the treatment might prove effective. The peripheral nerve evaluation determines the feasibility of electrode implantation and involves a 2 to 3-week period of stimulation with a temporary electrode to assess the potential benefits of the therapy. If significant benefit is achieved, patients may undergo permanent implantation. The exact mechanism of action through which sacral nerve stimulation provides its therapeutic effect is unclear (Mowatt 2007, Pettie 2012, Tan 2011).

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The InterStim® Therapy System (Medtronic Inc., Minneapolis, MN) is a sacral nerve stimulation device that has been approved by the FDA to treat chronic fecal incontinence in patients who have failed or could not tolerate conservative treatments.

Evidence and Source Documents

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Sacral Nerve Stimulator for Fecal Incontinence

Medical Technology Assessment Committee (MTAC)

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence

BACKGROUND

Urinary incontinence (UI) refers to an involuntary leak of urine. There are several types of UI. Stress UI, the most common form, is an involuntary leak on effort or exertion and urge UI is an involuntary leak accompanied or immediately preceded by a sense of urgency. Mixed UI is a combination of stress and urge UI. A related condition is urinary retention, the inability to completely empty the bladder. Another diagnosis is overactive bladder syndrome (OAB), an urge that occurs with us without a leak of urine, and usually occurs with increased urinary frequency and nocturia. The condition is often categorized as either OAB dry (without incontinence) or OAB wet (with incontinence). The prevalence of urinary incontinence in women is approximately 50% when defined as any urine loss and is 8-36% when limited to bothersome urine loss. About half of all cases are stress incontinence. Urinary incontinence that is severe enough it cannot be easily concealed can have a major impact on quality of life, especially if it includes urinary urgency. Severe urinary incontinence has been found to increase the risk of urinary tract infections in post-menopausal women, and the risk of falls and hip fractures in elderly women (Gray, 2005). Treatments for urge incontinence include the use of absorbent pads, bladder training/pelvic floor muscle exercises, treatment with medications (anti-cholinergic agents, antispasmodics, tricyclic antidepressants), topical estrogen, pelvic floor electrical stimulation, and surgery. The most common treatment for urinary retention is self-catheterization. Sacral nerve stimulation using an implantable device (bladder pacemaker) is proposed as an additional alternative to surgery for patients with urge incontinence, urgency-frequency symptoms or urinary retention. (It is not proposed for stress incontinence, the most common form of urinary incontinence). The InterStim Therapy for Urinary Control is an FDA-approved device developed by Medtronic. Consistent with the protocol in clinical trials, patients undergo percutaneous test stimulation in an outpatient setting before implantation. This involves insertion of an electrode into a sacral foramen. An external device produces continuous stimulation. The implantable InterStim system uses an implanted lead stimulating the appropriate sacral nerve root, most commonly S3. The proximal part of the lead is tunneled under the skin and connected to the neurostimulator which is placed in a subcutaneous pocket in the lower abdomen. The physician can use a microprocessor-based console programmer to set stimulation settings. There is also a handheld programmer that patients can use to turn the stimulator on and off, and to adjust the voltage output amplitude. The battery operating the device is expected to last 7 to 9 years. It is challenging to evaluate the efficacy of treatments for urinary incontinence because there is no gold standard for outcome assessment. In addition, there is a high placebo effect in randomized incontinence studies; as many as 30-40% of patients in placebo groups report success. The high placebo effect has been attributed to several factors including the strong subjective component in voiding dysfunction, and potentially therapeutic effects of study design components such as keeping a voiding diary and interacting with study personnel (Dmochowski, 2001). Because of the high placebo effect, in order to show that an intervention is effective, it is necessary to show that it has an impact beyond that of a placebo. Sacral nerve stimulation for urinary incontinence was reviewed by MTAC in February 1999 and February 2001. The technology did not meet MTAC evaluation criteria. An evidence update was conducted outside of MTAC in October 2002. The GHP Urology Department has requested an updated review.

01/2001: MTAC REVIEW

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence

Evidence Conclusion: The Schmidt et al. study found a significant improvement in urinary incontinence symptoms at 6 months among patients who received an InterStim device compared to patients receiving standard medical treatment. This study has several threats to validity including substantial selective loss to follow-up, self-report data and lack of blinding or intention-to-treat analysis. Moreover, the research team had with financial ties to the manufacturer of the device. Due to the potential biases in this study, the existing data are insufficient to permit conclusions about the effectiveness of this technology.

Articles: Eleven articles were identified. Six articles were not directly relevant, did not include clinical outcomes or were review articles; five articles presented empirical data on clinical outcomes. Articles were selected based on study type. There were three randomized controlled trials (RCTs) and two case series. The three RCTs were done by a single group of investigators. Only one of the 3 RCTs were examining urinary incontinence as the

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outcome. An evidence table was created for this RCT: Schmidt RA, Jonas U, Oelson KA, Janknegt RA, Hassouna MM, Siegel SW, Kerrebroek for the Sacral Nerve Stimulation Study Group. J Urol 1999; 162: 352-57. See Evidence Table.

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/2002: MTAC REVIEW
Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Evidence Conclusion: The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the Interstim device to standard medical treatment for 6 months, among patients who demonstrated during a 3-7-day testing period that they responded to the Interstim device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) Treatment was not blinded and did not allow for a placebo effect of the Interstim device and; 3) The intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing).
Articles: The search yielded 17 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were three articles on a single randomized controlled trial and five case series. The three RCT articles reported on different patient populations enrolled in the same trial (those with urge incontinence, urgency-frequency and non-obstructive urinary retention) and were all critically appraised. The Schmidt study was included in the February 2001 MTAC review. Evidence tables were created for the following articles: Schmidt RA, Jonas U, Oleson KA et al. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. *J Urol* 1999; 162: 352-357. See Evidence Table. Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. *J Urol* 2000; 163: 1849-1854. See Evidence Table. Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. *J Urol* 2001 165: 15-19. See Evidence Table.

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/01/2007: MTAC REVIEW
Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Evidence Conclusion: The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the InterStim device to standard medical treatment for 6 months, among patients who demonstrated in a 3-7-day testing period that they responded to the device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) treatment was not blinded and did not allow for a placebo effect of the InterStim device and; 3) the intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing). An alternative study design to evaluate the effectiveness of InterStim among patients who respond to a test trial would be to compare InterStim to a different treatment that patients had not already failed. Especially in a non-blinded study with some subjective outcomes, bias can be introduced if one group perceives that they are receiving a new and innovative treatment and the other group is receiving the same treatment they have already received. There are no new RCTs to supplement the above data.
Articles: The ideal study would be a randomized controlled trial comparing InterStim therapy to a placebo and/or established alternative intervention. At the time of the 2002 evidence review, conducted outside of the MTAC meeting, there were several RCTs by the same group of investigators. The RCTs compared InterStim to standard medical therapy. No new RCTs evaluating the efficacy and/or safety of the InterStim device were identified. There

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was one additional publication on the original RCT, evaluating psychosocial outcomes in a subset of the study population (Das et al., 2004; Urol). One new RCT was identified on a related topic, comparing two methods for predicting which patients would proceed to device implantation (Borawski et al., 2007). The study did not compare the effectiveness of InterStim treatment compared to placebo or an alternative treatment and was thus not reviewed further. In addition, there were several new case series with sample sizes of approximately 30 patients. Since higher grade evidence has been published, the small case series were not reviewed. *The RCTs on InterStim that have been critically appraised are:* Schmidt RA, Jonas U, Oelson KA et al. for the Sacral Nerve Stimulation Study Group. J Urol 1999; 162: 352-57. See Evidence Table. Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. J Urol 2000; 163: 1849-1854. See Evidence Table. Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. J Urol 2001 165: 15-19. See Evidence Table.

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Sacral Nerve Stimulator

2/11/2013: MTAC REVIEW

Evidence Conclusion: Based on evidence from one randomized controlled trial and several observational studies, the Kaiser Medical Technology Assessment Team found that the evidence on the safety and efficacy of sacral nerve stimulation for treating severe fecal incontinence is of insufficient quality and quantity to determine whether sacral nerve stimulation is medically appropriate for the treatment of fecal incontinence. The best evidence comes from the randomized controlled trial conducted by Tjandra and colleagues (see below) (Kaiser 2011).

Results from a RCT that included 120 patients with severe fecal incontinence suggest that compared to optimal medical therapy patients who were treated with sacral nerve stimulation had significantly fewer incontinence episodes per week, days with incontinence, days with straining, and significantly better quality of life at 12 months. Adverse events included pain at implant site, seroma, and excessive tingling in the vaginal region. All patients in the sacral nerve stimulation group needed the program readjusted. The mean number of readjustments per person was three. Adjustments included changes in the electrode used for stimulation as well as changes in amplitude and rate. This study had several limitations: power was not assessed, results are only applicable to patients with severe incontinence, and patients included in the study were refractory to medical therapy and pelvic floor exercises, which was the control group treatment (Tjandra 2008).

Outcomes at 12 months (Tjandra 2008)

	SNS	Control	P-value
	mean ± standard deviation		
Incontinence episodes/week	3.1±10.1	9.4±11.8	<0.05
Days with incontinence/week	1.0±1.7	3.1±1.8	<0.05
Days with straining/week	1.4±2.0	4.5±2.3	<0.05
Days using pads/week	2.2±3.0	3.2±3.1	0.085
Fecal incontinence quality of life (FIQL) index*			
Lifestyle	3.3±0.7	2.3±0.9	<0.05
Coping/behavior	2.7±0.9	1.9±0.9	<0.05
Depression/self-perception	3.3±0.8	2.6±0.8	<0.05
Embarrassment	2.8±0.9	1.8±0.6	<0.05

Abbreviations: SNS= sacral nerve stimulation.
* FIQL score range= 1 to 4 with a higher score indicating better quality of life.

Conclusion: There is limited evidence on the safety and efficacy of sacral nerve stimulation for the treatment of fecal incontinence.

Articles: In February 2011, Kaiser Permanente's Medical Technology Assessment Team reviewed implantable sacral nerve stimulators for fecal incontinence. The randomized controlled trial that was included in the Kaiser technology assessment was also selected for review as this was the highest quality study assessing the effects of sacral nerve stimulation for the treatment of fecal incontinence. Since the Kaiser Technology Assessment, several observational studies were identified that evaluated the effects of sacral nerve stimulation. None of these studies were selected for review as they did not compare sacral nerve stimulation to other treatments.

The following study and technology assessment were selected for review: Kaiser Permanente. Implantable sacral nerve stimulators for severe fecal incontinence. February 2011;
http://pkc.kp.org/national/cpg/intc/topics/03_19_125.html
Accessed November 6, 2012.

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The use of Sacral Nerve Stimulation for Fecal Incontinence meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
HCPC Codes	**Description**
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system

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Date Created	Date Reviewed	Date Last Revised
3/5/2013	03/05/2013[MDCRPC], 11/03/2013 [MPC], 09/02/14 [MPC], 11/04/2014 [MPC] ,09/01/2015 [MPC], 07/05/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/18/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
11/04/2014	MPC approved to adopt MCG* Implanted Electrical Stimulator, Sacral Nerve (A-0645) for medical necessity determinations for non-Medicare members
12/09/2015	Added LCA and CPT codes
04/07/2020	Added CPT codes 64590 and 64595
04/18/2023	Updated Medicare Billing and coding A53017

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KAISER PERMANENTE®

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Clinical Review Criteria
Seat Lift Chair (Mechanism Only)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Seat Lift (280.4)
Local Coverage Determinations (LCD)	Seat Lift Mechanism (L33801)
Local Coverage Article	Seat Lift Mechanisms – Policy Article (A52518)

For Non-Medicare Members

I. A seat lift mechanism is covered if **All of the following** criteria are met:
   A. Has DME benefit
   B. The patient must have severe arthritis of the hip or knee or have a severe neuromuscular disease.
   C. The seat lift mechanism must be a part of the physician's course of treatment and be prescribed to effect improvement, or arrest or retard deterioration in the patient's condition.
   D. The patient must be completely incapable of standing up from a regular armchair or any chair in their home. (The fact that a patient has difficulty or is even incapable of getting up from a chair, particularly a low chair, is not sufficient justification for a seat lift mechanism. Almost all patients who are capable of ambulating can get out of an ordinary chair if the seat height is appropriate and the chair has arms.)
   E. Once standing, the patient must have the ability to ambulate.

II. Coverage of seat lift mechanisms is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position.

III. Coverage is limited to the seat lift mechanism, even if it is incorporated into a chair (E0627). Payment for a seat lift mechanism incorporated into a chair (E0627) is based on the allowance for the least costly alternative (E0628, E0629).

IV. The physician ordering the seat lift mechanism must be the treating physician or a consulting physician for the disease or condition resulting in the need for a seat lift. The physician's record must document that all appropriate therapeutic modalities (e.g., medication, physical therapy) to enable the patient to transfer from a chair to a standing position have been tried and failed.

This criteria set is not applicable to seat lift mechanisms for wheelchairs. Please see the Mobility Assistive Devices criteria.

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist including details outlined in criteria above

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Background

The seat-lift mechanism is a device that is installed in a chair to help the patient to stand when they are unable to do so from a low chair that has arm rests to support the patient to a standing position. It should be one of those devices that operates smoothly, can be controlled by the patient, and effectively assists a patient standing up and sitting down without assistance.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0627	**Seat lift mechanism, electric, any type**
E0629	**Seat lift mechanism, nonelectric, any type**
E0172	**Seat lift mechanism placed over or on top of toilet, any type**

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Dates	Date Last Revised
05/01/1998	08/03/2010[MDCRPC],06/07/2011[MDCRPC],04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	02/16/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/16/2022	Updated applicable codes

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Clinical Review Criteria
Sensory Integration Therapy (SIT)

- For children with developmental and behavioral disorders

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 15, Coverage of Outpatient Rehabilitation Therapy Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

The sensory integration (SI) framework was first described by an occupational therapist Jean Ayres, PhD, in the early 1970s and refers to the body's way of handling and processing sensory inputs from the environment. This was based on a theory that the sensory system develops over time just like other higher order learning skills (such as cognition, language, and academic performance) and that deficits can occur in the process of developing a well-organized sensory system. A well-organized sensory system can integrate input from multiple sources primarily the three basic senses: vestibular, proprioceptive, and tactile. The vestibular system responds to gravity and movement, and the proprioceptive system receives inputs from joints and muscles. When these systems interact with the tactile sensation, sensory integration takes place. Normally, effective sensory integration occurs automatically, unconsciously, and without effort, but for some children it does not develop as efficiently as it should. Any dysfunction or disorder in the SI process may lead to problems in learning, response to sensory input, behavior, or motor development. According to Ayres' theory these could be manifested as coordination problems; unusually high or low activity level; delays in speech, language, or motor skills; delays in academic achievements; under-reactivity to sensory stimulation; sensitivity to touch, movements, sounds, or sights; poor organization of behavior; lack of self-control; poor self-concept; and other signs and symptoms (Ayres 1972, 1977).

Based on her theory, Ayres developed the sensory integration therapy (SIT) with the goal of improving the way the brain processes and adapts to sensory information, as opposed to teaching specific skills. The therapy involves activities that are believed to organize the sensory system by providing vestibular, proprioceptive, and tactile

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sensory input. Techniques used include vestibular stimulation such as swinging in a hammock, using swing balls, bounce pads or scooter boards; tactile stimulation achieved by brushing parts of the child's body or the use of weighted vests and other clothing (Ayres 1977).

Since that sensory integration dysfunction was described, sensory-based therapies have been increasingly used by occupational therapists and other health professionals to treat children with a range of symptoms and disabilities including autism, attention deficit hyperactivity disorder, fragile-x syndrome, brain injuries and others (Zimmer 2014). SIT is usually provided by certified therapists with special training and mentorship in the theory, techniques, and assessment tools unique to sensory integration theory. It is delivered in one-on-one sessions individualized to the child, one to three times a week, for several months or years. In these therapy sessions, the therapists combine primitive forms of sensation with motor activities according to a manualized protocol (Schaaf 2014).

Some authors distinguish sensory integration therapy from sensory-based interventions (SBIs) which are adult-directed sensory strategies that are applied to the child, most often in the school environment, to improve behaviors associated with modulation disorders. SBIs require less engagement of the child and are integrated into his/her daily routine to improve behavioral regulation (Case-Smith 2014).

SIT is controversial and a topic for debate by many professionals in medicine, psychology, and education (May-Benson 2010). According to a Policy Statement from the American Academy of Pediatrics on SIT (Zimmer et al, 2012) proponents of SI theory believe that inappropriate or deficient sensory processing is a developmental disorder responsive to therapy and that treatment can improve developmental outcomes. A definition of sensory processing disorder has been proposed but is not universally accepted. Standardized measures such as the Sensory Profile have been developed to classify a child's sensory deficit. However, the possible diagnosis of a sensory processing disorder remains a challenging clinical issue, and it is unclear whether children who present with findings described as sensory processing difficulties have an actual disorder of the sensory pathway of the brain or that the deficits observed are associated with other developmental and behavioral disorders. The symptoms described in children with sensory processing disorders, overlap the behavioral differences seen in children with autism spectrum disorders, attention-deficit hyperactivity disorder, and developmental coordination disorders. Evaluating the effectiveness of sensory integration therapy presents another challenge due to the wide spectrum of symptom severity and presentation of the disorder, variations in response due to several factors, and lack of consistent outcome measures (Zimmer 2012).

SIT is a therapy and thus it is not regulated by the FDA. SIT has been reviewed by MTAC earlier in 2005 and did not meet the committee's evaluation criteria. It is being re-reviewed based on requests for its coverage.

Medical Technology Assessment Committee (MTAC)

Sensory Integration Therapy

11/28/2005: MTAC REVIEW

Evidence Conclusion: The results of Vargus' (1999) meta-analysis show that sensory integration therapy was not more effective than other alternative therapies in improving psychoeducational, behavior, language, motor, and sensory perceptual functions among the groups studied. The studies included in the meta-analysis did not provide sufficient data on the ages of participants, the types of disabilities, or details on therapies provided. There were also variations and differences in the characteristics of the participants, intervention methods, hours of therapy received, ratio of therapists to children, evaluation of the therapy, duration between therapy and re-testing, and outcomes measured. The authors of the meta-analysis were thus unable to determine the effect of sensory integration therapy among different ages or among individuals with different types of disabilities.
Humphries and colleagues (1992) compared sensory integrative therapy among children with learning disabilities and sensory integration dysfunction to another active treatment (perceptual-motor training), and to no treatment. There were some significant baseline differences between the study groups, and both the sensory integrative therapy and the perceptual-motor therapy were performed by the same occupational therapists, which may be a potential source of bias. Their results show significant pretest-posttest differences between the three groups in the motor functions but not in the psychoeducational variables. The difference in the motor performance between the two active therapies was statistically insignificant. In conclusion, the current literature does not provide a clear definition or description of the sensory integration therapy and does not provide evidence that the therapy is more effective than an alternative therapy or no treatment for children with learning disabilities, or neurodevelopmental delay.
Articles: The search yielded 126 publications, the majority of which were review articles. There were four systematic reviews; two meta-analyses: Ottenbacher 1982 and Vargus 1998; an article combining the results of only two studies (Kaplan 1993); and a number of controlled trials. Many of the studies revealed by the search were

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conducted in the 1970s and 1980s, their sample sizes varied from 10 to 92 participants, and the majority were poorly controlled. The search on the use of sensory integration therapy for autistic children revealed one small case series with 10 children. The most recent meta-analysis and a randomized controlled trial (RCT) were critically appraised. The RCT selected was included in the meta-analysis but was reviewed, as it was the largest trial identified and had a relatively better-quality design. *Evidence tables were made for the following studies:* Vargas S, Camilli G. A meta-analysis of research on sensory integration treatment. Am J Occup Ther. 1999; 53:198-198. See Evidence Table 1. Humphries T, Wright M, Snider L, McDougal B. A comparison of the effectiveness of sensory integrative therapy and perceptual-motor training in treating children with learning disabilities. J Dev Behav Pediatr. 1992; 13:31-40. See Evidence Table 1.

The use of Sensory integration therapy in the treatment of neuro-developmentally delayed children does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

12/06/2015: MTAC REVIEW
Sensory Integration Therapy
Evidence Conclusion: The results of the meta-analysis (Vargus, et al, 1999) reviewed earlier for MTAC suggested that the benefits of sensory integration therapy on psychoeducational and motor functions was significantly better than no treatment among the individuals studied, but it was not superior to other alternative treatments. The authors cautioned about interpreting the results and concluded that there was insufficient evidence to determine the effectiveness of the SI approach. The search for more recent evidence after that last review identified a pilot trial that investigated the effectiveness of SI interventions in children with autism spectrum disorders, a RCT that compared SIT to usual care in children with autism, and a larger RCT that compared SIT to two other active treatments and a control among children with mild mental retardation. Schaaf and colleagues, 2014 (Evidence table 1), randomly assigned 32 children aged 4-8 years, with autism and sensory difficulties to either an occupational therapy/sensory intervention (OT/SI) group or a control group. The study was randomized, and controlled, with proper randomization procedure, and power analysis. However, it was very small and parents who rated their child's goals and other outcomes were not blinded to the treatment allocation, which is a source of bias. In addition, the OT/SI was not compared to an alternative occupational therapy with the same intensity and duration of intervention. The overall results showed significant positive improvement in Goal Attainment Scores (GAS) in the two study groups, but children in the OT/SI group scored significantly higher than the controls.
The only other statistically significant differences between the two groups were for the less care-giver assistance during self-care, and social activities observed in the treatment group. There were no statistically significant differences between the study groups in adaptive behaviors. The authors concluded that the results of the study provide preliminary support for the efficacy of manualized SI intervention. They however, noted that the results should be interpreted with caution until they are replicated in future larger studies. Pfeiffer and colleagues, 2011 (Evidence table 2), conducted a pilot trial to identify appropriate outcome measures, and address the effectiveness of sensory integration (SI) interventions in children with autism spectrum disorders (ASD). They randomized 37 children with ASD, 6-12 year of age to undergo either a fine motor (FM) or sensory integration therapy. Pretests and posttests measured social responsiveness, sensory processing, functional motor skills, and social-emotional factors. The study was randomized, controlled, and blinded. However, it was a small pilot trial with no power analysis or follow-up after the therapy ended. Its overall results showed significant positive improvement in GAS in the two study groups. Children in the SIT group had more significant changes in GAS and improvement in mannerism vs. those in the FM group. The differences in the other outcomes were statistically insignificant. The authors discussed limitations to the study and suggestions for future studies. They explained that standardized measures for determining progress are often inappropriate for children on the autistic spectrum because of the wide variety in behavior and developmental levels among the children, and their ability to complete the test while maintaining its validity. The authors also indicated that another challenge for using a standardized measure is the fact that the SIT forms, activities, and goals are individualized to the specific needs of each child, resulting in a wide range of goals and outcomes among the participants within a study. Wuang and colleagues, 2009 (Evidence table 3) compared the effect of SIT, neurodevelopmental treatment (NDT), and perceptual-motor (PM) approach, and no treatment in 160 children 7-8 years of age with mild mental retardation. 120 were randomly assigned to one of the three active treatments and 40 children who fulfilled the inclusion criteria but could not attend the sessions because of its timing, were not randomized, did not receive any intervention during the study period, but were used as controls.
Each of the active interventions was delivered in a 1-hr. session 3 days per week for 40 weeks, and the children were assessed with measures of sensorimotor function at baseline and after completion of the study. The results show that postintervention, the active treatment groups significantly outperformed the control group on almost all measures. The SIT group demonstrated a greater pretest-posttest change on fine motor, upper-limb coordination, and SI functioning. The PM group showed significant gains in gross motor skills, whereas the NDT group had the smallest change in most measures. The study had its advantages and limitations discussed in evidence table 3. Among the limitations is the inclusion of a selected group of patients, non-adjusting for confounding factors, and a lack of long-term follow-up. The authors recommended that the results be replicated in more studies with long- term

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follow-up. A 2012 Policy Statement by the American Academy of Pediatrics on sensory integration therapies for children with developmental and behavioral disorders states that is unclear whether children who present with sensory-based problems have an actual "disorder" of the sensory pathways of the brain or whether these deficits are characteristics associated with other developmental and behavioral disorders. Because there is no universally accepted framework for diagnosis, sensory processing disorder generally should not be diagnosed. Other developmental and behavioral disorders must always be considered, and a thorough evaluation should be completed. Difficulty tolerating or processing sensory information is a characteristic that may be seen in many developmental behavioral disorders, including autism spectrum disorders, attention-deficit/hyperactivity disorder, developmental coordination disorders, and childhood anxiety disorders. Occupational therapy with the use of sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan. However, parents should be informed that the amount of research regarding the effectiveness of sensory integration therapy is limited and inconclusive. Important roles for pediatricians and other clinicians may include discussing these limitations with parents, talking with families about a trial period of sensory integration therapy, and teaching families how to evaluate the effectiveness of a therapy (Zimmer 2012).

Conclusion: The evidence remains insufficient to support the effectiveness of sensory integration therapy in improving the behaviors and functional skills in children with developmental and/or behavioral disorders. Due to the individual nature of SIT and the large variation in individual therapists and patients, large multicenter randomized controlled trials among a more diverse population, with blinded assessment, and long-term follow-up are needed to determine the effectiveness the efficacy of this therapy and durability of outcomes.

Articles: The search for studies published after the 2005 MTAC review, revealed over 150 publications, the majority of which were unrelated to the current review. There were three systematic reviews without meta-analyses, two small RCTs among children with autism spectrum disorders (ASD), one quasi-randomized trial among children with mild mental retardation, a number of small non-randomized comparative studies, observational studies with no controls, case series, and case reports on sensory integration therapy for children. The three randomized controlled trials were selected for critical appraisal. Pfeiffer BA, Koenig K, Kinnealey M, et al. Effectiveness of sensory integration interventions in children with autism spectrum disorders: a pilot study. Am J Occup Ther. 2011 Jan-Feb; 65(1):76-85. See Evidence Table 1. Schaaf RC, Benevides T, Mailloux Z, et al. An intervention for sensory difficulties in children with autism: a randomized trial. J Autism Dev Disord. 2014 Jul; 44(7):1493-506. See Evidence Table 2. Wuang YP, Wang CC, Huang MH, et al. Prospective study of the effect of sensory integration, neurodevelopmental treatment, and perceptual-motor therapy on the sensorimotor performance in children with mild mental retardation. Am J Occup Ther. 2009 Jul-Aug; 63(4):441-452. See Evidence Table 3.

The use of Sensory Integration Therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/11/2022: MTAC REVIEW
Sensory Integration Therapy

Evidence Conclusion: The evidence remains insufficient to determine the safety and effectiveness of sensory integration therapy in improving the behavior and functional skills in children with ASD or other developmental and/or behavioral disorders. The published trials evaluating the effectiveness of ASI as described by Ayres, in improving the behavior and functional skills in children with developmental and/or behavioral disorders are limited by their small number, sample sizes, variable outcome measures, lack of blinding when parent-reported outcome measures used, and the short study durations. Due to these limitations, the published trials and the qualitative systematic reviews only provide low strength evidence suggesting that SIT may lead to some improvement in subsets of sensory and motor skills in selected children with ASD. None of the three published RCTs had a long-term follow-up to determine the safety of the intervention on the child and /or therapist, as well as durability of the observed effects. Large double-blinded, multicenter RCTs in children diagnosed with developmental disorders and sensory processing problems; that adhere to the core principles of ASI, using the Fidelity Measure of ASI; with an active comparator and blinded assessment of objective outcomes sensitive to the changes expected following ASI intervention; and with long-term follow-up, are needed to determine the safety, effectiveness, and durability of outcomes of the therapy.

Articles: PubMed and Cochrane database were searched from November 2014 through February 2022, using the search terms: sensory integration, sensory integrative dysfunction; sensory processing disorder, sensory integration therapy, SIT, learning disability, ASD, autism, neuro-developmental delay, and Ayres sensory integration, with variations.The search was limited to English-language publications in peer-reviewed journals, among human populations, and children 0-18 years. Experimental studies, abstracts, case reports, case series with less than 25 patients, reviews, comments, and editorials were excluded. Preference was given to meta-analyses and randomized controlled trials reporting clinical outcomes. Reference lists and PubMed related articles were also examined for

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additional articles. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website https://clinicaltrials.gov/ was conducted using the same methodology. See Evidence Tables.

The use of Sensory Integration Therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Non-Medicare - Considered Not Medically Necessary:

CPT® Codes	Description
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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10/30/2005	10/30/2005[MDCRPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	06/07/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/07/2022	Added April 2022 MTAC review; MPC approved to adopt MTAC's recommendation of non-coverage and continue existing the policy of insufficient evidence

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Clinical Review Criteria

Serum Biomarker Tests for Multiple Sclerosis

- gMS®Dx Testing
- gMS®Pro EDSS Testing

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Cytogenetic Studies (190.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Multiple sclerosis (MS) is a chronic illness of the central nervous system. Diagnosis of MS can be very difficult as there are no clinical findings that are unique to MS. The revised McDonald's Criteria, which incorporated clinical, radiologic, and laboratory findings are often used to diagnose MS. However, because the use of these criteria frequently results in delayed diagnosis, researchers have been trying to find reliable biomarkers that would help to establish a diagnosis (Harris 2009).

The **gMS®Dx test**, a new blood-based test for MS biomarkers, was developed by Glycominds to help physicians identify patients with a high probability of developing MS. The biomarker used in the gMS®Dx test is based on IgM antibodies against the a-glucose antigen (GAGA4). The test is designed to be used in patients as a part of the MS diagnostic work-up and is recommended for use in suspected MS patients for which the diagnosis of MS has not yet been confirmed. The results of the test are reported as negative (patient may still have MS or other neurological disease, continue with routine testing), positive (patient has a high likelihood of having MS), high positive (patient has a very high likelihood of having MS) (Glycominds 2012). One advantage of the gMS®Dx test is that blood samples are relatively easy to obtain and are minimally invasive. A limitation of using biomarkers for diagnosing MS is that they may be affected by other systematic events such as viral infections (Harris 2009). An additional limitation of the gMS®Dx test is that the biologic basis for the MS biomarker is unclear (Freeman 2009).

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Multiple sclerosis (MS) is a complex disease with heterogeneous clinical presentation and disease course. Because prognosis is so hard to predict there has been interest in indentifying biomarkers that are associated with disease progression (Harris 2009).

Glycominds has developed the **gMS®Pro EDSS test**, a blood-based test that uses biomarkers to identify patients at high risk for severe disease progression. The biomarkers used in the gMS®Pro EDSS test are based on IgM antibodies against the a-glucose antigen (GAGA2, GAGA3, GAGA4, GAGA6). The aim of this test is to help clinicians choose the most appropriate disease treatment. The test is designed for use in patients at their first episode and for patients with relapse-remitting multiple sclerosis during their first decade of the disease. The results of the test are reported as negative (patient has a low risk to fast disability progression as measured by EDSS) or positive (patient has a high risk to fast disability progression as measured by EDSS) (Glycominds 2012). One advantage of the gMS®Pro EDSS test is that blood samples are relatively easy to obtain and are minimally invasive. A limitation of using biomarkers for diagnosing MS is that biomarkers may be affected by other systematic events such as viral infections (Harris 2009). An additional limitation of the gMS®Pro EDSS test is that the biologic basis for the MS biomarkers is unclear (Freeman 2009).

Medical Technology Assessment Committee (MTAC)

gMS®Dx and gMS®Pro EDSS

06/18/2012: MTAC REVIEW

Evidence Conclusion: Diagnostic accuracy**:** Results from a recent observational study with several limitations suggest that the gMS®Dx test has a sensitivity or 33.7% (95% CI, 30.2 to 37.3) and a specificity of 98.5% (95% CI, 91.7 to 100) for differentiating relapsing remitting multiple sclerosis (RRMS)/secondary progressive multiple sclerosis (SPMS) from other neurological disorders (Brettschneider 2009). Impact on diagnosis: There is insufficient evidence to determine whether the gMS®Dx test will impact diagnosis. Impact on patient management: There is insufficient evidence to determine whether the gMS®Dx test will change patient's management. Conclusion: Diagnostic accuracy: Weak evidence suggest that the gMS®Dx test has a sensitivity or 33.7% and a specificity of 98.5% for differentiating RRMS/SPMS from other neurological disorders. Impact on diagnosis: There is insufficient evidence to determine whether the gMS®Dx test will impact diagnosis. Impact on patient management: There is insufficient evidence to determine whether the gMS®Dx test will change patient's management.

gMS®Pro EDSS testing

06/18/2012: MTAC REVIEW

Evidence Conclusion: Accuracy: A prospective cohort study that included 286 patients with clinically isolated syndrome (CIS) evaluated the prognostic value of the gMS®Pro EDSS test. Results from this study suggest that that the gMS®Pro EDSS test does not significantly predict prognosis, conversion to McDonald MS, or EDSS progression in patients with CIS. Results from this study should be interpreted with caution as this is an exploratory analysis (Freedman 2011). Results from a retrospective study of 100 RRMS patients taken at their first presentation of RRMS suggest that using a panel of 4 different antibodies had a sensitivity of 37.9% and a specificity of 83.3% for predicting early relapse in patients with RRMS following their first presentation. Results from this study should be interpreted with caution as this is a retrospective exploratory analysis (Freedman 2009). Impact on patient management: No studies were identified that address the impact of gMS®Pro EDSS on patient's management. Conclusion: Accuracy: There is insufficient evidence to determine the accuracy of the gMS®Pro EDSS test. Impact on patient management: There is insufficient evidence to determine whether the gMS®Pro EDSS test will change patient's management.

Articles: gMS®Dx test: Several observational studies were identified that addressed the diagnostic accuracy of the gMS®Dx test. The largest study was selected for review. No studies were identified that addressed the impact of the test on diagnosis or patient's management. The following study was selected for review: Brettschneider J, Jaskowski TD, Tumani H, et al. Serum anti-GAGA4 IgM antibodies differentiate relapsing remitting and secondary progressive multiple sclerosis from primary progressive multiple sclerosis and other neurological diseases. J Neuroimmunol. 2009; 217:95-101. **gMS®Pro EDSS test**: Two studies were identified that addressed the accuracy of the gMS®Pro EDSS test. No studies were identified that addressed the clinical utility of the gMS®Pro EDSS test. The following study was selected for review: Freedman M, Metzig C, Kappos L, et al. Predictive nature of IgM anti-alpha-glucose serum biomarker for relapse activity and EDSS progression in CIS patients: a BENEFIT study analysis. Mult Scler. 2011. [Epub ahead of print] See Evidence Table. Freedman MS, Laks J, Dotan N, Altstock RT, Dukler A, Sindic CJ. Anti-alpha-glucose-based glycan IgM antibodies predict relapse activity in multiple sclerosis after the first neurological event. Mult Scler. 2009; 15:422-430. See Evidence Table.

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The use of gMS®Dx and gMS®Pro EDSS testing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes for this service. Often submitted with unlisted code 84999.	

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Date Created	Date Reviewed	Date Last Revised
07/03/2012	07/03/2012[MDCRPC], 05/07/2013[MDCRPC], 3/04/2014[MDCRPC], 01/06/2015[MPC], 09/06/2016[MPC], 07/11/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	07/03/2012

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Supervised Exercise Therapy on Patients with Intermittent Claudication from Peripheral Vascular Disease (SET for IC in PAD)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (20.35)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente considers medical supervision of peripheral vascular rehabilitation programs medically necessary for the treatment of persons with symptomatic peripheral artery disease (PAD) (i.e., intermittent claudication).

Program Description

- Up to 36 sessions over a 12-week period are considered medically necessary if **ALL of the following** components of a supervised exercise therapy (SET) program are met:
  - consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in members with claudication; *and*
  - be conducted in a hospital outpatient setting, or a physician's office; *and*
  - be delivered by qualified auxiliary personnel to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; *and*
  - be under the direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist trained in both basic and advanced life support techniques; *and*
  - Member must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET program. At this visit, the member must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

Kaiser Permanente considers medical supervision of peripheral vascular rehabilitation programs experimental and investigational for persons with absolute contraindications to exercise and for all other indications because the value of such supervision for other indications is not well documented by the available peer-reviewed published medical literature.

Kaiser Permanente considers the PADnet System and testing program experimental and investigational for evaluation of peripheral artery disease and other indications because of insufficient evidence of its effectiveness.

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Background

Atherosclerosis is a systemic disease that affects arteries of different sizes including large and medium arteries. Atherosclerosis narrows the lumen of the arteries because of an accumulation of fibrous material in the inner layers of the arteries. When the arteries of the lower extremities are affected, the disease is called lower extremity peripheral artery disease (PAD) (Linda Harris et al., 2019).

The prevalence of lower extremity PAD is less than 12% but increases after the age of 40. Risk factors for peripheral artery disease are the same as those for coronary disease. These include smoking, hypertension, hypercholesterolemia, diabetes, and metabolic syndrome. Other factors include age, gender, ethnicity, family history and genetic influences, and homocysteinemia (Hageman, Fokkenrood, Gommans, van den Houten, & Teijink, 2018) (Linda Harris et al., 2019).
Symptoms of peripheral artery disease include lower extremity pain, nonhealing wound or ulcer, skin discoloration or gangrene. Lower extremity pain includes pain in the calf, thigh, buttock, or foot. The pain is associated with activity and relieved with rest (intermittent claudication). The pain can be atypical or occurs at rest (ischemic rest pain). Intermittent claudication, the most common symptom, is defined as a leg pain that occurs during walking, forces the patient to stop walking, and resolves after 10 minutes of rest, after which the patient can resume walking with pain occurring again after walking the same distance. Claudication can be unilateral or bilateral. Ischemic rest pain is due to diffuse ischemia and is limited to the forefoot and toes. The pain can be diffuse and severe with numbness, paralysis of the extremity, pallor, coolness, and lack of pulses (David Neschis et al., 2019).

Diagnosis is made with history of risk factors, symptoms of PAD, and physical examination. However, ankle-brachial index (ABI) ≤0.9 establishes the diagnosis in individuals with atypical symptoms or ambiguous pulse examination (David Neschis et al., 2019).

The objective of the treatment is to control the claudication and reduce the risk of cardiovascular disease complications. Treatment can be medical or surgical. Initial treatment includes cardiovascular risk modification, exercise, and pharmacotherapy. In the absence of improvement after initial treatment, revascularization (percutaneous intervention, surgical bypass) is recommended. For patients with lifestyle-limiting claudication, cilostazol (100 mg twice daily) may be indicated (Mark Davies et al., 2019).

Nevertheless, it seems that exercise, particularly supervised exercise therapy, is the mainstay of the treatment for improving walking performance and quality of life (Hageman, Fokkenrood, Gommans, van den Houten, & Teijink, 2018).

Supervised exercise therapy (SET) consists of several sessions, on a treadmill, lasting 45 to 60 minutes per session. Each session comprises 35 minutes of intermittent walking including 5 to 10 minutes of warm-up and cool-down periods. In addition, five minutes are added to the walking time to allow the patient to achieve 50 minutes of intermittent walking. SET consists of three weekly sessions lasting more than three months. During the exercise, medical professionals such as physiologist, physical therapist, or nurse supervise the sessions on person to person basis and monitor patient's claudication threshold and cardiovascular system. If there is suspicion of angina, or the patient is unable to continue the exercise, he or she is referred to a physician (Mark Davies et al., 2019).

Medical Technology Assessment Committee (MTAC)

Supervised Exercise Therapy on patients with intermittent claudication from peripheral vascular disease (SET for IC in PAD)

Date: 10/14/2019

Evidence Conclusion:

- Moderate-quality evidence indicates that supervised exercise therapy may be more effective than usual care or placebo or walking advice in terms of walking performances in patients with intermittent claudication due to atherosclerosis who are fit for exercise on the short-term.
- Moderate evidence suggests that supervised exercise therapy may improve quality of life compared to usual care, or placebo in patients with intermittent claudication due to peripheral artery disease on the short-term.
- The evidence is insufficient to draw conclusion on the effectiveness of supervised exercise therapy vs medications.

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

- Moderate-quality evidence indicates that SET may be more effective than unsupervised exercise therapy on the short-term. However, there is no difference in quality of life between the groups.

Articles: PubMed was searched through September 2019 with the following search terms: Supervised Exercise Therapy AND (intermittent claudication OR peripheral vascular disease) with the filter meta-analysis. Randomized controlled trials were also searched for. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded twenty-six items, but 17 were selected after reading their titles. Of the 17 articles, two were thoroughly reviewed. See Evidence Table.

The use of Supervised Exercise Therapy on patients with intermittent claudication from peripheral vascular disease (SET for IC in PAD) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
93668	Peripheral arterial disease (PAD) rehabilitation, per session

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/14/2019	11/05/2019[MPC] ,11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	01/07/2020

[MPC] Medical Policy Committee

Revision History	Description
11/05/2019	MPC approved to adopt clinical criteria for commercial members
01/07/2020	MPC approved proposed criteria for commercial members

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Sex-Hormone Binding Globulin (SHBG)

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Criteria

For Medicare and Non-Medicare Members

Medical necessity review no longer required.

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Background

Causes of abnormal SHBG include the following:

- Increased SHBG concentrations: aging, hyperthyroidism, high estrogen concentrations, liver disease, HIV, anti-seizure drugs
- Decreased SHBG concentrations: moderate obesity, insulin resistance, type 2 diabetes, hypothyroidism, growth hormone excess, exogenous androgens/anabolic steroids, glucocorticoids, progestins, nephrotic syndrome
- Free testosterone — If serum free testosterone concentration is measured, the following points should be kept in mind:
  - Serum free testosterone should be performed by equilibrium dialysis and only in those few laboratories that specialize in endocrine testing.
  - The free testosterone concentration, as calculated from the total testosterone, SHBG, and albumin concentrations, may also be reliable, but there are many different equations for this calculation and they give vastly different results, some of which reflect the results obtained by equilibrium dialysis better than others. Consequently, it is essential that the result be compared with the normal range for the laboratory that performed the assay.
  - Free testosterone measured by an analog method, which is the assay most commonly offered by hospital and commercial laboratories, does not correlate with the results of equilibrium dialysis. This test gives misleading information and should never be ordered.
  - The problem with the analog method was illustrated in a study in which sera from patients who had a variety of SHBG concentrations were assayed by each of the above methods. The results using each of the assays correlated well with the results using each of the other methods, except for free testosterone by the analog method, in which the results were both systematically lower than in the other methods and varied as a function of SHBG.
  - Bioavailable testosterone, ie, the total of free testosterone and that bound weakly to albumin, which is not precipitated by ammonium sulfate, also appears to accurately reflect androgen status.

When during the day should the serum testosterone concentration be measured? — Interpretation of serum testosterone measurements in young men should take into consideration its diurnal fluctuation, which reaches a maximum at about 8 AM and a minimum, approximately 70 percent of the maximum, at about 8 PM. It is easier to distinguish subnormal from normal when normal is higher, so the measurements should always be made in the

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morning, ideally between 8 to 10 AM. Food, especially glucose ingestion, also decreases the serum testosterone concentration, so the blood should also be drawn fasting.

How often should testosterone be measured? — The serum testosterone concentration fluctuates somewhat even early in the morning, although to a limited degree. If a single 8 to 10 AM value is well within the normal range, testosterone production can be assumed to be normal. If a single 8 to 10 AM value is low or borderline low or does not fit with the clinical findings, the measurement should be repeated once or twice before making the diagnosis of hypogonadism. If the results are equivocal, measurement of free testosterone can be considered.

Sex hormone-binding globulin (SHBG) is a serum protein that binds to circulating androgens and estrogens, specifically testosterone and estradiol, with high affinity and serves as a transporter/reservoir. It is believed that SHBG regulates the access and action of these hormones. Initially it was thought that when bound to SHBG these sex hormones were biologically inactive. However, emerging evidence suggests that even sex hormones bound to SHBG may be biologically active. SHBG is produced mainly in the liver; however, other tissues including the placenta, testis, brain, and endometrium also produce SHBG. Age and obesity along with a variety of hormonal, nutritional, metabolic, and genetic factors have been found to influence the production of SHBG. Several conditions such as diabetes, polycystic ovarian syndrome, obesity, hypothyroidism, and hyper-insulinemia are associated with low levels of SHBG; however, causality has yet to be proven. Because of SHBG association with type 2 diabetes, there has been growing interest in the use of SHBG levels as a tool for the early identification of this disease (Brand 2010, Dahan 2006, Hoppé 2010, Xita 2010).

Medical Technology Assessment Committee (MTAC)

Sex-Hormone Binding Globulin

02/14/2011: MTAC REVIEW

Evidence Conclusion: *Men:* Two prospective cohort studies evaluated the association between SHBG levels and the risk of type 2 diabetes in men. The first study followed 1,454 men from the Troms study, a population-based prospective cohort study, who did not have diabetes at baseline for a mean of 9.1 years. Seventy-six men were diagnosed with diabetes (incidence rate of 5.8 per 1,000 person years). After controlling for age, HDL-cholesterol, systolic blood pressure, and waist circumference there was no association between SHBG and the risk of diabetes (Vikan 2010). The second study followed 1,128 men aged 40-70 years who participated in the Massachusetts Male Aging Study, a population-based prospective cohort study, for an average of 13 years. Ninety men were diagnosed with diabetes (incidence rate of 6.2 per 1,000 person years). Results from this analysis suggest that in men, even after controlling for age, BMI, high blood pressure, smoking, alcohol intake, and physical activity, SHBG levels were associated with the development of type 2 diabetes (Laksham 2010). It should be noted that the mean levels of SHBG were higher in the Vikan study compared to the Laksham study (52.7 nmol/l vs. 32.0 nmol/l). This may be due to the fact that blood sample were drawn at different times of the day. Diabetes status was determined through self-repot in both studies. Additionally, neither study adjusted for insulin levels, which have been found to inhibit SHBG production. An earlier systematic review and meta-analysis of 3 prospective cohort studies found that men with higher SHBG levels (>28.3 vs. ≤28.3 nmol/l) had a 52% lower risk of type 2 diabetes (RR 0.48, 95%CI 0.33-0.69) (Ding 2006). *Women:* One prospective cohort study was identified that evaluated the association between SHBG levels and the risk of type 2 diabetes in postmenopausal women. In this study, 1,612 women were followed for a median of 4.7 years and 116 women were diagnosed with diabetes. Results from this study suggest that in postmenopausal women SHBG levels are associated with the development of type 2 diabetes even after adjusting for age, race/ethnicity, education, income, family history of diabetes, examination site, insulin resistance, and adiposity.

Relative hazards of developing incident type 2 diabetes by quartile of baseline SHBG level

	Model 1*	Model 2†	Model 3§
		HR (95% CI)	
SHBG (nmol/l)			
Q1 (8.9-37.8)	1.0 (Ref)	1.0 (Ref)	1.0 (Ref)
Q2 (38.0-51.4)	0.39 (0.25-0.61)	0.49 (0.31-0.76)	0.41 (0.24-0.69)
Q3 (51.5-71.5)	0.29 (0.18-0.47)	0.44 (0.26-0.74)	0.53 (0.30-0.92)
Q4 (71.8-255.5)	0.24 (0.14-0.42)	0.43 (0.24-0.76)	0.52 (0.27-0.98)
P-trend	<0.0001	0.0004	0.017

*Adjusted for age, race/ethnicity, education, income, family history of diabetes, and examination site.
†Adjusted for model 1 plus BMI and homeostasis model assessment of insulin resistance (HOMA-IR).
§Adjusted for model 2 plus LDL, HDL, triglycerides, use of lipid-lowering medication, systolic blood pressure, total daily caloric intake, physical activity, smoking, inflammatory factors (IL-6 and CRP), age at menopause, years since menopause, type of menopause, age at first live birth, five or more live births, past use of hormone replacement therapy or oral contraceptive.

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An earlier systematic review and meta-analysis of 2 prospective cohort studies found that women with higher SHBG levels (>60.0 vs. ≤60.0nmol/l) had an 80% lower risk of type 2 diabetes (RR 0.20, 95%CI 0.12-0.30) (Ding 2006). Conclusion: Several observational studies suggest that lower SHBG levels are associated with an increased risk of developing of type 2 diabetes; however, SHBG cut points for determining increased risk have not been established. Additionally, there is insufficient evidence to determine the clinical utility of using SHBG to predict type 2 diabetes.

Articles: The literature search revealed several case-control, cross-sectional, and prospective cohort studies that examined the association between SHBG and the risk of type 2 diabetes. Three recent prospective cohort studies were selected for review. No studies were identified that addressed the clinical utility of using SHBG to predict type 2 diabetes. The following studies were critically appraised: Kalyani RR, Franco M, Dobs AS, et al. The association of endogenous sex hormones, adiposity, and insulin resistance with incident diabetes in postmenopausal women. *J Clin Endocrinol Metab 2009;* 94:4127-4135. See Evidence Table. Lakshman KM, Bhasin S, and Araujo AB. Sex hormone-binding globulin as an independent predictor of incident type 2 diabetes in men. *J Gerontol a Biol Sci Med Sci 2010;* 65A: 503-509. See Evidence Table. Vikan T, Schirmer H, Njolstad I, and Svartberg J. Low testosterone and sex hormone-binding globulin levels and high estradiol levels are independent predictors of type 2 diabetes in men. *Eur J Endocrinol 2010;* 162:747-754. See Evidence Table

The use of SHBG does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medical necessity review no longer required:

CPT® or HCPC Codes	Description
84270	Sex hormone binding globulin (SHBG)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
02/14/2011	04/05/2011[MDCRPC], 02/07/2012[MDCRPC],12/04/2012[MDCRPC] ,10/01/2013[MPC], 08/05/2014 [MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC] , 10/05/2021[MPC] , 10/04/2022[MPC]	10/21/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/05/2016	Added exclusion language for symptoms of erectile dysfunction, fatigue, impotence or low libido as the medical literature does not support its use in these circumstances.
10/21/2020	Updated criteria to medical necessity review no longer required to align with current review processes.

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Clinical Review Criteria
Extracorporeal Shock Wave Therapy (ESWT)

- Chronic Plantar Fasciitis
- Lateral Epicondylitis (Tennis Elbow)
- Non-Union or Delayed Union Fractures

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"Extracorporeal Shock Wave Therapy (ESWT)"** for medical necessity determinations. Use the Non-Medicare criteria below.

Non-Medicare Members

Indication	Policy
Chronic Plantar Fasciitis Lateral Epicondylitis (Tennis Elbow) Non-Union or Delayed Union Fractures	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Evidence and Source Documents

Extracorporeal Shock Wave Therapy (ESWT) for Delayed or Nonunion Fractures
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis

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Background

Extracorporeal shock waves are characterized by high positive pressure with a rapid rise time and short (microsecond) duration. The shock waves are concentrated into small focal areas of 2 to 8 mm to optimize therapeutic affects and minimize the impact on adjacent tissues. There are several types of shock wave generating systems; they can involve electrohydraulic, electromagnetic or piezoelectric mechanisms. The shape of the pulses differs depending on the mechanism. In all of the systems, shock waves are concentrated by focusing reflectors on the target site. The shock waves can be further localized using imaging modalities such as ultrasound. Beneficial effects are expected to be observed between 6-12 weeks after treatment (Speed 2004; Wilner & Strash, 2004).

Extracorporeal shock wave therapy (ESWT) is used a non-invasive alternative to surgery for patients with chronic plantar fasciitis who have not responded to conservative therapy such as use of orthotics, physical therapy, night splints, heel cups and treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Plantar fasciitis is believed to result from a biochemical imbalance that places abnormal tension on the plantar fascia which leads to inflammation and tension on the calcaneal periosteum. The mechanism by which ESWT relieves symptoms of plantar fasciitis is not known; however, there may be an effect through tissue disruption of the tendinous fibers followed by neovascularization and replenishment of the extracellular matrix (Atkin, 1999; Wilner & Strash, 2004).

The HealthTronics OssaTron (October 2000), Dornier Epos Ultra (January 2002), Medispec Orthospec (April, 2005) and Orthometrix Orbasone (August, 2005) devices have all been approved by the FDA for the treatment of chronic proximal plantar fasciitis in individuals aged 18 or older who have a history of unsuccessful conservative treatments. The OssaTron and Orbasone are electrohydraulic devices, the Epos Ultra uses electromagnetic technology and the Orthospec uses sound waves.

Low-intensity ultrasound treatment was approved by the FDA in 2000 for treating non-union fractures. Healing is delayed in approximately 10% of the fractures that occur in the United States. The definitions of non-unions differ, but a fracture is generally considered to be a non-union if it has not healed by 6-9 months. Factors contributing to the occurrence of delayed unions and non-unions include the location and severity of the fracture, the extent of soft tissue damage, adequacy of stabilization or fixation, and lifestyle factors such as smoking and high alcohol intake (Hadjiargyrou et al., 1998; Biederman et al., 2003).

Some investigators believe that extracorporeal shock wave treatment (ESWT) has greater potential for treating delayed union and non-union fractures than ultrasound. Shockwaves are characterized by high positive pressure with a rapid rise time and short duration. Following the high positive pressure is an exponential decrease in pressure. The low-frequency components of shock waves allow them to pass through fluid and body tissues with less energy loss than ultrasound. Thus, shock wave treatment may be better than ultrasound for penetrating tissues and delivering adequate pressure for stimulation of bone growth (Rompe et al., 2001; Speed 2004; Wilner & Strash, 2004).

ESWT has not been approved by the FDA for treating non-union or delayed union fractures. The use of shock waves for bone repair has been studied in animal models and initial clinical studies.

Extracorporeal shock wave therapy (ESWT) is used as a non-invasive alternative to surgery for patients with soft tissue conditions including lateral epicondylitis (tennis elbow). ESWT is generally reserved for patients who have not responded to conservative therapy such as physical/occupational therapy, bracing or splinting, local steroid injections and non-steroidal anti-inflammatory drugs (NSAIDs).

Lateral epicondylitis is characterized by pain at the epicondyle on the lateral side of the elbow. The etiology is not well known, but it is generally believed to be due to musculotendinous lesions. The onset of pain can occur abruptly after an unaccustomed activity or can develop gradually in individuals who perform activities requiring repetitive and vigorous use of the forearm. Pain is often mild at first but can worsen over time (Buchbinder 2004; Melikyan, 2003).

Medical Technology Assessment Committee (MTAC)

Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis

BACKGROUND

Plantar fasciitis is the most common cause of inferior heel pain characterized by deep pain in the plantar aspect of the heel particularly on arising from the bed in the morning. While the pain may subside with activity, in some

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patients it persists, interrupting the activities of daily living. Approximately 10% of people develop this condition throughout their lifetime (Riddle and Schappert 2004). While the etiology has not fully been established, it is believed to result from a biomechanical abnormality that places tension on the plantar fascia and leads to inflammation and tension on the calcaneal periosteum. Several risk factors such as bone spurs, pronated foot type, obesity, limb-length discrepancy and weight-bearing appear to increase the risk of plantar fasciitis (Theodore, Buch et al. 2004). In the past, conservative therapies for plantar fasciitis, such as rest and stretching, have been successful (Digiovanni, Nawoczenski et al. 2006). Orthotics, physical therapy, night splints, heel cups and treatment with non-steroidal anti-inflammatory drugs (NSAIDs) have also been used in acute cases. While conservative therapies are successful in 85%-90% of patients (Gill 1997), there remain some persistent cases of plantar fasciitis. Extracorporeal shock wave therapy (ESWT) is a noninvasive intervention for patients with chronic plantar fasciitis who have not responded to conservative therapy. Thought to be an alternative to surgical intervention, the mechanism by which ESWT relieves symptoms of plantar fasciitis is not fully understood. The shock waves are believed to stimulate an extracellular response causing neovascularization, promoting tissue repair and regeneration (Atkin, 1999; Wilner & Strash, 2004). Shock waves are characterized by high positive pressure with a rapid rise time and short (microsecond) duration and are concentrated into small focal areas to optimize therapeutic effects and minimize the impact on adjacent tissues. With a variety of devices on the market, shock waves might involve electrohydraulic, electromagnetic or piezoelectric mechanisms and, in each case, the shape of the pulse differs. Beneficial effects are expected to be observed between 6-12 weeks after treatment (Speed 2004; Wilner & Strash, 2004). Please only refer to the criteria listed above for coverage determinations conservative management). These include the HealthTronics OssaTron (October 2000), Dornier Epos Ultra (January 2002), Medispec Orthospec (April 2005) and Orthometrix Orbasone (August 2005).

12/2001: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: There were two RCTs evaluating shock wave generating devices for chronic plantar fasciitis. The Ogden study was the only RCT evaluating the OssaTron system. The Rompe study evaluated a similar device, the Siemens Osteostar. The Ogden study had substantial threats to validity including inadequate description of randomization and statistical analysis techniques and incomplete presentation of data. In the Ogden article, a significantly higher proportion of patients in the active treatment group than the placebo group met success criteria at 12 weeks. The Rompe study was single blind and had a small sample size; selection bias is a possibility. Rompe found a significantly greater reduction in pain in the active treatment group compared to the placebo group at 6 weeks. Neither study discussed possible adverse effects of treatment or presented long-term effectiveness data. Articles: The search yielded 10 articles. There were three empirical articles on extracorporeal shock wave treatment for chronic plantar fasciitis using the OssoTron system. One of these articles was a randomized controlled trial and 2 were case series. There were 4 articles on shock wave stimulation using devices other than the OssoTron system, 3 case series and one RCT. The two RCTs were critically appraised: Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clin Orthop 2001; (387): 47-59. See Evidence Table**.** Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: A prospective single-blind study. Arch Orthop Trauma Surg 1996; 115; 75-79. See Evidence Table.

The use of OssaTron in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria for effectiveness.*

12/11/2001: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: A new, valid randomized controlled trial (Buchbinder et al.) did not find that treatment with extracorporeal shock wave therapy using a device made by Dornier MedTech America was more effective than placebo treatment for plantar fasciitis. The Buchbinder et al. study was stronger methodologically than previous RCTs (Ogden et al., Rompe et al.) that had suggested that extracorporeal shock wave therapy might be effective. Unlike the earlier studies, Buchbinder et al. was double blind, adequately described the statistical procedures used and did an intention to treat analysis. Buchbinder et al. provides reasonably strong evidence that extracorporeal shock wave therapy does not improve pain and function 12 weeks after treatment in patients with plantar fasciitis. **Articles:** The search yielded five articles, two of which were included in the previous MTAC review. Of the three new articles, two were case series and one was a randomized controlled trial using the Dornier MedTech OPOS Ultra extracorporeal shock wave device. Buchbinder R, Ptasznit R, Gordon J. et al. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis. JAMA 2002: 288: 1364-1372. See Evidence Table.

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The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria for effectiveness.*

12/08/2004: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: There is conflicting evidence from four double-blind, sham-controlled randomized controlled trials. According to primary outcome assessment at 12 weeks, two of the RCTs reviewed (Buchbinder; Haake) did not find that ESWT was significantly more effective than a sham intervention at 12 weeks while the other two (Theodore; Ogden) did find a significant benefit of ESWT. It is not clear why findings varied. Clinical experts have stated the belief that efficacy is dependent on machine types and study protocols. Three studies used Dornier shock wave devices and the fourth (Ogden) used the OssaTron device. Three studies (all except Buchbinder) only included patients who had failed conservative therapy. The total number of shocks delivered was 2000-4000 in the negative studies and 1500-3800 in the positive studies. The energy of individual impulses may have been lower in the negative studies. Haake used shock waves of 0.08 mJ/mm2 and in Buchbinder, shockwaves varied between 0.02-0.33 mJ/mm2. In the positive studies, shock waves were 0.22 mJ/mm2 and 0.36 mJ/mm2. There were financial links with the device manufacturer in the positive studies, and there did not appear to be links in the negative studies. The studies either had a total of 12 weeks follow-up, or patients were unblinded at 12 months and eligible for other treatments. Therefore, high-quality comparative data on the effectiveness of ESWT beyond 12 weeks are not available. None of the studies reported serious adverse effects associated with ESWT.
Since the highest grade of evidence in previous reviews of this item was randomized controlled trials (RCTs), only RCTs and meta-analyses of RCTs were considered for the update. Ideally, RCTs of shock wave therapy for plantar fasciitis would have the following characteristics: Use a commercially available device Sham-controlled, or use of alternative treatment Double-blind Sufficient statistical power No financial conflicts of interest Long-term follow-up for efficacy and safety
Articles: The search yielded 18 articles, several of which were reviews. There were six publications reporting on five randomized controlled trials (two articles on the same study) and a meta-analysis of both controlled and uncontrolled studies. The meta-analysis was excluded because it was not limited to controlled studies, and only considered articles published through 2000, prior to the initial MTAC review. Three sham-controlled RCTs with sufficient statistical power were critically appraised. One RCT was excluded because it was not sham-controlled and another because it had a small sample size and no evaluation of statistical power. The studies reviewed include: Haake M, Buch M, Schoellner C et al. Extracorporeal shock wave therapy for plantar fasciitis: randomized controlled multicentre trial. BMJ 2003 327:75. See Evidence Table. Theodore GH, Buch M, Amendola A. et al. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ank Int 2004; 25: 290-297. See Evidence Table. Ogden JA, Alvarez RG, Levitt RL et al. Electrohydraulic high-energy shock wave treatment for chronic plantar fasciitis. J Bone Joint Surg 2004; 86-A: 2216-2228. See Evidence Table. Buchbinder R, Ptasznit R, Gordon J. et al. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis. JAMA 2002: 288: 1364-1372. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria for effectiveness.*

04/02/2007: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: There is some new evidence that ESWT treatment is effective in the short-term (3 months) for treating chronic plantar fasciitis that is unresponsive to conservative therapies. Both randomized controlled trials reviewed for the 2007 MTAC update found significantly greater reduction in pain after 3 months with active ESWT treatment compared to a placebo intervention. Overall, the findings from double-blind placebo-controlled RCTs are mixed. Some, including the two recent studies, have found a significant benefit with ESWT treatment whereas other studies did not. Studies have varied in the type of design used and the protocol e.g. number of sessions, energy level, number of shocks delivered, etc. The positive studies such as the two new studies, but not the negative studies, appear to have financial links with the device manufacturer, although specific biases introduced by industry funding were not identified. The absolute benefit of ESWT in statistically significant studies tended to be small, e.g. 1 point or less difference between groups on a 10-point visual analogue scale. Evidence of long-term effectiveness is lacking. None of the RCTs had blinded assessment of pain outcomes beyond 3 months. None of the studies reported serious adverse effects associated with ESWT. No Cochrane collaboration meta-analysis was identified. The Kaiser Interregional New Technology Committee (INTC) reviewed this topic in November 2006 and concluded that there was insufficient evidence of efficacy based on methodological limitations of studies and lack of long-term follow-up. New RCTs identified in the literature

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search were screened using the same criteria as in the previous MTAC review. These criteria are: Use of a commercially available device Included patients who meet FDA approved indication for treatment Sham-controlled, or use of alternative treatment Double-blind Sufficient statistical power No financial conflicts of interest Long-term follow-up for efficacy and safety
Articles: Four double-blind sham-controlled RCTs have been reviewed by MTAC (Haake et al., 2003; Theodore et al., 2004; Ogden et al., 2004; Buchbinder et al. 2002). Two additional double-blind sham-controlled RCTs conducted with patients who had failed conservative therapy for at least 6 months were identified. Both used commercially available devices. Neither study had long-term follow-up of effectiveness or had financial links with the device manufacturers. These two studies were critically appraised. Other new RCTs were excluded from further review. Two studies (Porter and Shadbolt, 2005; Wang et al., 2006) used ESWT as the initial treatment, not an FDA-approved indication. Another RCT (Rompe et al., 2005) compared two techniques for delivering ESWT; there was no comparison group that did not receive shockwave treatment. References for the critically appraised studies are as follows: Malay DS, Pressman MM, Assili A et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: Results of a randomized, double-blinded, multicenter intervention trial. J Foot & Ankle Surg 2006; 45(4): 196-210. See Evidence Table. Kudo P, Dainty K, Clarfield M et al. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shockwave therapy (ESWT) device: A North American Confirmatory Study. J Orthop Res 2006; 24: 115-123. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

04/21/2014: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: While the 2007 MTAC review identified two RCTs to support short-term effectiveness of ESWT when compared with placebo, the cumulative body of evidence (including four RCTs from previous reviews) was conflicting and lacked support of long-term effectiveness. The current literature search identified one meta-analysis pooling data from seven RCTs specifically aimed at examining the effectiveness of ESWT compared to placebo. Three additional trials were identified that compare ESWT to endoscopic plantar fasciotomy (EPF). The meta-analysis by Aqil and colleagues included seven RCTs with strict inclusion criteria. Due to differences in outcome measures and follow-up timeframes, pooled analysis of only four of the included studies was possible. Ultimately, ESWT had favorable results compared with placebo with five of the six included studies reaching significance after short term follow up (12 weeks). (Aqil, Siddiqui et al. 2013). Saxena et al. treated 25 athletes experiencing chronic plantar fasciitis with EPF, ESWT or placebo ESWT (P-ESWT). At one year follow up, the overall Visual analogue Scale (VAS) and Roles and Maudsley (RM) scores showed statistical improvement within both the EPF and ESWT groups. Treatment outcomes in the EPF group were significantly better than both ESWT and P-ESWT. The investigators report, however, that patients enrolled in ESWT were able to continue with their exercise regimen, while the EPF group were delayed in their return to athletic activity by 2.8 months on average (Saxena, Fournier et al. 2013). Radwan and colleagues randomized 65 patients to either ESWT or EPF for the treatment of resistant plantar fasciitis. At follow-up (3 weeks, 3 months and 12 months), both groups achieved progressive improvements, however, the majority of improvements in the ESWT group were seen between week three and week 12 while the EPF group saw more improvement lasting from week three to 12 months post-intervention. With that said, there were no significant differences detected between groups through the different time periods for any measured parameter except for the AOFAS maximum walking distance and gait sub-scores at three weeks (ESWT group p=005 and EPF group, p=002) (Radwan, Mansour et al. 2012). Finally, in 2010 Othman and colleagues prospectively evaluated 37 patients with chronic plantar fasciitis who self-selected either EPF or ESWT treatment after discussion of possible outcomes. Their results maintain similar trends with slightly better results seen in the EPF group but identification of the ESWT intervention as the preferred treatment option due to the benefits of no complications, no immobilization and earlier return to work (Othman and Ragab 2010). In general, study quality was good with randomization and appropriate comparison groups. For the most part, outcome measures were consistent throughout the selected literature, however, the intensity and the frequency of ESWT application varied and sample sizes were relatively small. The results from the recent meta-analysis provide evidence to suggest that ESWT is a safe and effective treatment of chronic plantar fasciitis compared to placebo in the short term. When compared to surgical intervention, however, ESWT does not perform as well. EPF produces better outcomes but is associated with morbidities such as prolonged healing, loss of time from work, nerve injury and tarsal instability. **Conclusion**: There is insufficient evidence from large, well design randomized trials that ESWT is an effective treatment for chronic plantar fasciitis. There is insufficient evidence to support the safety of ESWT as a treatment option for chronic plantar fasciitis. **Articles:** The literature search revealed over 200 publications which included systematic reviews and practice

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recommendations. After articles were screened for randomization and outcome comparison one meta-analysis pooling data from RCTs and three RCTs/clinically controlled trials that compared ESWT with the surgical intervention, endoscopic plantar fasciotomy (EPF), were identified. The following articles were selected for critical appraisal: Aqil A, Siddiqui MRS, Solan M, Redfern DJ, Gulati V, Cobb JP. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: a meta-analysis of RCTs. Clinical Orthopedic Related Research 2013; 471:3645-3652. See Evidence Table. Saxena A, Fournier M, Gerdesmeyer L, Gollwitzer H. Comparison between extracorporeal shockwave therapy, placebo ESWT and endoscopic plantar fasciotomy for the treatment of chronic plantar heel pain in the athlete. Muscles, Ligaments and Tendons Journal 2012;2(4):312-316. See Evidence Table. Radwan YA, Mansour AMR, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. International Orthopaedics 2012; 36:2147-2156. See Evidence Table. Othman AMA, Ragab EM. Endoscopic plantar fasciotomy versus extracorporeal shock wave therapy for treatment of chronic plantar fasciitis. Arch Orthop Trauma Surg 2010; 130:1343-1347. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis

BACKGROUND

Extracorporeal shock waves are characterized by high positive pressure with a rapid rise time and short (microsecond) duration. The shock waves are concentrated into small focal areas of 2 to 8 mm to optimize therapeutic effects and minimize the impact on adjacent tissues. There are several types of shock wave generating systems; they can involve electrohydraulic, electromagnetic or piezoelectric mechanisms. The shape of the pulses differs depending on the mechanism. In all of the systems, shock waves are concentrated by focusing reflectors on the target site. The shock waves can be further localized using imaging modalities such as ultrasound. Beneficial effects are expected to be observed between 6-12 weeks after treatment (Speed 2004; Wilner & Strash, 2004). Extracorporeal shock wave therapy (ESWT) is used as a non-invasive alternative to surgery for patients with soft tissue conditions including lateral epicondylitis (tennis elbow). ESWT is general reserved for patients who have not responded to conservative therapy such as physical/occupational therapy, bracing or splinting, local steroid injections and non-steroidal anti-inflammatory drugs (NSAIDs). Lateral epicondylitis is characterized by pain at the epicondyle on the lateral side of the elbow. The etiology is not well known, but it is generally believed to be due to musculotendinous lesions. The onset of pain can occur abruptly after an unaccustomed activity or can develop gradually in individuals who perform activities requiring repetitive and vigorous use of the forearm. Pain is often mild at first but can worsen over time (Buchbinder 2004; Melikyan, 2003). Two ESWT devices, the Siemens Sonocur (July 2002) and the HealthTronics OssaTron (March 2003) have been approved by the FDA for the treatment of chronic lateral epicondylitis in individuals age 18 or older who have a history of unsuccessful conservative treatments. The OssaTron is an electrohydraulic device and the Sonocur uses electromagnetic technology. Extracorporeal shockwave therapy for epicondylitis was previously reviewed by MTAC in February,2005 and did not meet MTAC evaluation criteria.

02/07/2005: MTAC REVIEW

Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis

Evidence Conclusion: This review evaluated ESWT for patients with epicondylitis who had failed conservative therapy. Three double blind sham-controlled RCTs were identified, with mixed findings. The Melikyan and Haake studies did not find significant differences between the active treatment and control group on any outcome measure. Rompe found that the group receiving active ESWT had a significantly better outcome at 3 months. Pain reduction but not function was better in the treatment group at 12 months. The Melikyan study may have been underpowered (did not discuss power), but the Haake and Rompe studies were planned to have sufficient sample sizes to detect clinically significant differences. Differences in study methodology include whether the use of concurrent conservative treatments was allowed, whether local anesthesia was used during ESWT and the specific shockwave devices used. In the Haake study, patients were not restricted from using conservative treatments after ESWT. Rompe permitted use of other treatments after 3 months. Melikyan did not mention use of additional treatments. The Haake study used local anesthesia during the intervention, but Rompe and Melikyan, one positive and one negative study, did not. (Anesthesia may make it more difficult to locate the area of greatest pain). The Rompe study used the Siemens SONOCUR plus, Melikyan used the Dornier Epos Ultra and Haake used both of these. There were eight articles reporting on seven randomized controlled trials (two publications on the same study). In addition, there was a Cochrane Library review of randomized controlled trials conducted in 2001. The Cochrane review included only two trials, too few for a meaningful meta-analysis. Most of the RCTs identified were published after the Cochrane Review was completed. Individual RCTs were considered for critical

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appraisal. Ideally, RCTs of shock wave therapy for epicondylitis would have the following characteristics: Use a commercially available device, include patients who meet FDA approved indication for treatment, Sham-controlled, or use of alternative treatment, Double-blind, Sufficient statistical power, No financial conflicts of interest, Long-term follow-up for efficacy and safety
Articles: Three of the six RCTs included patients who met the FDA approval criterion of a history of unsuccessful conservative treatment. All of these were double-blind, sham-controlled, used commercially available devices and did not report significant financial conflicts of interest. These three RCTs (four articles) were critically appraised, the citations are as follows: Melikyan EY, Shahin E, Miles J et al. Extracorporeal shock-wave treatment for tennis elbow. J Bone Joint Surg (Br) 2003; 85-B: 852-855. See Evidence Table. Haake M, Konig IR, Decker T. et al. Extracorporeal shock wave therapy in the treatment of lateral epicondylitis. J Bone Joint Surg 2002; 84-A: 1982-1991. Additional data reported in Haake et al. Arch Orthop Trauma Surg 2002; 122: 222-228. See Evidence Table Rompe JD, Decking J. Schoellner C et al. Repetitive low-energy shock wave treatment for chronic epicondylitis in tennis players. Am J Sports Med 2004; 32: 734-743. See Evidence Table.

The use of extracorporeal shock wave treatment in the treatment of lateral epicondylitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

04/02/2007: **MTAC REVIEW**
Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis
Evidence Conclusion: A Cochrane collaboration review concluded that shock wave therapy provides little or no benefit in terms of pain and function in epicondylitis. In meta-analyses of 2 to 3 studies each, shockwave therapy was not significantly better than placebo for the vast majority of outcomes. A limitation of the Cochrane review was that, due to differences in study methods, summary estimates could be obtained only for a few studies at a time, not for all of the trials they identified. Several of the RCTs included in the Cochrane review were examined in greater depth. Three double-blind sham-controlled RCTs, conducted among patients who had failed conservative therapy, were evaluated for the 2005 MTAC review. Findings were mixed. Two studies did not find significant differences between the active treatment and control group on any outcome measure; one of these may have been underpowered. The third found that the group receiving active ESWT had a significantly better outcome at 3 months, and pain reduction but not function was better in the treatment group at 12 months. One additional well-conducted RCT with patients who had failed conservative treatment was identified for this update (Pettrone et al., 2005). The Pettrone study, in which no local anesthesia was used, found that ESWT was significantly more effective than placebo at reducing pain 50% or more after 12 weeks (61% in shockwave group, 29% in placebo group). The new study appeared to be the only RCT evaluated for MTAC in which the authors received a substantial financial contribution from the manufacturer. The body of literature on shockwave therapy for epicondylitis does not permit a clear conclusion about efficacy. Findings from RCTs are contradictory, and a Cochrane review concluded that treatment provides little or no benefit. Differences in outcome may be due in part to variability in study design e.g. type of device, whether or not local anesthesia was used and whether use of any conservative treatments were permitted after ESWT. A Canadian brief technology assessment that searched the literature through March 2005 was identified (CADTH, 2007). There was no quantitative meta-analysis. The authors concluded that results from RCTs have been conflicting. A Cochrane collaboration systematic review was identified that included literature published through February 2005. The meta-analysis in the Cochrane review was of limited scope due to the inability to combine trials with varying methodology e.g. different outcome measures, time frames for analysis, etc. Due to the limited meta-analysis in the Cochrane review, individual RCTs were also examined for this MTAC update. For the previous MTAC review, the following criteria were used to identify the strongest and most relevant RCTs: Use of a commercially available device, Included patients who meet FDA approved indication for treatment, Sham-controlled, or use of alternative treatment, Double-blind, Sufficient statistical power, No financial conflicts of interest, Long-term follow-up for efficacy and safety
Articles: In 2005, the 3 RCTs that most closely met the above criteria were critically appraised. Other RCTs screened at that time did not include patients meeting the FDA-approved criterion of a history of unsuccessful conservative treatment. One new RCT was identified that was placebo-controlled, double-blind, used a commercially available device (Sonocur) and included patients who had failed conservative treatment. The Cochrane review and new RCT were critically appraised: Buchbinder R, Green SE, Youd JM. Shockwave therapy for lateral elbow pain. Cochrane Library 2007: Volume 1. Date of most recent update: March 2006. See Evidence Table.

The use of extracorporeal shock wave treatment in the treatment of lateral epicondylitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Extracorporeal Shock Wave Therapy (ESWT) for Delayed or Nonunion Fractures

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BACKGROUND
Healing is delayed in approximately 10% of the fractures that occur in the United States. The definitions of non unions differ, but a fracture is generally considered to be a non-union if it has not healed by 6-9 months. Factors contributing to the occurrence of delayed unions and non-unions include the location and severity of the fracture, the extent of soft tissue damage, adequacy of stabilization or fixation, and lifestyle factors such as smoking and high alcohol intake (Hadjiargyrou et al., 1998; Biederman et al., 2003). Low-intensity ultrasound treatment was approved by the FDA in 2000 for treating non-union fractures. Some investigators believe that extracorporeal shock wave treatment (ESWT) has greater potential for treating delayed union and non-union fractures than ultrasound. Shockwaves are characterized by high positive pressure with a rapid rise time and short duration. Following the high positive pressure is an exponential decrease in pressure. The low-frequency components of shock waves allow them to pass through fluid and body tissues with less energy loss than ultrasound. Thus, shock wave treatment may be better than ultrasound for penetrating tissues and delivering adequate pressure for stimulation of bone growth (Rompe et al., 2001; Speed 2004; Wilner & Strash, 2004). ESWT has not been approved by the FDA for treating non-union or delayed union fractures. The use of shock waves for bone repair has been studied in animal models and initial clinical studies. MTAC has not previously reviewed ESWT for treating delayed or non-union fractures.

02/07/2005: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Delayed or Nonunion Fractures
Evidence Conclusion: There is insufficient evidence to determine whether extracorporeal shock wave treatment is effective for treating delayed unions and non-unions. Only case series data were available; these described the proportion of cases that healed at the end of the study period. Since the studies did not include concurrent comparison or control groups, it is not possible to know what the healing rate in these groups of patients would have been without the shock wave intervention. The authors of both studies that were reviewed called for controlled studies to be conducted. Treatment of delayed unions or non-unions are not FDA-approved indications for ESWT. The search yielded 19 articles, some of which were on related treatments or related conditions. Ideally, studies on the effectiveness of shock wave therapy would have the following characteristics: Randomized controlled trial, Use a commercially available device, Include patients who meet FDA approved indication for treatment, Sham-controlled, or use of alternative treatment, Double-blind, Sufficient statistical power, No financial conflicts of interest, Long-term follow-up for efficacy and safety
Articles: There were no randomized or non-randomized controlled studies. The empirical literature consisted of two prospective and one retrospective case series. The two prospective case series were critically appraised. The citations for the reviewed articles are as follows: Biedermann R, Martin A, Handle G et al. Extracorporeal shock waves in the treatment of nonunions. J Trauma 2003; 54: 936-942. See Evidence Table. Rompe JD, Rosendhl T, Schollner C et al. High-energy extracorporeal shock wave treatment of nonunions. Clin Orthoped Rel Res 2001; 387: 102-111. See Evidence Table.

The use of extracorporeal shock wave treatment in the treatment of delayed union or nonunion fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound
0513T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)

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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Creation Date	Review Dates	Date Last Revised
12/12/2001	04/06/2010[MDCRPC], 02/11/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
07/18/2018	Removed coverage statement for FEHB, Changed the Medicare coverage language for code 28890
08/04/2020	Removed deleted CPT codes 0299T and 0300T; Added CPT codes 0512T and 0513T; Added Medicare LCA A57642

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Clinical Review Criteria
Sacroiliac Joint Fusion (SIJ Fusion)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Sacroiliac Joint Injections and procedures (L39464)
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for ***Open or Percutaneous (minimally invasive) SIJ Fusion***, Kaiser Permanente has chosen to use their own Clinical Review Criteria for medical necessity determinations. Please refer to the Non-Medicare criteria below. ***Please Note:** Noridian currently does not cover RFA ablation of the SIJ joint. Potential candidates for SIJ fusion must be evaluated on a case-by-case basis regarding this issue referenced in above LCD.

For Non-Medicare Members

Effective until June 1, 2023

A. Open sacroiliac joint fusion is medically necessary when **ALL of the following** are met:
   1. Appropriate imaging studies demonstrate localized sacroiliac joint pathology
   2. The individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery
   3. And **ONE of the following**:
      a. Post-traumatic injury of the SI joint (e.g., following pelvic ring fracture)
      b. As an adjunctive treatment for sacroiliac joint infection or sepsis
      c. Management of sacral tumor (e.g., partial sacrectomy)
      d. When performed as part of multisegmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis)

B. Open sacroiliac joint fusion is not covered for **ANY** other indication, including the following, because it is considered experimental, investigational or unproven:
   1. Mechanical low back pain
   2. Sacroiliac joint syndrome
   3. Degenerative sacroiliac joint
   4. Radicular pain syndromes

C. Percutaneous or minimally invasive sacroiliac joint stabilization (e.g., iFuse Implant System™, SImmetry® SI Joint Fusion System) for sacroiliac joint fusion (CPT code 27279) are not covered for ANY indication because there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Effective June 1, 2023

A. Open sacroiliac joint fusion is medically necessary when **ALL of the following** are met:
   1. Appropriate imaging studies demonstrate localized sacroiliac joint pathology
   2. The individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery
   3. And **ONE of the following**:
      a. Post-traumatic injury of the SI joint (e.g., following pelvic ring fracture)
      b. As an adjunctive treatment for sacroiliac joint infection or sepsis
      c. Management of sacral tumor (e.g., partial sacrectomy)
      d. When performed as part of multisegmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis)

B. Open sacroiliac joint fusion is not covered for **ANY** other indication, including the following, because it is considered experimental, investigational or unproven:
   1. Mechanical low back pain
   2. Sacroiliac joint syndrome
   3. Degenerative sacroiliac joint
   4. Radicular pain syndromes

C. Percutaneous or Minimally Invasive sacroiliac joint fusion, using an FDA-approved implant, placed across the SI joint and intended to promote bone fusion, is considered medically necessary for the treatment of low back/buttock pain resulting from degenerative sacroiliitis or sacroiliac joint disruption when **ALL of the following** criteria are met:

   1. Adults 18 years of age or older with sacroiliac joint pain for greater than 6 months (or greater than 18 months for pregnancy induced pelvic girdle pain)

   2. Significant pain originating from sacroiliac joint (e.g., pain rating of at least 5 on a 0 to 10 numeric scale)

   3. Pain is located at or close to the posterior superior iliac spine (PSIS) with possible radiation into buttocks, posterior thigh, or groin and can point to the location of pain (Fortin Finger Test)

   4. Sacroiliac joint diagnosed as etiology of pain by response (pain) to 3 or more provocative examination maneuvers that stress the sacroiliac joint (e.g., FABER test*, thigh thrust*, pelvic gapping test*, pelvic compression*, Gaenslen's test*) *see below for definitions*

   5. Clinical documentation that pain limits activities of daily living (ADL).
      a. ADLs are defined as feeding, bathing, dressing, grooming, meal preparation, household chores, and occupational tasks that are required for daily functioning

   6. Failure to respond to at least **6** months of alternative treatments consisting of **ALL of the following**
      a. Anti-inflammatory medication, one or more of the following:
         - Non-steroidal anti-inflammatory drugs (oral or topical), unless contraindicated
         - Acetaminophen
      b. A trial of Physical Therapy in the last 12 months, which should include some of the following features:
         - Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits

         *If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable.

   7. Trials of the following interventions:
      a. At least 2 (two) intraarticular SI joint *steroid* injections (location confirmed by either contrast spread or both A/P and lateral views). If patient fails to get 80% or greater pain relief as measured by a standard pain questionnaire, should have a second steroid injection at least one month later. *If this is unsuccessful in long-term relief, proceed to b.*

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
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   b. Trial of at least 2 (two) *anesthetic* injections in the lateral branch (location confirmed by either contrast spread or both A/P and lateral views), with at least 80% reduction in pain as measured by a standard pain scale, for the expected duration of the anesthetic used. 2 week minimum between the 2 injections.
   c. If anesthetic injection is successful, patient should have an RFA ablation* (*RFA ablation not covered and therefore not required for Medicare patients)*. If the anesthetic injection is not successful, or if post ablation, the pain is not reduced by less than 80% after 1 month, patient should consult with an SI joint surgeon regarding other options.

8. Alternative or contributing diagnoses MUST be absent (e.g., hip osteoarthritis, L5-S1 spine degeneration, tumor, infection, fracture). Diagnostic imaging of the SI Joint should exhibit DJD or disruption but can be read as "normal" as long as the following imaging findings are met:
   a. Imaging (CT or MRI) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint and rules out concomitant hip pathology;
   b. Imaging of the ipsilateral hip (plan radiographs, CT or MRI) that excludes the presence of osteoarthritis
   c. Imaging of the lumbar spine (CT or MRI) that excludes neural compression or other degenerative conditions that can be causing low back or buttock pain

9. There is an absence of generalized pain behavior
   a. (e.g., somatoform disorder)
   b. or generalized pain disorders (e.g., fibromyalgia)

NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery. For persons with recent nicotine use (unless there is evidence of cord compression, or other indications for urgent intervention, noted below), documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to SI joint fusion

* Provocative examination maneuvers definitions:

- **Faber (Patrick's) Test:** Applies tensile force on the anterior aspect of the SI joint on the side tested
  Flexion, Abduction and External Rotation (FABER). The patient is supine with one leg extended and the other flexed at the knee. The lateral malleolus of the flexed leg lies across the other leg superior to the patella. The test may also be performed so that the foot of the flexed leg is in contact with the medial aspect of the knee of the contralateral leg. The flexed leg is then allowed to fall into abduction, and from this position the examiner increases the external rotation by increasingly pressing the patient's knee down toward the examining table with one hand. The examiner must immobilize the pelvis on the extended contralateral side to prevent it from moving during the test.

- **Thigh Thrust Test (Posterior Shear Test):** *Applies anteroposterior shear stress on the SI joint*
  Patient lies in supine position with 90 degrees of flexion in the hip and knee on the side being tested. The examiner stabilized the contralateral side of the pelvis over the anterior superior iliac spine ASIS and applied a light manual pressure to the participant's flexed knee along the longitudinal axis of the femur.

- **Pelvic Gapping Test (SIJ distraction test):** Applies tensile forces on the anterior aspect of the SI joints
  Patient lies supine, and the examiner applies a vertically orientated, posteriorly directed force to both the anterior superior iliac spines (ASIS). The presumed effect is a DISTRACTION of the anterior aspect of the SIJ. A test is positive if it reproduces the patient's symptoms. This indicates SIJ dysfunction or a sprain of the anterior sacroiliac ligaments.

- **Pelvic Compression:** Applies compression force across the SI joints
  Patient is placed in a side-lying position, with the affected side up, facing away from the examiner, with a pillow between the knees. The examiner places a steady downward pressure through the anterior aspect of the lateral ilium, between the greater trochanter and ilia crest.

- **Gaenslen's test:** Applies torsional stress on the SI joints
  The patient lies supine with the affected side leg near the edge of the table. For safety, the patient's shoulders are positioned toward the middle of the table. The patient then draws the non-affected side leg into full flexion and holds the flexed knee. The examiner stabilizes the let with their hand placed over the patient's hand. This action keeps the ilium on the non-tested side in a slightly posterior and stable position during the maneuver.

If requesting these services, please send the following documentation to support medical necessity:

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- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of imaging reports (if applicable)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The sacroiliac joint (SIJ) connects the sacrum to the pelvis (iliac bone) on each side of the lower spine and transmits the load of the body to the lower extremities. The joint is reinforced by strong ligaments that secure the fit of the joint, and help the sacrum support the weight of the spine and head. The SIJ has a unique anatomy as it is classified as one type of joint anteriorly, and as another posteriorly. In the front, it is synovial and classified as a diarthrodial joint (a freely movable type of joint), while in the back it is fibrous or ligamentous and classified as synarthrodial (an immobile or nearly immobile joint) (Vleeming 2012, Polly 2017, Thawrani 2019).

The unique anatomic and physiologic characteristics of the SIJ makes it vulnerable to unusual mechanical stress or strain. Too much motion (hypermobility), or too little motion (hypomobility) of the joint, may lead to sacroiliac joint pain or dysfunction. This may be caused by a specific traumatic event (disruption) such as a motor vehicle accident, fall, lifting, pregnancy and childbirth; or can develop over time (degeneration) because of osteoarthritis, anatomical abnormalities such as scoliosis, leg length difference as, well as a complication of lumbar or lumbosacral fixation procedures. SIJ pain may be localized to the lower buttocks or radiates into the groin, lower back and lower extremity. It is believed that the SIJ may be the source of up to 15-30% of chronic low back pain (Rashbaum 2017, Polly, 2015, 2016.2017, Dengler 2017. Thawrani 2019).

The clinical evaluation and diagnosis of SIJ pain is challenging due to the wide variability in its clinical presentation and the overlap with the lumbar spine and hip pains. Back strain from lifting, facet syndrome, disc herniation, inflamed spinal cord roots, and sciatica can be confused with SI joint dysfunction. The joint is not easily palpated or manipulated, and there are no reliable pathognomonic or specific clinical history or physical examination findings. Imaging alone cannot accurately diagnose SJI dysfunction or differentiate between spine. hip, and SIJ pain. Assessing the pain location, patient posture/movement, and provocative manual testing are useful in making a probable diagnosis of SIJ disfunction. The most definitive evaluation is image-guided injection of anesthetic solutions into the joint which is diagnostic if there is at least 75% symptom relief (Polly 2017, Thawrani 2019).

Conservative non-surgical measures including oral analgesics, physical therapy, osteopathic and chiropractic manipulation are typically the first line therapies used for SIJ pain. Periarticular or intraarticular SIJ steroid injection and radiofrequency neurotomy of the sacral never are sometime used as last options of nonoperative management to provide short-term pain relief in some patients, but with variable success and insufficient data on the long-term effectiveness. SIJ fusion has been proposed as a potential option when the nonoperative measure have failed. Surgical fusion of the joint immobilizes the joint and eliminates its motion, which is believed to cause the inflammation and pain (Dangler 2017, Polly 2017 Tran 2019).

Traditional sacroiliac joint fusion is an open surgery that involves an incision to access the joint, removal of cartilaginous material from the joint, and use of bone grafts and screws to help the fusion. Open surgical fusion of SIJ was first reported in the early 1900s. However, it is not routinely used because of the challenges and risks associated with the procedure including the bone harvesting, potential damage to surrounding anatomic structures, intraoperative blood loss, wound size, extended hospital stays, and limits on postoperative weightbearing. Minimally invasive surgical (MIS) methods have thus been introduced over the years to provide the potential benefit of permanent stabilization of the SIJ with smaller surgical incision; less operative time, blood loss, and perioperative morbidity; and potentially faster healing (Heiney 2015.Polly 2016, Dengler 2017).

The minimally invasive SIJ fusion approach and technique differ according to the device used, but in general the steps for performing the procedure are similar. The surgery is generally performed under general anesthesia and fluoroscopy monitoring. With the patient lying face down on the operating table, a 2-3 cm incision is made in the side of the buttock and the gluteal muscles are dissected to access the ilium. A small guide pin is then inserted through the side of the ilium to create a small hole and an opening is then broached or drilled through the ilium to

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provide passage for the implants to reach the sacrum. If a bone graft is necessary, the SIJ is cleared of cartilage and soft tissues, and a bone graft is packed into the joint space (the bone graft is typically collected from a different area of the ilium or from shavings left behind from broaching the ilium). The implant instruments are guided through the passage in the ilium, and are put into place using screws, pins, or a mallet. For the triangular shaped titanium implants, a second and third device are implanted in the same procedure. The incision site is then irrigated, and the wound closed. Patients requiring treatment in both joints could undergo staged procedures (Rudolf 2012).

Reported adverse events associated with the procedure include neuropathic pain, neural impingement, postoperative hematoma, urinary retention, nausea, vomiting, SIJ pain, trochanteric bursitis, iliac bone fracture, malpositioning of the implant, wound problems, and the need for reoperations. A major risk of SIJ fusion is its failure to alleviate pain. It is also reported that because the SIJ is a key energy transfer mechanism, its fusion may possibly displace the pressure typically absorbed in the pelvis to the lower spine, creating pain and pressure in the lower back (adjacent segment disease). The latter complication was reported in about 5% of sacroiliac joint fusion patients within 6 months of surgery (Schell 2016).

Medical Technology Assessment Committee (MTAC)

Sacroiliac Fusion (SI Fusion) for Sacroiliac Joint Dysfunction

12/08/2014: MTAC REVIEW

Evidence Conclusion: Lower back pain is extremely common and the sacroiliac (SI) joint has been implicated as one of the potential sources dating all the way back to the early 1900s (Goldthwait and Osgood 1905). Formed by the connection of the sacrum and the right and left iliac bones, the SI joint lies at the junction of the spine and the pelvis. Held together by a collection of strong ligaments the SI joint only allows for limited rotation and translation. The SI joint plays a primary role in supporting the weight of the upper body. Pregnancy, gout, rheumatoid arthritis, psoriasis, ankylosing spondylitis, and other conditions that cause abnormal wear may aggravate the joints by placing an increased amount of stress on the SI joints. There are many different terms for SI joint problems, including SI joint dysfunction, SI joint syndrome, SI joint strain, and SI joint inflammation. With the most common symptoms being pain, stiffness and burning the diagnosis of SI joint conditions can prove difficult for a multitude of reasons. For starters, there are no widely accepted guidelines for diagnosis and treatment nor has any imaging modality established definitive symptoms that correlate with a visible pathology. These issues are further complicated by the large spectrum of different etiologic factors and variability that contribute to the pain. As a result, diagnosis of SI joint dysfunction relies on thorough history and physical examination. Conventional treatments for SI joint dysfunction typically consist of non-operative interventions such as injections and anti-inflammatory oral medications. However, oral steroids and physical therapy can also be helpful (Ashman, Norvell et al. 2010). In the event that conservative interventions fail, SI joint fusion has been proposed as an additional treatment option. A variety of techniques have been described over the years without the wide acceptance of a single technique. Generally speaking, the surgery entails removal of the cartilage in the SI joints followed by an implant of plates or screws to hold the bones together. The technique may even employ the use of bone grafts to promote fusion. Ultimately, the surgery is designed to eliminate SI joint motion with the overall goal to relieve pain. Several implants have received 501(k) approval from the Food and Drug Administration (FDA) and are detailed in table 1. Minimally invasive (MIS) SI joint fusions have not previously been reviewed by the Medical Technology and Assessment Committee (MTAC) and are currently being reviewed due to increased requests for coverage.
Articles: The literature search revealed just under 200 articles. No randomized control trials (RCTs) comparing MIS SI joint fusion with non-surgical treatment for the treatment of chronic low back pain due to sacroiliac joint dysfunction were identified. The only comparison studies were cohorts investigating MIS SI joint fusion versus open surgical techniques or SI joint denervation and were not selected because they did not include a nonsurgical group. Currently, there are numerous trials registered with the NIHCT set to compare MIS SI joint fusion with conservative management. The majority of the literature base was small and retrospective. The best available publications were two prospective cohorts with no comparison groups and a retrospective medical chart review of 18 patients who underwent MIS SI joint fusion surgery. The following publications were selected for critical appraisal: Wise, CL and Dall, B. Minimally invasive sacroiliac arthrodesis outcomes of a new technique. *J Spinal Disord Tech* 2008;**21**(8):579-584. **[Evidence Table 1]**. Cumming, J and Capobianco, RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Annals of Surgical Innovation and Research* 2013;**7**(1):12-18. **[Evidence Table 2]**. Duhon BS, Cher DJ, Wine KD, et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Medical Devices: Evidence and Research* 2013;**6:**219-229. **[Evidence Table 3]**

Minimally invasive sacroiliac joint fusion, with or without bone grafts and other metal implant devices and does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Sacroiliac Fusion (SI Fusion) for Sacroiliac Joint Dysfunction
04/08/2019: MTAC REVIEW
Evidence Conclusion:

- Moderate quality evidence from two open-label short-term, industry sponsored RCTs with subjective outcomes, suggest that sacroiliac joint fusion using triangular titanium implants may be more effective than conservative measures in reducing pain and improving function at 6 months among selected patients with a confirmed diagnosis of SIJ chronic disabling pain or dysfunction.
- An ideal RCT would be a sham-controlled trial or blinded assessment of the outcomes.
- The SIJ fusion procedure was associated with a low rate of adverse events, but some were severe and required re-operation. Reported adverse events include neuropathic pain, neural impingement, respiratory failure, trochanteric bursitis, iliac bone fracture, wound problems, recurrent SIJ pain, malposition or loosening of the implant, recurrent SIJ pain due to implant malposition, and the need for revision surgeries.
- There is insufficient to determine the net health outcome of the SI fusion procedure.
- There is insufficient evidence from RCTs to determine the long-term comparative efficacy and safety of minimally invasive SIJ fusion versus nonsurgical management of patients with SIJ dysfunction.

Articles: The literature search for studies published after the last MTAC review identified 6 systematic reviews (three with quantitative meta-analyses), two randomized control trials (published in multiple articles) comparing minimally invasive SIJ joint fusion with non-surgical treatment for the treatment of chronic low back pain due to sacroiliac joint dysfunction, one observational study with 4 years follow-up, and a retrospective study with six-years follow-up data. One meta-analysis pooled the results of the two published RCTs together with an observational study to identify the patient characteristics that may predict clinical outcome after surgical or nonsurgical treatment. The two RCT were selected for critical appraisal, and the outcome of the meta-analysis was summarized. See Evidence Table.

Sacroiliac Joint Fusion (SIJ Fusion) for Sacroiliac Joint Pain/Dysfunction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Minimally Invasive Sacroiliac Joint Fusion (MIS SIJF) for Sacroiliac Joint Pain/Dysfunction
07/12/2021: MTAC REVIEW
Evidence Conclusion:

- Moderate strength evidence from two open-label, industry sponsored RCTs with subjective outcomes, and high crossover rate after 6 months, suggest that minimally invasive sacroiliac joint fusion using the iFuse TTI system may be more effective (for up to six months) than conservative measures in reducing pain and improving function among selected patients with a confirmed diagnosis of SIJ chronic disabling pain or dysfunction.
- There is insufficient evidence from RCTs with long -term follow-up of patients in their initial randomization group, to determine the long-term comparative efficacy and safety of minimally invasive SIJF versus nonsurgical management of patients with SIJ dysfunction. The crossover of participants from the conservative treatment arm to the SIJF limits the long-term comparative assessment.
- Low-to moderate strength evidence from industry sponsored observational studies suggest that the benefits observed with SIJF using iFuse implanted via the lateral transiliac approach may be sustained for the 24 months follow-up duration.
- There is insufficient evidence to determine the safety and efficacy of the SIJF to patients with other sources of back pain who were excluded from the trials. Also, it is unclear if the procedure may be safe and effective in patients with other chronic disease and comorbidities e.g., osteoporosis, diabetes. cardiovascular diseases and others.
- The publishes studies indicate that SIJF procedure was associated with a low rate of adverse events, but some were severe and required re-operation. Reported adverse events include neuropathic pain, neural impingement, respiratory failure, trochanteric bursitis, iliac bone fracture, wound problems, recurrent SIJ pain, malposition or loosening of the implant, recurrent SIJ pain due to implant malposition, and the need for revision surgeries.
- The comparative studies of minimally invasive procedures evaluated lateral transiliac SIJF using iFuse triangular titanium implants, and the result may not be generalized to other devices or implantation approaches used for SIJF.

Articles: The literature search for studies published after the last MTAC review did not identify any more recent meta-analyses or RCTs on the effectiveness and safety of SIJF compared to nonsurgical therapies. The search however, revealed a report on the two-year follow-up of the iMIA randomized controlled trial reviewed earlier

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(Dengler, et al, 2019); one observational study assessing the long-term outcomes for patients enrolled in the INSITE randomized controlled trial and the SIFI single-arm prospective multicenter study (LOIS study, Whang et al, 2019); a small observational single-arm study assessing the safety and effectiveness of SIJF using a 3D-printed TTI (Patel et al 2020); a systematic review on the safety profile on minimally invasive SIJF (Shamrock, et al, 2019) a cost utility analysis of MIS SIJF from a National Health Service (NHS) England perspective; and a protocol for a meta-analysis on SIJF versus conservative management for low back pain attributed to the SIJ (Chen et al 2020). See evidence tables.

The two long-term observational follow-up of patients participating in the iMIA and INSITE studies were selected for critical appraisal; and the results of the systematic review on the safety of the procedure was summarized.

Minimally Invasive Sacroiliac Joint Fusion (MIS SIJF) for Sacroiliac Joint Pain/Dysfunction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed

Considered Not Medically Necessary:
Effective until June 01,2023

CPT® Codes	Description
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
08/27/2014	09/02/2014[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	04/27/2023

[MPC] Medical Policy Committee

Revision History	Description
06/23/2016	Added NCD/LCD Medical Director review language
09/08/2015	Revised LCD L35008
09/06/2016	Added GH policy for Medicare members and new criteria for non-Medicare members
05/07/2019	MPC approved to adopt policy of non-coverage for SIJ Fusion for Sacroiliac Joint Pain/Dysfunction
05/05/2020	Added Medicare LCD L36000 and LCA A57596 for percutaneous/minimally invasive SIJ fusion Added clarification that policy addresses open and percutaneous/minimally invasive SIJ fusion. Added CPT code 27280.
05/21/2020	Removed Medicare LCD L36000 and LCA A57596 for percutaneous/minimally invasive SIJ fusion as it is from Wisconsin Physicians Service instead of Noridian

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09/07/2021	MPC approved to adopt MTAC's recommendation of non-coverage, maintaining a non-coverage policy for Minimally Invasive Sacroiliac Joint Fusion (SIJF). Added MTAC's review from 7/12/2021.
01/10/2023	MPC approved to adopt revised changes to the SI Joint Fusion criteria to allow coverage in certain situations. Requires 60-day notice; effective June 01, 2023.
03/06/2023	Updated applicable CPT code 0775T effective 1/1/23.
04/27/2023	Clarified indications for Medicare due to new LCD not covering RFA ablation of SI Joint.

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KAISER PERMANENTE®

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Clinical Review Criteria
Subcutaneous Implantable Cardioverter Defibrillator (SICD)

- Substernal Implantable Cardioverter Defibrillator

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Claims Processing Manual, Change Request 11605 – Transmittal 4513, section 19: Extravascular Implantable Cardioverter Defibrillator (EV ICD) **Covered if performed as part of an approved Investigational Device Exemption (IDE) study*
National Coverage Determinations (NCD)	Implantable Automatic Defibrillators (20.4)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

The use of the SICD may be considered medically necessary for all appropriate pacemaker patients who meet the following criteria:

A. Have a contraindication to a transvenous ICD due to at least **ONE of the following**:
   1. Lack of adequate vascular access; or
   2. The need to preserve existing vascular access due to chronic dialysis; or
   3. Repeat transvenous ICD placement not indicated due to complications with previous transvenous ICD placement; or
   4. Congenital heart disease; or
   5. Increased risk for bacteremia

The use of the SICD is considered investigational when the above criteria are not met.
The use of a substernal ICD (CPT Codes 0571T-0580T, 0614T) is considered investigational.

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Background

Cardiovascular disease is the most common cause of death in the Western world, and sudden cardiac death (SCD) accounts for approximately 60% of all cardiovascular mortality. SCD is responsible for ~300,000 annual deaths in the United States; with ventricular fibrillation (VF) accounting for up to one-third of cases (Zipes 1998, Estes 2011, Majithia 2014, Rhyner 2014).

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The implantable cardioverter defibrillator (ICD) was developed and introduced to clinical practice around the 1980s to address this issue of fatal SCD from ventricular tachyarrhythmia. The ICD continuously monitors the heart, identifies malignant ventricular tachyarrhythmia, and delivers an electric counter shock to restore normal rhythm. The first defibrillator received FDA approval in 1985 to be used in patients who had survived cardiac arrests. In 2002, the FDA expanded its use to patients with a history of a heart attack and depressed heart function. ICDs are widely used and studies have shown significant mortality benefit in selected patients at increased risk of SCD. However, the use of ICDs may at times be complicated with the implantation procedure, programing, device malfunction, and lead performance deterioration by time. Traditionally, the ICD is implanted transvenously by creating a pocket in the subclavicular areas and gaining vascular access to reach the heart. This approach has its drawbacks and is associated with short- and long-term adverse events. Reported complications associated with ICD systems include lead dislodgement, lead fracture, conductor coil breaks, pneumothorax, cardiac perforation, pericardial effusion, cardiac tamponade, and systemic infection. Lead malfunction occurs in up to 40% of the transvenous leads at 8 years after implantation. Lead failure either generates inappropriate shocks or impedes appropriate therapy. Extraction of the lead is recommended in cases of lead fracture, malfunction, or other mechanical problems that prevent safe and effective ICD shock therapies. This extraction is complex and can be associated with significant risks including death (Olde Nordkamp 2012, Weiss 2013, Aziz 2014, Chang 2014Majithia 2014).

The complications associated with the intracardiac leads of the implantable cardioverter defibrillators have led to the development of a totally subcutaneous ICD (S-ICD) with the intention to provide the same protection, but with less procedural and device-related risks. The S-ICD system senses, detects, and treats malignant ventricular tachycardia (VT)/ventricular fibrillation (VF) without requiring vascular access or fluoroscopy. The S-ICD system (model SQ-RX 1010, Cameron Health, Inc., San Clemente, CA) includes a dedicated external programmer, a subcutaneous pulse generator enclosed in a titanium case, and a single subcutaneous electrode containing both sensing and defibrillating components. The lead-electrode is composed of proximal and distal sensing electrodes separated by a shocking coil. The pulse generator is implanted in a subcutaneous pocket created over the fifth intercostal space between the mid and anterior axillary lines. The single lead is tunneled from the xiphoid process to the pocket and to the sternal manubrium joint. Fixation is achieved with the addition of a suture sleeve at the level of the xiphoid and a single suture at the superior parasternal portion of the lead. Implantation of the device relies entirely on anatomic landmarks and does not require fluoroscopy (although some investigators advocate brief screening to verify the final position). The currently used pulse generator weighs 145 g, has a volume of 69 ml, and an estimated 5-year battery life. The greatest advantage of S-ICD is that the lead does not pass through the central veins in the chest, nor is it attached to the tissue within the heart chambers. However, the pulse generator of the S-ICD is approximately twice the volume and weight of the currently used transvenous ICD, which may prevent its use in children, and increase the risk of erosion, discomfort, and infection. In addition, the weight of the device may cause its dislodgement and changes in the shock configuration (Olde Nordkamp 2012, Weiss 2013, Aziz 2014, Chang 2014, Grace 2014, Majithia 2014).

The S-ICD system detects changes in the ventricular rate by using subsurface electrocardiography through a primary, secondary, or alternate vector. The device is programmed to select the vector that best avoids double QRS counting or T-wave oversensing events that could lead to misinterpretation of the rhythm and delivery of inappropriate shock. The heart rate is measured as the average of 4 consecutive sensed intervals. VF is diagnosed when 18 of 24 consecutive sensed events exceed the shock zone limit. Once the system detects a malignant arrhythmia, it delivers up to 80 J shock to terminate the arrhythmia and will automatically reverse polarity if the initial shock fails to terminate the arrhythmia. The mean defibrillation threshold is significantly higher than with transvenous devices, and some investigators suggest that high-energy shocks may be harmful to the myocardium (Aziz 2014, Majithia 2014, Nair 2014).

Unlike the conventional ICD devices, S-ICD is unable to provide long-term bradycardia pacing or antitachycardia pacing due to the absence of an endocardial lead. It is thus not suitable for patients with an indication for antibradycardia pacing or cardiac resynchronization therapy, or for those with a history of repetitive monomorphic ventricular tachycardia that would benefit from antitachycardia pacing. S-ICD may not be used concurrently with unipolar pacemaker as that would interfere with the S-ICD arrhythmia detection. This absence of bradycardia pacing in the S-ICD might lead to more bradycardia related events as syncope or even death. The device may be potentially useful for patients who are not eligible for transvenous ICDs, or are at high risk of complications e.g. subjects with congenital heart disease, complicated vascular anatomy, at high risk of infection, or in patients in whom vascular access is limited or needs to be conserved e.g. for renal dialysis or long-term intravenous drug therapy (Akerstrom 2013, Olde Nordkamp 2012, Chang 2014, Majithia 204).

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S-ICD received US FDA approval in September 2012, "To provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmia in patients who do not have sympathetic bradycardia, incessant (continual) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia Pacing". The FDA required that a post-approval registry be created to track outcomes of patients and devices for at least 60 months after implantation.

S-ICD has not been previously reviewed by MTAC; it is being reviewed based on a request for the Clinical Review Unit for coverage decision.

Medical Technology Assessment Committee (MTAC)

Subcutaneous Implantable Cardioverter Defibrillator

10/20/2014: MTAC REVIEW

Evidence Conclusion: The results of the published observational studies suggest that S-ICD may be accurate in detecting and reversing induced ventricular arrhythmias, however, the incidence of inappropriate therapy was as high as 13.1% (in a mean duration of 11 months in Weiss et al 2013). Inappropriate shock therapy may decrease the quality of life and increase the mortality risk.
The published studies evaluated the accuracy, efficacy and safety of S-ICD in reversing induced rather than spontaneous arrhythmias. The arrhythmia is not always predictable and as seen in one study (Kobe 2013) the S-ICD system had to be changed to transvenous ICD in a patient who needed antitachycardia pacing (ATP) therapy. A group of investigators (Gold and colleague 2012) noted that though there is no reason to suspect that electograms may differ between induced and spontaneous rhythms of similar rates and regularity, this possibility of this difference cannot be excluded. *Conclusion:* The results of the published literature indicate that: There is some evidence that S-ICD may be accurate in detecting and reversing induced ventricular arrhythmias. There is insufficient evidence to date, to determine the efficacy or effectiveness to S-ICD in terminating spontaneous VT/VF episodes. S-ICD may lead to inappropriate shock therapy in up to 13.1% of cases. There is insufficient evidence to determine the long-term safety of the S-ICD system. There is insufficient evidence to determine that S-ICD is safer or more effective than conventional transvenous ICD. No randomized controlled trial that compared the two devices head to head was published to date. There is insufficient evidence to determine that the use of S-ICD prevents or reduces sudden death from ventricular arrhythmias.
Articles: The literature search revealed over 300 citations on subcutaneous implantable cardioverter defibrillator. The majority were reviews or opinion pieces. No published RCTs that compared the safety and efficacy of the S-ICD head to head with the conventional transvenous ICD or other therapeutic interventions were identified; only the published rationale and design of the ongoing PRAETORIAN trial that is comparing the subcutaneous to the transvenous implantable defibrillators. There were a number of published observational studies including those that led to the European approval as well as the pivotal study (Weiss et al, 2013) leading to the US Food and Drug Administration approval. The search also identified a paper documenting the early results from the EFFORTLESS S-ICD Registry that was created to document the clinical, system, and patient-related outcome data from patients implanted with S-ICD in multiple centers in Europe and New Zealand. The pivotal prospective study (Weiss et al, 2013) and a study with a comparison group (Kobe 2013) were selected for critical appraisal: Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013; 128(9):944-953. See Evidence Table. Köbe J, Reinke F, Meyer C, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. Heart Rhythm. 2013;10 (1):29-36. See Evidence Table.

The use of Subcutaneous Implantable Cardioverter Defibrillator does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Subcutaneous ICD (SICD)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed

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33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

Substernal ICD

Medicare - Considered medically necessary when performed as part of an approved Investigative Device Exemption (IDE) study:
Non-Medicare – Considered not medically necessary - experimental, investigational or unproven:

CPT® or HCPC Codes	Description
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0575T	Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional
0576T	Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/23/2014	11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	03/01/2022

MPC Medical Policy Committee

Revision History	Description
07/18/2016	Added NCD 20.4
09/08/2015	Revised LCD L35008
11/07/2017	MPC approved to adopt criteria for SICD
03/01/2022	Added Medicare links and codes related to substernal ICD, noted that substernal ICD is considered investigational for non-Medicare.

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Clinical Review Criteria
Signal-Averaged Electrocardiography (SAECG)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Signal-Averaged Electrocardiography (SAECG)" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Signal-averaged electrocardiography (SAECG) is a technique involving computerized analysis of small segments of a standard ECG to detect abnormalities that would be otherwise obscured by "background" skeletal muscle activity.

Sudden cardiac death (SCD) is a major health problem worldwide. It has been estimated that between 184,000 and 462,000 Americans die suddenly each year from sustained ventricular tachycardia or ventricular fibrillation. The majority have coronary artery disease and left ventricular dysfunction. Multiple large clinical trials have shown that prophylactic implantable cardioverter defibrillator (ICD) can prevent or abort these arrhythmic events and reduce mortality. It is thus critically important to identify those patients at risk to prevent potentially lethal arrhythmias (Cain 1996, Iravanian 2005, Goldberger 2008, Pandey 2010, Stein 2008).

Several invasive and noninvasive approaches or tests have been studied to stratify the patient with risk of ventricular arrhythmia and sudden death. Noninvasive methods include measurement of QRS duration on the 12-

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lead ECG, measurement of heart rate variability (HRV) and baroreflex sensitivity, detection of non-sustained ventricular tachycardia; signal averaged electrocardiography (SAECG), and several others (Stein 2008).

SAECG was introduced in the 1970s primarily for the detection of patients at high risk of sudden cardiac death after myocardial infarction. It is based on the idea that most life-threatening ventricular arrhythmias are reentrant in nature among patients with structural heart disease. The arrhythmias require an area of slow conduction to allow their perpetuation. These areas of delayed conduction within the ventricular myocardium (ventricular late potentials) can often be demonstrated by invasive electrophysiological studies performed in sinus rhythm. SAECG seeks to detect the occurrence of late activation within the myocardium noninvasively via surface ECG electrodes. It involves computerized analysis of segments of a standard surface ECG to compare and average consecutive QRS complexes (usually around 300) and produce a filtered QRS complex that provides information on the presence of ventricular late potentials (Chandrasekaran 1999, Stein 2008, Liew 2010).

Medical Technology Assessment Committee (MTAC)

Signal-Averaged Electrocardiography (SAECG)

12/19/2011: MTAC REVIEW

Evidence Conclusion: The literature search did not identify any randomized controlled trials that examined the effect of stratifying patients at risk of sudden death based on SAECG, or its effect on improving health outcomes. The results of the published studies showed that the sensitivity of SAECG to predict arrhythmic events ranged from 15% to 75%. It had very low positive predictive value which indicates that it is not a useful when used alone to identify high risk patients. However, SAECG had a high negative predictive value, which may indicate that it could potentially be useful in identifying low-risk patients. Bailey and colleagues (2001) conducted a meta-analysis to examine the utility of various tests for risk stratification. The analysis included 44 studies that evaluated the accuracy of signal-averaged electrocardiography, heart rate variability, severe ventricular arrhythmia on ambulatory electrocardiography, left ventricular ejection fraction, and electrophysiological studies in predicting risk major arrhythmic events (MAE) after a myocardial infarction (MI). There were variations between the studies in patient characteristics, cutoff points for the tests, and reporting of cause of cardiac death. In addition, the authors of the meta-analysis did not evaluate the quality of the studies, test for homogeneity or publication bias. Overall the analysis shows that the sensitivity of all tests ranged from 42.8% to 62.4% and the specificity ranged from 77.4% to 85.8%. The pooled sensitivity of SAECG was 62.4% (95% CI; 56.4-67.9%) (ranging from 35%-94% in 22 studies involving 9,883 patients), and the pooled specificity was 77.4% (95% CI; 73.6-80.8%, range 62-95.5%). The technology had a low positive predictive value ranging from 8-29%, but a high negative predictive value (81-99%) suggesting that it may have the potential of avoiding unnecessary implantation of a cardioverter-defibrillator (ICD). 3-stage stratification yielded a low-risk group (80.0% with a two-year MAE risk of 2.9%), a high-risk group (11.8% with a 41.4% risk) and an unstratified group (8.2% with an 8.9% risk equivalent to a 2-year incidence of 7.9%). The authors concluded that sensitivities and specificities for the 5 tests were relatively similar and no one test was satisfactory alone for predicting risk. Combinations of tests in stages allowed the authors to stratify 92% of patients as either high-risk or low-risk. They noted that these data suggest that a large prospective study to develop a robust prediction model is feasible and desirable. The CARISMA study (Huikuri 2009) also evaluated the ability of several invasive and noninvasive risk markers to predict arrhythmias after an acute myocardial infarction, with the potential to be treated with an ICD. 5,869 consecutive patients from 10 European centers were screened 2-7 days after experiencing an acute myocardial infarction (AMI), but only 312 met the inclusion criteria and were included in the study. Risk stratification was performed 6 weeks after the AMI using echocardiography, Holter monitoring, microvolt T-wave alterans, SAECG, standard 12-lead ECG, and electrophysiological studies. The primary endpoint was ECG-documented fatal or near-fatal cardiac arrhythmia (ventricular fibrillation or symptomatic sustained ventricular tachycardia). The arrhythmic events were documented with implantable ECG loop recorder. Patients were followed up for 2 years during which 25 (8%) experienced a fatal or non-fatal tachyarrhythmias. The strongest predictor for these events was heart rate variability ($p<0.001$) as measured by Holter monitor. This was followed by induction of sustained monomorphic ventricular tachycardia during programmed electrical stimulation ($P=0.003$). QRS duration measured from SAECG had a lower predictive value especially after adjustments were made for clinical variables. An assessment made for AHRQ in 1998 also found that SAECG had variable sensitivity and specificity, poor positive predictive value, but relatively high negative predictive value (NPV) for post MI fatal arrhythmic events. The high NPV was attributed to the low incidence of fatal arrhythmic events post MI, due to the increase use of antithrombotic therapy. The 2006 American College of Cardiology, American Heart Association and European Society of Cardiology guidelines (Zippes 2006) for management of patients with ventricular arrhythmias and prevention of

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sudden death, list SAECG with a Class IIb recommendation (Class IIb noted as usefulness/efficacy is less well established by evidence/opinion). The report notes that the presence of an abnormal SAECG was shown to increase the risk of arrhythmic events by 6- to 8-fold in a post-MI setting. However, the restoration of patency to the infarct-related coronary artery with fibrinolysis or angioplasty and the widespread use of surgical revascularization have modified the arrhythmogenic substrate, leading to a noticeable reduction in the predictive power of this tool. The report indicated that SAECG in isolation is no longer useful for the identification of post-MI patients at risk of ventricular arrhythmias. A number of health plans consider signal-averaged electrocardiography investigational and not medically necessary for all indications including risk stratification for arrhythmias after a myocardial infarction. Conclusion: In evaluating any method for risk stratification it is important to demonstrate that the test or marker can be used to select patients for a therapy or intervention that will improve outcome. Signal-averaged electrocardiography (SAECG) has been proposed as a noninvasive method for arrhythmia risk stratification. However, there is insufficient published evidence to its efficacy in establishing the risk of ventricular arrhythmias and sudden death. There is also insufficient evidence to determine clinical utility of SAECG testing in selecting patients for receiving pharmacological therapy, ICD implantation or other treatments.

Articles: The literature search did not identify any large prospective or randomized trials that examined the benefit of using SAECG for selecting patients for electro physiologic studies, or its clinical utility for selecting patients for prophylactic therapies and/or interventions and improving health outcomes. There was a large number of earlier studies conducted in the 1990s that examined the accuracy of SAECG and various other variables in predicting the risk of major arrhythmic events after a myocardial infarction, and a meta-analysis (Bailey 2001) that pooled the results of these studies published before 2001.The search also identified a more recent study (CARISMA study) that evaluated the ability of several invasive and noninvasive risk markers to predict arrhythmias that can potentially be treated with an ICD, and another study that compared the ability off SAECG and ejection fraction for predicting future cardiovascular events including life threatening arrhythmias in different cardiac diseases. The meta-analysis and CARISMA study were selected for critical appraisal: Bailey JJ, Berson AS, Handelsman H. Utility of current risk stratification test for predicting major arrhythmic events after myocardial infarction. *J Am Coll Cardiol* 2001; 38:1902-1911. See Evidence Table Huikuri HV, Raatikainen MJ, Moerch-Joergensen R, et al. Prediction of fatal or near-fatal cardiac arrhythmia events in patients with depressed left ventricular function after an acute myocardial infarction. *Eur Heart J.* 2009; 30:689-698. See Evidence Table

The use of SAECG does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
93278	Signal-averaged electrocardiography (SAECG), with or without ECG

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
01/03/2012	01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision	Description

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History	
09/01/2020	Added KPWA Medical Policy statement under Medicare section

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Clinical Review Criteria
Wireless Motility Capsule

- SmartPill for the Evaluation of Gastrointestinal Motility Disorders

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Wireless Motility Capsule***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastrointestinal (GI) symptoms including abdominal pain, bloating, vomiting, diarrhea, and constipation, are common in the general population and may lead to patient distress, impairment in functioning, and loss of productivity. Many of these symptoms may be linked to motility disorders, which may affect any region of the GI tract and include gastroparesis, intestinal pseudo-obstruction, and slow transit constipation. Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. It is manifested by upper GI symptoms including nausea, vomiting, early satiety, and objective evidence of delayed gastric emptying. Patients with slow transit constipation commonly present with lower GI symptoms such as abdominal pain, infrequent hard stools, and evidence of delayed colonic transit on objective testing. Sometimes it is hard to differentiate between upper and lower GI involvement and some patients may experience overlapping symptoms due to the involvement of multiple regions of the GI tract. In addition, signs of gastroparesis and chronic constipation are often confused with symptoms from conditions such as irritable bowel syndrome (IBS) and functional dyspepsia. It is thus important to localize the transit abnormalities to a specific GI lesion to accurately diagnose the disorder and guide the appropriate management (Williams 2011, Arora 2015, Gronlund 2017).

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Motility disorders are hard to diagnose and cannot be measured by routine imaging or endoscopic examinations. A clinical diagnosis is based on physiological tests most of which have some inconsistency in performance, making it hard to interpret the results, and may require using more than one test to make a diagnosis. Experts in the field indicate that currently, there are no gold standards or true motility measures to validate methods used for the assessment of gut motility, and that no current standardized tool can concurrently assess transit time and distinguish between motility abnormalities in the various parts of the GI tract (Stein 2013, Gronlund, 2017).

Commonly used methods for evaluating patients with suspected gastroparesis include gastric emptying scintigraphy, antroduodenal manometry, upper GI barium series, and gastric emptying breath testing utilizing a stable carbon isotope. Scintigraphy is often considered the reference standard for measuring gastric emptying time despite its limitations. It involves exposure to radiation, and lacks standardization between centers as regards meal composition, monitoring times, reported endpoints, and normal values. It also takes long time periods of imaging and may require multiple visits to the investigating facility (Kuo 2008, Stein 2013, Wang 2015, Saad 2016).

The main diagnostic methods used for the evaluation of possible slow-transit constipation include radiopaque marker (ROM) examination, small bowel and colonic scintigraphy, colonic and anorectal manometry, and lactulose breath testing. ROM is widely used, and may be considered a reference standard, but has its drawbacks including radiation exposure, inability to access regional gut transit, and the lack of standardized protocol for the test and its interpretation. In addition, some protocols require multiple visits, which may affect compliance (Rao 2009, Sarosiek 2010, Tran 2012, Stein 2013, Saad 2016)

A wireless motility/pH gastrointestinal monitoring system was developed in 2003, as a radiation-free noninvasive alternative to traditional nuclear and radiological measurements used for the evaluation of GI motility disorder. The system provides a method of measuring regional and whole gut transit time in a single standardized ambulatory test. It consists of a wireless motility capsule (WMC, SmartPill), a SmartPill Data Receiver, a Docking Station, and a system computer loaded with SmartPill Software. WMC is a data recording device 26.8mm in length and 11.7mm in diameter (about the size of a large vitamin pill). It consists of a rigid polyurethane shell containing a battery that lasts for a minimum of 120 hours, sensors for pH, temperature, and pressure; and a transmitter. WMC is a single use, orally ingestible, non-digestible capsule that provides real-time measurement of the temperature, pressure, and pH of its immediate surrounding. It can measure gastric emptying time (GET), small bowel transit time (SBTT), colonic transit time (CTT), and whole gut transit time (WGTT), but does not provide information on segmental colonic transit times, i.e. it is unable to show where the motility disturbance originates in the colon. It is to be noted that WMC measures the emptying of a non-digestible solid, unlike the gastric emptying scintigraphy and breath testing that measure gastric emptying of digestible solids. WMC may not correspond to physiological emptying of food; it does not empty with the meal but is generally cleared from the stomach by powerful inter-digestive antral contractions (phase III MMC [migrating motor complex] contractions) that occur after the meal has been emptied to clear the stomach of indigestible material. Thus, as some investigators indicate, the passage of WMC into the duodenum correlates only modestly with the gastric emptying of nutrients (Kuo 2011, Saad 2011, 2016, Tran 2012, Shin 2013, Gronlund 2017, Keller 2018).

A WMC study can be performed in a physician's office after the patient undergoes an overnight fast and discontinues medication that may potentially affect gastric pH and GI motility. The WMC is swallowed with 50ml water immediately following a standardized meal (egg sandwich [255 kcal, 2% fat, 1g fiber], or a nutritionally equivalent Smart Bar [260 kcal, 2% fat, 2g fiber]). Patient are given a data receiver and a diary for recording bowel movements, food intake, sleep, and GI symptoms. They can leave the clinical setting after the absence of any complications from ingesting the capsule is confirmed. The patients are not permitted to eat for 6 hours after which, they are instructed to consume the regular meals for the testing period of 3-5 days; to avoid vigorous exercise; refrain from alcohol, smoking, and the use of GI medications that could affect motility. The capsule travels through the gastrointestinal tract, collecting, recording, and transmitting data to the SmartPill Data Receiver worn on a patient's belt or around the neck. It is then excreted naturally from the body within a day or two. The data recorder is returned to the physician’s office and the information downloaded via a docking station for analysis (Rao 2009, Saad 2011).

The SmartPill GI Monitoring System (WMC SmartPill®, SmartPill Corporation, Buffalo, NY, USA; now Medtronic, Minneapolis, MN, USA), was cleared by the Food and Drug Administration (FDA) in July 2006, for the evaluation of delayed gastric emptying in the absence of mechanical obstruction. In 2009, the FDA expanded the use of the SmartPill to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow or versus normal transit constipation.

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The WMC testing is not approved for use in the pediatric population and is not indicated for the diagnosis of IBS or functional dyspepsia. It is contraindicated in patients with suspected or known swallowing disorders; strictures, fistulas, or physiological/mechanical GI obstruction; GI surgery within the past 3 months; severe dysphagia to food or pills; Crohn's disease or diverticulitis; implanted or portable electro-mechanical medical device; or a history of gastric bezoar (a ball of swallowed foreign material most often composed of hair or fiber). WMC is also contraindicated in patients with a cardiac pacemaker or defibrillator due to concerns related to the capsule's radio transmission of data to the receiver (Farmer 2013, Saad 2016).

Reported adverse events and /or equipment failure associated with WMC testing, include inability of the patient to swallow the capsule, equipment failure of the capsule to record or transmit data, failure of the receiver to record and download data, and software malfunction necessitating repeat testing. The most severe, but rare adverse event reported was the capsule retention in the stomach, small intestine or colon, which required operative removal of the device in a small number of patients. Other reported side effects include abdominal pain, dysphagia, nausea, and diarrhea (Saad 2016).

Medical Technology Assessment Committee (MTAC)

Wireless Motility Capsule (WMC; SmartPill) for the Evaluation of Gastrointestinal Motility Disorders

01/14/2019: MTAC REVIEW

Evidence Conclusion:

Diagnostic accuracy of wireless motility capsule (WMC)

- It is difficult to estimate the accuracy of a test when there is no standardized gold standard to compare it with. The reference standards commonly used in practice and in the literature, are mainly gastric scintigraphy for gastroparesis and radiopaque markers (ROM) for colonic transit disorders. These may be considered reference tests, but according to the experts on the field, none is a perfect test. In addition, the tests are not usually conducted according to a standardized technique protocol as regards meal composition, monitoring times, and interpretation. Moreover, WMC and the reference tests were not always performed simultaneously (in some cases conventional tests were performed months earlier) which would not provide accurate comparison as patients with dysmotility may have major day-to-day variability on repeat transit testing. The upper limits for small and large bowel transit times measured by WMC differed between some studies. WMC measures the emptying of a non-digestible solid, unlike the gastric emptying scintigraphy and breath testing that measure gastric emptying of digestible solids. WMC does not empty with the meal but is generally cleared from the stomach powerful inter-digestive antral contractions that occur after the meal has been emptied to clear the stomach of indigestible material.
- The published literature shows wide variations in the calculated accuracy of the wireless motility capsule for the diagnosis of GI dysmotility. The sensitivity of WMC ranged from 59% to 86%, and its specificity ranged from 64% to 81% for gastroparesis when compared with gastric scintigraphy; the overall concordance between the tests ranged from 35% to 81%.
- When compared with radiopaque markers (ROM) for the detection of slow-transit constipation, WMC had a sensitivity of 43-87% and specificity of 67-98%. The concordance ranged between 64% and 87%.
- WMC was found to be less accurate than barium testing of small bowel dysmotility disorders.
- The analysis of the results from one study (Wang, 2015) suggests that regional GI transit time and pH values measured by the WMC may be affected by the testing protocol, gender, age, and country where the test is performed. The authors thus concluded that standardization of the test is essential for cross referencing in clinical practice and research; and presented normative values for regional transit times for reference in clinical practice.
- The results were based on the analyses of prospectively or retrospectively collected data from records of patients referred to tertiary centers specializing in managing severe dysmotility disorders. Retrospective studies have their limitations and are subject to bias and confounding. Patients referred for further investigations in tertiary centers tend to have more severe symptoms, are refractory to therapy and/or have failed several conventional tests. This would affect the accuracy and predictive value of the test and limit generalization of the results.

Safety of WMC

The published studies do not provide sufficient data to determine the safety of WMC.

Clinical utility of WMC

- The literature search did not identify any randomized controlled trials the examined the clinical utility of using WMC in patients with GI motility disorders, i.e. it impacts on managing the patients and improving their health outcomes. All published studies were secondary analyses of prospectively or retrospectively collected patient data obtained from chart reviews or electronic health records.

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- The published secondary analyses of data provide weak evidence suggesting WMC may provide more diagnostic information compared to conventional methods used for evaluating gastrointestinal motility disorders, and the modification of the management plans.
- There is insufficient evidence to determine that the use of WMC improves the health outcomes of patients with gastrointestinal motility disorders.

Articles: The literature search identified an earlier comprehensive AHRQ systematic review (Stein et al, 2013) on the comparative effectiveness of wireless motility capsule and other diagnostic technologies used for evaluating gastroparesis and constipation. The search for studies published after the AHRQ literature review identified over 50 publications; the majority of which were review articles or studies unrelated to the current review. Related articles included two recent observational studies on the diagnostic performance of WMC in patients with suspected gastroparesis, a study that examined the influence of several variables on the outcomes of the WMC testing, two studies on the use of WMC in the assessment of GI dysmotility in patients with diabetes mellitus, and few retrospective studies on the clinical utility of WMC in patients with GI dysmotility. The results of the AHRQ systematic review on the comparative accuracy of WMC vs. alternative tests used for the diagnosis GI dysmotility, as well as the recent validation studies, the study on the variables affecting the outcome of the test, and selected studies evaluating the clinical utility of WMC and using gastric scintigraphy and ROM as reference standards for evaluating the accuracy of WMC for upper and lower GI dysmotility respectively were reviewed and summarized.

The use of Wireless Motility Capsule (WMC; SmartPill) for the Evaluation of Gastrointestinal Motility Disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

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Date Created	Date Reviewed	Date Last Revised
02/05/2019	02/05/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt criteria of non-coverage; added 01/2019 MTAC review

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Inpatient Skilled Nursing Facility

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Criteria

For Medicare Members

On initial review, Kaiser Permanente will use the Recovery Facility Care guidelines (MCG*) for inpatient skilled nursing facility, but if criteria are not met, then the Medicare Benefit Policy Manual (chapter 8, section 30) for inpatient skilled nursing facility coverage must be used. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

For Non-Medicare Members

To meet Skilled Nursing facility coverage eligibility requirements, **ALL of the following** 3 factors must be met:

Admission:

A. Must meet **One** or more of the following to qualify for admission to Skilled Nursing Service, Skilled Rehab Service or both:
   1. **Requires Skilled Nursing** of RN, LPN, PT, OT, or SLP: Inherent complexity of service is such that it can be performed safely and/or effectively only by, or under, general supervision of licensed professionals and cannot be provided by non-skilled personnel. Requires skilled services on a daily basis. Patients functional or medical complexity are such that outcome would be compromised with less than daily skilled services. Multiple skilled nursing services are required daily 7d/wk. **Skilled Nursing Services** must meet **ONE or more** of the following:
      a. Injections: IV, IM, SQ (new &/or complex needs, not typically for insulin)
      b. Intravenous: fluids, meds, or line flushes
      c. Nebulizers: oxygen eval saturations when unstable, complex
      d. Enteral feedings new or enteral pt with recent change in medical condition requiring monitoring
      e. Care of new colostomy or teaching ostomy care associated with complication
      f. Frequent suctioning, trach, &/or vent needs
      g. Frequent irrigation, replacement of urinary catheters; care of new/complex suprapubic catheter
      h. Treatment Stage III/IV pressure ulcers; widespread skin disorder or complex wounds requiring RN/LPN wound treatment
      i. Nursing evaluation of unstable & complex medical condition, e.g. recovery from septicemia, coma, severe respiratory disease, uncontrolled pain
      j. Nursing rehab teaching, e.g. bowel & bladder training, adaptive aspects of care.
   2. **Skilled Rehab Services:** Requires rehab teaching, training, or monitoring. Complexity and sophistication of treatment is such that the specialized skills of a therapist are needed. Pt is significantly below baseline level of function and is able to learn and retain new information and skills. **Note:** Rehab services are not required for deconditioning/ temporary reduction in function which could reasonably be expected to spontaneously improve as pt gradually resumes activities. Repetitious exercises to improve gait or maintain strength and endurance and assistive walking are appropriately provided by supportive personnel and do not meet skilled rehab criteria.
      Must meet **ALL of the following** below for **Skilled Rehab Services**:
      a. Requires establishment and ongoing assessment of a complex rehab treatment plan such as gait training in patients with neurological, muscular or skeletal abnormality, use of new assistive device, compensatory strategies, cg training, monitoring of activity tolerance with vital signs or O2 checks.

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   b. Patient requires more than minimal or light physical assist for basic ADLs and mobility (based on evidence that patients needing only minimal assist do comparably well with Home Health therapy and do not need daily rehab)
   c. Does not require one or two more hospital days to arrange home care plan. If pt requires only one or two more hospital days to arrange home care plan, then would not require inpt SNF daily rehab or nursing.
3. Patients receiving **elective total joint replacements** often need additional caregiving assistance that can be provided by non-professional staff and intermittent therapy services (not daily). In the event a total joint replacement patient is referred to SNF for daily therapy**, you must** check functional mobility levels; patients requiring minimal assistance or less (<25% assist) generally do not require daily therapy by a licensed therapist. Some patients have post-operative pain or nausea which may impede progress initially. For those patients, an additional day or two in the hospital may avoid a SNF stay. Elective Total Joint patients must meet **one** of the following:
   a. Patient requires moderate or greater level of assistance with overall mobility. (This does not mean that there is just one area where patient needs moderate assistance. i.e.: min A with t/f and gait, but Mod A with supine<>sit would not indicate a daily need.)
   b. Patient is functioning at minimal assist with mobility- review with NHS/ CRUS MD to determine if patient has need for daily therapy at this high functional level.

B. **Requires inpatient SNF level of care** - Complexity and frequency of needs for skilled services require inpt setting; requires multiple skilled treatments daily (can be combination of nursing & rehab) or need for daily skilled services exceeds care available at lesser levels such as home with Home Health.
C. **SNF inpatient services are reasonable and medically necessary** (i.e. consistent with the nature and severity of the individual's illness or injury, the individual's particular medical needs, and accepted standards of medical practice. The services must also be reasonable in terms of duration and quantity.)

For continued stay and discharge
Kaiser Permanente has elected to use MCG* Recovery Facility Care Guidelines for inpatient skilled nursing facility coverage medical necessity determinations.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our Nursing Home Services department, you may request a copy of the criteria that is being used to make the coverage determination. Call Nursing Home Services for more information regarding the case under review.

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Background
Skilled nursing facility services are frequently required to transition patients from the hospital setting to home. At times these services must be delivered in a skilled nursing facility because of patient care needs and clinical condition. When the member has coverage for this care the skilled nursing facility admission criteria must be met for eligibility. Members who require this level of care but do not have coverage must pay for the service themselves. Because the majority of members requiring this service have Medicare coverage, Medicare criteria were used as a guide in the development of the Kaiser Permanente criteria.

Evidence and Source Documents
Medicare criteria

Applicable Codes

POS 26

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Date Created	Date Reviewed	Date Last Revised
08/11/1998	07/13/2009 MDCRPC, 07/06/2010MDCRPC, 05/03/2011MDCRPC, 03/06/2012MDCRPC, 01/08/2013MDCRPC, 11/05/2013MPC, 09/02/2014MPC, 02/03/2015MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC,12/07/2021MPC,12/06/2022MPC	02/03/2015

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
SpaceOAR (Spacing Organs at Risk)
- Rectal Protection during Prostate Cancer

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Criteria
For Medicare Members
No review required.

For Non-Medicare Members
No review required.

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Background
Prostate cancer is the most common cancer (excluding skin cancer) and the third leading cause of cancer death in men in the United States (American cancer Society Cancer facts and figures 2017). Treatment options for prostate cancer include active surveillance and watchful waiting, radical prostatectomy, radiation therapy, hormone therapy, chemotherapy, immunotherapy and other treatment modalities depending on the stage of the disease, patient age, health condition, and personal preference.

External beam radiation therapy (EBRT) remains one of the primary treatment modalities for patients with localized prostate cancer. Studies show that it is highly effective in patients with a localized disease, and that a dose escalation improves biochemical control in intermediate risk patients. However, dose escalation can also increase the risk of urinary and bowel toxicity (Pinkawa 2011, Uhl 2013, Chung 2016).

Advances in in radiotherapy treatment techniques including image-guided radiation therapy (IGRT) and intensity modulated radiation therapy (IMRT) that limit the margins and conform the high dose radiation volume, have allowed increasing the radiation dose to ≥78Gy while maintaining an acceptable toxicity profile. However, as the prostate is directly adjacent to the rectum, the anterior rectal wall cannot be completely spared from the high dose region regardless of the treatment technique. The rectum is the most radiation sensitive organ within the pelvic tissue and is the primary organ at risk (OAR) with external beam radiation therapy. Studies showed that rectal toxicity is associated with both the total radiation dose to a specific volume and the volume inside a specific isodose, and that Grade ≥2 rectal toxicity is significantly associated with the volume of rectum receiving >70Gy (V70) (Noyes 2012, Pinkawa 2013, Song 2013, Wolf 2015, Chung 2016, Hamstra 2017).

Researchers have been evaluating methods to create more space between the prostate and rectum to allow for prostate dose escalation while reducing anterior rectal wall radiation exposure. One of the promoted approaches involves the placement of a temporary injectable spacer to push the rectum away from the prostate before treatment planning and maintain the space throughout the treatment period. Different injectable agents including

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human derived products (e.g. hyaluronic acid and collagen), synthetic polyethylene-glycol (PEG) hydrogel, and implantable absorbable balloons have been evaluated as spacing materials (Song 2013, Mariados 2015).

SpaceOAR (Spacing **O**rgans **A**t **R**isk), Augmenix, Inc., Waltham MA, USA, is an absorbable polyethylene glycol (PEG) hydrogel that expands the perirectal space as an injectable liquid and then solidifies into a soft absorbable spacer between the prostate and rectum. It consists of two liquid hydrogel precursors, that after hydro dissection with a saline solution, are injected using a small needle under transrectal ultrasound (TRUS) guidance through the perineum to the perirectal space (between the Dennonvilliers' Fascia and the frontal rectal wall). There, the liquid hydrogel polymerizes (solidifies) within seconds and creates a physical barrier between the prostate and rectum. The additional space created by the spacer has a volume of about 10-15 ml. The solidified hydrogel is compression resistant and is maintained for approximately three months. It should be absorbed in approximately six months and the degradation products cleared via renal filtration (Pinkawa 2011, Rucinski 2015, Wolf 2015).

Potential complications that may be associated with the use of the SpaceOAR system include, but are not limited to pain and discomfort associated with SpaceOAR or hydrogel injection; needle penetration and/or injection of the hydrogel into the bladder, prostate, rectal wall, rectum, or urethra; infection or local tissue inflammatory reactions; urine retention, bleeding, rectal mucosal damage, ulcers, necrosis, constipation; rectal urgency; injection of air, fluid or SpaceOAR hydrogel intravascularly; device functional failure or its inability to maintain the space stability during the course of radiation therapy; prolonged or delayed procedure; and incomplete absorption of the hydrogel (FDA decision summary, FDA website, accessed May 2017).

Medical Technology Assessment Committee (MTAC)

SpaceOAR

06/21/2017: MTAC REVIEW

Evidence Conclusion: The SpaceOAR pivotal trial (See Evidence Table 1) is a multicenter single-blinded phase III trial that evaluated the safety and effectiveness of SpaceOAR among 222 patients undergoing prostate image guided intensity modulated radiation therapy (IG-IMRT).The study included men with clinical stage T1 or T2 prostate cancer, Gleason score ≤7, and PSA concentration ≤20 ng/ml. Patients with prostate volume>80cm^3, extracapsular extension of the disease, >50% positive biopsy cores as well as those with prior prostate surgery or radiation therapy were excluded from the study. After undergoing initial treatment planning, and implantation of fiducial markers, the study participants were randomized in a 2:1 to receive spacer injection or no injection (control). Patients, but not the providers were blinded to their treatment allocation. Planning scans were then performed followed by image guided intensity modulated radiation therapy (79.2Gy in 1.8-Gy fractions). The primary effectiveness endpoint was the proportion of patients achieving >25% rectal volume receiving at least 70Gy (rV70) due to spacer placement, and the safety endpoint was the proportion of spacer and control patients with ≥grade 1 rectal toxicity or procedural adverse event (AEs) in 6 months. The results showed a significant reduction in the mean rectal V70 (>70Gy) in the post vs. pre- treatment plan. Overall 97.3% of spacer patients experienced ≥25% reduction in rectal volume receiving at least 70Gy (rV70).

Mean ± SD rectal dose volume at baseline and post- spacer dose plans

parameter	rV50	rV60	rV70	rV80
% before spacer	25.7 ± 11.1	18.4 ± 7.7	12.4 ± 5.4*	4.6 ± 3.1
% after spacer	12.2 ± 8.7	6.8 ± 5.5	3.3 ± 3.2**	0.6 ± 0.9
% absolute reduction	13.442	11.563	9.078	3.933
% relative reduction	52.3	62.9	73.3	86.3
P value	<0.0001	<0.0001	<0.0001	<0.0001

As regards the primary safety endpoint, the results showed no significant differences in the rates of ≥grade 1 rectal or procedural adverse event (AEs) in 6 months between spacer and control groups (34.2% and 31.5% respectively (p =0.7). 10% of the patients in the spacer group experienced mild transient procedural perineal discomfort and other symptoms.

Acute and late (up to 15 months) rectal toxicity

Rectal toxicity	Spacer (n=148)	Control (n= 73)	P value
Acute toxicity: from procedure through 3-months visit, n (%)			
Grade 0	108 (73.0%)	49 (68.0%)	0.525
Grade 1	34 (23.0%)	20 (27.8%)	
Grade >2	6 (4.1%)	3 (4.2%)	
Late toxicity Between the 3rd and 15th month visits			

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Grade 0	145 (98.0%)	66 (93.0%)	0.044
Grade 1	3 (2.0%)	4 (5.6%)	
Grade >2	0 (0.0%)	1 (1.4%)	

The results show that the rate of rectal toxicity in the control group was low, which as the authors indicated was very low compared to earlier studies, and attributed that to several potential factors including the use of different toxicity scales, uniform use of both IMRT and IGRT, small PTV (planning target volume) margin, MRI planning, and strict dosimetric constraints with centralized pretreatment review of the plans. The extended follow-up reported by Hamstra and colleagues (2017), suggest that the benefit observed with the hydrogel spacer at 15 months was maintained at a median of 37 months of follow-up. However, this extended follow-up was optional and the long-term data were available for 66% of the patients at 30 months, and 17.5% at 40 months. The trial was randomized and controlled. However, it had its limitations. The providers were not blinded to the treatment allocation; the study had strict inclusion/exclusion criteria, which may limit generalization of its results, and the follow-p duration was insufficient to determine the long-term safety of the technology. The extended 3 years follow-up was voluntary and only 66% were followed up for 30 months, and 17.5% at 40 months, In addition the study was performed under an investigational setting, was sponsored by the manufactures, and the principal investigators had financial ties with the industry. Pinkawa and colleagues, 2017 compared the numbers of interventions resulting from bowel problems during the first 2 years after RT to assess the benefit of the using hydrogel spacer before prostate cancer radiotherapy (RT) according to patient's perspective. The study included 167 consecutive prostate cancer patients treated with radiotherapy (RT) in the years 2010 to 2013. 101 patients received 76-80Gy with hydrogel, and 66 were treated with up to 76Gy without hydrogel. All patients were surveyed prospectively before RT, at the last day of RT, and at a median of 2 and 17 months after RT using a validated questionnaire (Expanded Prostate Cancer Index Composite). The outcome was the difference between using and not using hydrogel on the rate of interventions resulting from bowel problems during the first 2 years after radiotherapy. The results show that treatment for bowel symptoms was performed less frequently with a using a spacer (0 with spacer vs. 11 % with no spacer; $p < 0.01$). Similarly there were less endoscopic examinations in patients receiving a spacer versus those who did not receive one (3 vs. 19 % respectively; $p < 0.01$). Mean bowel function scores did not change for patients with a spacer in contrast to patients without a spacer (mean decrease of 5 points) >1 year after RT in comparison to baseline. None of the spacer parents vs. 12% of those with no spacer reported a new moderate/big problem with passing stools ($p < 0.01$). The authors concluded that spacer injection is associated with a significant benefit for patients after prostate cancer RT. However, the study was only observational and patients were not randomized to the treatment groups.

Conclusion:

- There is insufficient published evidence to recommend for or against the use of SpaceOAR in prostate cancer patients treated with external beam radiotherapy.
- The only published RCT trial to date, had its limitations and does not provide sufficient evidence to determine the long-term safety and efficacy of the hydrogel spacer, or to determine its effect on the net health outcome outside the investigational setting.

Articles: The literature search for published studies on the efficacy and safety of injecting a temporary hydrogel spacer between the rectum and prostate in patients undergoing extremal beam radiotherapy revealed one randomized controlled trial (pivotal trial), a retrospective comparative study, observational studies with no controls, as well as a number of phase I/II studies investigating the feasibility, efficacy, safety, and/or dosimetric benefits of the spacers. The literature search also identified a small nonrandomized observational study that compared SpaceOAR to a saline inflated balloon (ProSpace) in terms of spacer volume, stability and radiation dose reduction to the anterior rectal wall. The pivotal RCT was selected for critical appraisal. Hamstra DA, Mariados N, Sylvester J, et al. Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol Phys*. 2017 Apr 1; 97(5):976-985. Mariados N, Sylvester J, Shah D, et al. Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phy.* 2015; 92:971-977

The use of SpaceOAR (Spacing Organs at Risk) Hydrogel for Rectal Protection during Prostate Cancer Radiotherapy does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Medical Necessity Review not required:

CPT® Codes	Description
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

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Date Created	Date Reviewed	Date Last Revised
08/01/2017	08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/07/2020

[MPC] Medical Policy Committee

Revision History	Description
01/08/2018	Medicare - No review required
07/07/2020	Removed deleted CPT code 0438T

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Single Photon Emission Computed Tomography (SPECT)

- Evaluation of Origin of Behavior Problems

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Single Photon Emission Computed Tomography (SPECT) (220.12).
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Evaluation of Origin of Behavior Problems

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

No review required for SPECT for other indications.

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Background

Single Photon Emission Computed Tomography (SPECT) is a nuclear medicine technique that can be used to image almost any organ system. SPECT imaging is performed by acquiring multiple images (aka projections) with a gamma camera. A topographic reconstruction algorithm is then applied to the multiple two-dimensional projections, resulting in a three-dimensional dataset. To acquire the images, the gamma camera is rotated around the patient. The camera typically moves 3-6o each time until a 360 rotation is achieved. Each image takes approximately 15-20 seconds, for a total scanning time of approximately 15-20 minutes.

Brain imaging with SPECT is generally performed with the radiopharmaceutical hexamethylpropylene amine oxime (99mTC-HMPAO). 99mTC emits gamma rays that are detectable by a gamma camera. When attached to HMPAO, it can be taken up by brain tissue at a rate proportional to brain metabolism. Brain blood flow is highly correlated to local brain metabolism and energy use. Areas of the brain that are undergoing increased neuronal activity consume greater amounts of oxygen and energy and are perfused more, and areas of the brain that area less functionally active are perfused less. The SPECT image thus indirectly reflects cerebral metabolism. Patients undergoing brain SPECT are exposed to approximately 2-8 mSv of radioactivity, a level comparable to a CT scan. 99mTC-HMPAO SPECT brain scanning provides similar information about local brain function to FDG PET scans and functional MRI. Although PET has a higher resolution, the SPECT equipment is less expensive and may be more widely available. While MRI and PET are limited to hospitals due to their cost, SPECT equipment can be installed in physicians' offices (Overmeyer & Taylor, 2001).

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A report contracted by the American Psychiatric Association (APA) in 2005 concluded that SPECT is useful for research on psychiatric disorders, and for diagnosing cerebral trauma, seizure disorders and brain tumors for which there are detectible patterns of perfusion abnormalities. However, the authors found insufficient evidence to support the use of SPECT for the diagnosis and treatment of psychiatric disorders in the pediatric population. The APA report stated that there is a lack of evidence linking a particular structural or functional brain abnormality to a single psychiatric disorder. In addition, the authors cautioned that the long-terms effects of using the radioactive nucleotides associated with SPECT imaging in children and adolescents are not known.

A group of SPECT practitioners have criticized the APA report as being flawed and misleading (Wu et al, unpublished manuscript). They counter the APA claim that SPECT cannot yet diagnose psychiatric illness with the statement that clinicians do not rely on SPECT to make psychiatric diagnoses. Instead, SPECT practitioners use brain imaging as another source of data, along with clinical presentation, to help them make informed decisions about diagnosis. They also state that it is unfair to single out the possible danger associated with radioactive nucleotides used with SPECT imaging since children are treated with other nuclear medicine procedures such as studies for cardiovascular, cerebrovascular and orthopedic disease. They report that the average radiation exposure for one SPECT scan is similar to the exposure from a bone scan, brain CT scan or abdominal x-ray.

Medical Technology Assessment Committee (MTAC)

Single Photon Emission Computed Tomography

10/02/2006: MTAC REVIEW

Evidence Conclusion: In order to demonstrate that SPECT brain imaging is able to accurately diagnose behavior problems, there needs to be sufficient evidence that particular SPECT findings correlate with specific behavioral conditions, and that SPECT is sensitive and specific at diagnosing these conditions compared to a gold standard diagnostic tool. Most of the published studies on the first topic, SPECT findings associated with a clinical behavior problem are too small to produce reliable estimates. The largest study was by Amen and colleagues (1997). They compared SPECT scans of children with and without ADHD both at rest and while performing an intellectual stress task. The study found significantly decreased prefrontal activity during the intellectual stress activity in the ADHD group, but not the non-ADHD group. The Amen study is inconclusive due to the small sample size and lack of adjustment for confounding variables. Moreover, since only 65% of the participants with ADHD had decreased prefrontal activity during intellectual stress, it is not clear how the SPECT information would be used to help diagnose ADHD. In addition, Dr. Amen has a private clinic that performs SPECT which may bias the study's methods and conclusions. Gustafsson and colleagues performed a variety of tests on 28 children with ADHD, including brain SPECT and EEG. The investigators did not find a significant association between EEG and SPECT findings. They found several statistically significant correlations between regional cerebral blood flow detected by SPECT and several instruments, particularly the number of Minor Physical Abnormalities (MPA). The vast majority of statistical comparisons were not statistically significant, and since such a large number of comparisons were performed at $p<0.05$, some significant findings would be expected by chance alone. No empirical evidence was identified on the effectiveness of brain SPECT at assisting practitioners in making a clinical diagnosis, e.g. of ADHD. Such a study would compare the diagnosis made by practitioners with and without information from SPECT, with the diagnosis confirmed by a qualified objective third party. In addition, there was no empirical evidence on the long-term safety of SPECT brain imaging in children. In conclusion, there is insufficient evidence in the published literature on the ability of SPECT brain imaging to diagnose behavior problems or assist clinicians in making a diagnosis, and insufficient evidence on the safety of brain SPECT in the pediatric population.

Articles: Objective 1a: The ideal study design is a comparison of brain function or structure as assessed by SPECT among individuals with and without behavioral problems. Methodological features include sufficient sample size, appropriate selection of controls, matching or controlling for confounding variables, objective confirmation of diagnosis and appropriate statistical analysis. Several studies were identified that compared brain activity using SPECT among children with ADHD and healthy controls. The studies were generally limited by small sample sizes. Most included 20 or fewer children with ADHD and 7 or fewer controls. The largest study (n=54 ADHD, n=18 non-ADHD) was conducted by a prominent SPECT practitioner (Dr. Amen)—this study was critically appraised. Objective 1b: The ideal study of diagnostic accuracy would report the sensitivity and specificity of SPECT imaging and include an independent blinded comparison to a "gold standard" diagnosis. No studies that met the above criteria were identified. Only one study compared SPECT findings to another imaging technique, EEG (Gustafasson et al., 2000) and this study was critically appraised
Objective 2: A strong study would compare the accuracy of the diagnosis made with and without information from SPECT imaging, with the diagnosis confirmed by an objective expert such as experienced psychiatrist blinded to diagnosis. No relevant studies were identified. Objective 3: No studies were identified on the long-term safety of SPECT brain imaging in children. *The studies that were critically appraised were:*

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Amen DG, Carmichael BD. High-resolution brain SPECT imaging in ADHD. Ann Clin Psychiatry 1997; 9: 81-86. See Evidence Table. Gustafsson P, Thernlund G, Ryding E et al. Associations between cerebral blood flow measured by single photon emission computed tomography (SPECT), electro-encephalogram (EEG), behavior symptoms, cognition and neurological soft signs in children with attention-deficit hyperactivity disorder (ADHD). Acta Pediatr 2000; 89: 830-835. See Evidence Table.

The use of Single Photon Emission Computed Tomography in the evaluation of origin of behavior problems does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Evaluation of Origin of Behavior Problems - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
With ADHD dx F90.0-F90.9	
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day imaging
78830	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day imaging

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/26/2006	04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC	04/11/2011

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Speech Generating Devices

- Augmented and Alternative Communication Devices or Communicators

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Speech Generating Device (50.1)
Local Coverage Determinations (LCD)	Speech Generating Device (L33739)
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Augmentative Communication Devices, Electronic (KP-0516) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

MCG* are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider and/or specialist (neurology)
- Speech therapy notes

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Augmentative and alternative communication (AAC) is an area of clinical practice that attempts to temporarily or to permanently compensate for the impairment and disability patterns of children with severe oral and written expressive communication disorders. Interventions that use AAC should incorporate the individual's full communication abilities e.g. any existing speech or vocalization, gestures, manual signs, communication boards, and speech output communication devices. Abilities may change over time and the AAC may need to be modified as a child grows and develops.

AAC has four components: symbols, aids, techniques, and strategies. Aids are the physical objects or devices used to transmit or receive messages. These include books, communication boards, charts, mechanical or electronic devices, and computers. The AAC devices have variable capabilities, durability, and cost. The delivery of AAC services to children with severe spoken language disorders requires the collaboration and competence of

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families, professionals, and paraprofessionals. Effective, co-coordinated multidisciplinary and an integrated service is crucial in achieving optimal outcome for the children.

The role an AAC system plays in a particular child's life varies with the type and severity of the language disorder. Children with congenital language disorders who may benefit from AAC include those with cerebral palsy, dual sensory impairments, developmental apraxia, oro-motor dyspraxia, language learning disabilities, mental retardation, autism, and pervasive developmental disorders. Acquired language disorders include: traumatic brain injury, aphasia, spinal cord injuries, and other physical disabilities. Not all these indications are covered by health insurance companies.

Medical Technology Assessment Committee (MTAC)

Augmentative Communication Devices

02/13/2002: MTAC REVIEW

Evidence Conclusion: The study reviewed had several limitations; it had a small sample size, lacked a control group, used only subjective measures, and was subject to selection and observation biases. In conclusion the literature available does not provide enough evidence to determine the effect of the augmentative communication devices on the communication skills of children with speech impairments.

Articles: The search yielded 43 articles. Most were reviews, tutorials, notes, and discussions. The search did not reveal any randomized controlled trials, or meta-analyses, only four case reports and two studies that only measured young patients' or parents' satisfactions and /or utilization of the communication systems. The study with the larger sample size was selected for critical appraisal. *An evidence table was created for the following study:* Ko MLB, et al. Outcome of recommendations for augmentative communication in children. *Child Care, Health and Development* 1998; 24(3): 195-205. See Evidence Table.

The use of augmentative communication devices on the communication skills of children with speech impairments not voted using the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
92609	Therapeutic services for the use of speech-generating device, including programming and modification
E1902	Communication board, nonelectronic augmentative or alternative communication device
E2500	Speech generating device, digitized speech, using prerecorded messages, less than or equal to eight minutes recording time
E2502	Speech generating device, digitized speech, using prerecorded messages, greater than eight minutes but less than or equal to 20 minutes recording time
E2504	Speech generating device, digitized speech, using prerecorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time
E2506	Speech generating device, digitized speech, using prerecorded messages, greater than 40 minutes recording time
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access
E2511	Speech generating software program, for personal computer or personal digital assistant
E2512	Accessory for speech generating device, mounting system
E2599	Accessory for speech generating device, not otherwise classified

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Creation Date	Review Date	Date Last Revised
06/18/2001	03/02/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC] ,08/06/2013[MPC],11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	08/31/2015

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/31/2015	Added Update to Pub. 100-03 NCD Manual

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Sphenopalatine Ganglion (SPG) Block

- Allevio SPG Nerve Block Catheter
- SphenoCath
- TX360

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	Billing Medicare for the SphenoCath® and Other Similar Devices (A55585)
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Sphenocath Ganglion Block,*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

No review required at this time.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Sphenopalatine ganglion (SPG):

Robbins et al., 2016: The SPG is a triangular ganglion situated in the pterygopalatine fossa (PPF) on the medial wall. It is suspended by two branches of the maxillary nerve. The SPG received 3 inputs from the sensory, sympathetic, & parasympathetic fibers which innervate the face and head. The parasympathetic fibers originate from the superior salivatory nucleus (SSN) in the brainstem. The SSN stimulates the SPG whose activation results in pain/headache through several mechanisms (production of vasoactive peptides, neurogenic inflammation, vasodilation). SPG activation is therefore responsible for the clinical symptoms seen in migraine headaches, cluster headaches, trigeminal-mediated headaches and other headaches. Treatments that block SPG may alleviate headaches.

SPG block:

There are three methods to complete SPG block: transnasal, transoral, and transcutaneous blocks (Alexander et al., 2020). Some of these approaches utilized intranasal devices. Intranasal devices use catheter to perform

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sphenopalatine ganglion blockade. There are several devices including Sphenocath, Allevio SPG nerve block catheters, and Tx360 nasal applicator. Sphenocath is the focus of the current review.

Sphenocath:
Sphenocath is composed of an external sheath in which there is a catheter with a preformed angle (http://sphenocath.com/). The device is introduced in the nasal cavity and inserted in the superior part of the middle nasal turbinate while the patient is in supine position with extension of the cervical spine. The procedure can be performed under fluoroscopy to locate the tip of the sheath. The anesthetic agent, 1-2 ml of 2% lidocaine is then administered by the catheter. After the procedure, the patient remains in supine position for 10 minutes (Robins et al., 2016). Sphenocath may prevent nasal mucosal irritation due to its flexibility and physical integrity (http://sphenocath.com/).
There are several indications for the procedure. However, the review focuses on the efficacy and safety of the procedure on migraine and trigeminal neuralgia. Contraindications consist of allergy to lidocaine, stenosis of nasal canal, inability to thread the catheter, and severe cardiac arrhythmia (Forrest et al., 2018).

Migraine:
Migraine is an attack of intermittent headache lasting four to 72 hours with or without aura. Fifteen percent (15%) of US population has migraine. Patients with migraine experience pain with visual disturbances (flashes, sparks, luminous hallucinations), photophobia, aura. Migraine can be precipitated by emotions and is associated with nausea and vomiting. Several medications including triptans, nonsteroidal anti-inflammatory drugs (NSAIDs), opiate-based analgesics, and ergotamine tartrate are available for the management of acute episodic and chronic migraine (Mwanburi et al., 2018).

Trigeminal neuralgia:
Trigeminal neuralgia (TN) is a severe, shock-like, paroxysmal pain in the face along the divisions of the trigeminal nerve. It can be precipitated by touching the face. Its management consists of sodium channel blockers and neurosurgical intervention (second line treatment) (Maarbjerg et al., 2017).

Medical Technology Assessment Committee (MTAC)

Sphenopalatine ganglion block using Sphenocath device for migraine and trigeminal neuralgia

Date: 01/11/2021

Evidence Conclusion:

- No studies comparing Sphenocath device to other methods performing SPG block were identified. The studies reviewed were of very low quality.
- There is insufficient evidence to determine the efficacy and safety of sphenopalatine ganglion block using Sphenocath device in patients with migraine.
- There is insufficient evidence to determine the efficacy and safety of SPG block using Sphenocath device in patients with trigeminal neuralgia.

Articles:
PubMed was searched through December 3, 2020 with the search terms ((migraine) AND (sphenopalatine ganglion block OR sphenopalatine block OR SPG OR sphenopalatine ganglion)) AND (Sphenocath) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. RCTs, meta-analysis of RCTs, observational studies were included in the search. Regarding trigeminal neuralgia, search terms included: sphenopalatine ganglion block AND trigeminal neuralgia. Four studies were reviewed. Clinicaltrial.gov was also searched and found one study with no results (NCT03666663). See Evidence Table**.**

The use of Sphenopalatine ganglion block using Sphenocath device for migraine and trigeminal neuralgia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare and Non-Medicare: No review required – *may be submitted with the following code(s)*

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CPT® or HCPC Codes	Description
64999	Unlisted procedure, nervous system

Non-Medicare: No review required

CPT® or HCPC Codes	Description
64505	Injection, anesthetic agent; sphenopalatine ganglion

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Date Created	Date Reviewed	Date Last Revised
03/02/2021	03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
03/02/2021	MPC approved to adopt coverage Sphenopalatine Ganglion (SPG) Block

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KAISER PERMANENTE®

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Clinical Review Criteria
Spinal Cord Stimulator for Pain

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Electrical Nerve Stimulators (160.7) Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)
Local Coverage Determinations (LCD)	Spinal Cord Stimulators for Chronic Pain (L36204)
Local Coverage Articles (LCA)	Spinal Cord Stimulators for Chronic Pain (A57792)

For Non-Medicare Members

Dorsal column (spinal cord) neurostimulation is the surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space.

A. Kaiser Permanente covers a ***short-term*** trial of a dorsal column spinal cord stimulator (SCS) as medically necessary for the treatment of chronic, intractable pain secondary to **ONE of the following** indications:
   1. Failed Back Syndrome (FBS) with intractable neuropathic leg pain, (FBS or post-laminectomy syndrome is a condition characterized by chronic pain following back surgeries.) **OR**
   2. Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD) when **ALL of the following** criteria are met:
      a. Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification)
      b. Surgical intervention is not indicated
      c. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately
      d. Controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement

B. Kaiser Permanente covers ***permanent*** implantation of a dorsal column spinal cord stimulator (SCS) as medically necessary for the treatment of chronic, intractable pain secondary to **ONE of the following** indications:
   1. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation (Member experienced significant pain reduction (70% or more) with a 3- to 7-day trial)
   2. Covered for the **ONE of the following** indications:
      a. Failed Back Syndrome (FBS) with intractable neuropathic leg pain (FBS or post-laminectomy syndrome is a condition characterized by chronic pain following back surgeries.) **OR**
      b. Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD) when **ALL of the following** criteria are met:
         - Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, activity lifestyle modification

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- Surgical intervention is not indicated
- An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

High Cervical Epidural Neurostimulation (Spinal Cord Stimulator) for Migraine/Cluster Headaches
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies or provides better long-term outcomes than current standard services/therapies.

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Background

Spinal cord stimulation (SCS) involves insertion of a stimulator electrode into the spinal cord that is connected to a power source. Patients are routinely screened for their likelihood of being a good SCS candidate by temporary placement of a percutaneous epidural electrode. Patients who respond well during the trial period (generally defined as 50% pain relief) can undergo permanent electrode placement. Both temporary and permanent devices are manufactured by Medtronic, Inc.

The most common application of SCS in the United States is chronic low back pain; SCS has also been used for plexus lesions, peripheral nerve injury, reflex sympathetic dystrophy, post amputation pain syndromes, spinal cord injury, post cordotomy dysesthesia, peripheral vascular disease and angina pectoris (North, 1995).

MTAC has previously reviewed SCS. The initial review of SCS in April 2000 evaluated the use of SCS to treat intractable pain and was not limited to a particular disease or condition. At that time, the evidence consisted of case series and a small RCT with threats to validity on SCS for failed back pain syndrome (North, 1995). The item failed MTAC evaluation criteria. Conclusions about the North RCT in this review were: “Preliminary results of this RCT show that more patients assigned to reoperation choose to crossover to SCS than patients assigned to SCS opt for re-operation. It is not known from this study whether actual pain relief is greater for SCS than re-operation.”

In October 2000, a second review was conducted due to the publication of a RCT on the effect of SCS on functional status and pain in patients with chronic reflex sympathetic dystrophy (Kemler, 2000). Again, SCS failed MTAC evaluation criteria. Conclusions about the Kemler study in the MTAC report were: “In the intention to treat analysis, this new RCT did not find a difference in functional status improvement between the two groups. There was significantly greater improvement in the SCS group in two outcome measures (pain score as measured by a visual-analogue scale, global perceived effect of intervention), but not in health-related quality of life. A substantial proportion of patients experienced complications. The study had several limitations, which include:

- The choice of physical therapy as the comparison intervention. All patients in the study had already failed 6 months of physical therapy. This may have biased the study towards finding improved outcomes with the SCS intervention, which had not yet been attempted with these patients.
- Potential bias towards more positive responses on self-report measures among patients who received the SCS intervention (a new and more intensive intervention, patients were not blinded).
- The difference in scores between groups on the pain measure, although statistically significant, has unclear clinical significance.
- The analysis that compared patients who actually received SCS to those assigned to physical therapy is subject to selection and observation biases. The analysis is biased towards finding a positive outcome in the SCS group since only patients shown to benefit from SCS during the test period were included and the comparison group included patients previously found to receive no sustained benefit from physical therapy.

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Due to the above factors, the new evidence is not sufficient to permit conclusions about the effects of spinal cord stimulation on health outcomes for patients with reflex sympathetic dystrophy."

The current review attempted to identify any recent literature on the use of SCS for intractable pain; the review was not limited to any specific condition.

Medical Technology Assessment Committee (MTAC)

High Cervical Epidural Neurostimulation (Spinal Cord Stimulator) for Migraine/Cluster Headaches

BACKGROUND

Implanted electrical stimulation devices have been used for the management of chronic intractable pain since the late 1960s. One of the most commonly used devices is the spinal cord stimulation (SCS) system. This consists of a lead tipped with 4-16 electrodes and a small implantable device. The latter may be battery operated or powered by an externally worn power source. Electrical current from the lead generates parasthesia that can be adjusted in intensity and location to achieve the optimum pain relief (North 2003, 2005, Buchser 2006). Candidates for this therapy include patients with intractable chronic pain of the body and limbs, continued pain after back surgery, reflex sympathetic dystrophy, and complex regional pain syndrome. SCS has been used for decades to treat neurogenic pain. It is now being evaluated for the use in patients with migraines and cluster headaches. Patients with pacemakers, implantable cardioverter defibrillators, untreated drug addicts, and pregnant women are not candidates for the therapy (Arcidicono 2006). It is also contraindicated for patients with chronic anticoagulation, severe distortion or disease of the spinal column, or infection at the insertion site. Patient cooperation is essential for the successful use of SCS therapy. It should not be used by patients who cannot operate the device e.g. those with cognitive, psychiatric, or psychomotor disorders (North 2003, North 2005, and Arcidicono 2006). Spinal cord stimulation was approved by the FDA for the treatment of chronic intractable pain in the trunk and limbs, but it has not been approved for the use in migraines and cluster headaches. This technology has been reviewed previously for the use in back pain, leg pain, refractory angina, and critical leg ischemia

04/19/2010: MTAC REVIEW

High Cervical Epidural Neurostimulation (Spinal Cord Stimulator) for Migraine/Cluster Headaches

Evidence Conclusion: Currently, there is insufficient evidence to evaluate this technology as the literature only consists of case reports and case series with less than twenty-five participants. Two randomized controlled trials, the Precision Implantable Stimulator for Migraine (PRISM) and the Occipital Nerve Stimulator for the Treatment of Intractable Chronic Migraine (ONSTIM), have recently been completed and results are pending.

Articles: Currently, there is insufficient evidence to evaluate this technology as the literature only consists of case reports and case series with less than twenty-five participants. Two randomized controlled trials, the Precision Implantable Stimulator for Migraine (PRISM) and the Occipital Nerve Stimulator for the Treatment of Intractable Chronic Migraine (ONSTIM), have recently been completed and results are pending.

The use of High cervical epidural neurostimulation (Spinal Cord Stimulator) for the treatment of migraine/cluster headaches does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Spinal Cord Stimulators in the Treatment of Intractable Pain

04/12/2000: MTAC REVIEW

Evidence Conclusion: There is weak evidence from the case series studies that about half of patients with back or extremity pain who tolerate SCS for a year have a successful outcome one-year post-implantation. The Broggi et al. study provides weak evidence that long term success rates (i.e. 5 years) are low. Conclusions about efficacy cannot be drawn from the RCT because of the small sample size, high refusal rate and poor outcome measurement. Complications from SCS are mainly minor, but these often require reoperation. There is insufficient evidence to draw conclusions about the efficacy of SCS for peripheral vascular diseases, peripheral neuropathy, multiple sclerosis and reflex sympathetic dystrophy.

Articles: Articles were selected based on study type; there was one randomized controlled trial (RCT), there were no cohort studies or meta-analyses. The remaining empirical studies were case series. Most addressed one clinical area (predominantly failed back surgery syndrome) and several addressed intractable pains in multiple clinical areas. There was one small case series each on peripheral vascular disease (n=10), reflex sympathetic dystrophy (n=12) and peripheral neuropathy (n=10). Articles on critical limb ischemia, angina pectoris and spinal cord injury were not considered for this review (these conditions were not specified in the MTAC request).

Evidence tables were created for the three largest case series studies and one RTC. These examined:

Burchiel, KJ, Anderson, VC, Brown, FD, Fessler, RG, Friedman, WA, Pelofsky, S, Weiner, RL, Oakley, J, Shatin, D. Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain. Spine 1996; 21: 2786-2794. See Evidence Table**.** Failed back surgery syndrome (De la Porte, C, Van de Kelft, E.

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Spinal cord stimulation in failed back surgery syndrome. Pain 1993; 52: 55-61); See Evidence Table**.** Multiple conditions (Broggi, G, Serville, D, Dones, I, Carbone, G. Italian multicentric study on pain treatment with epidural spinal cord stimulation. Stereotact Funct Neurosurg 1994; 62: 273-278). See Evidence Table**.** (North, RB, Kidd, DH, Piantadosi, S. Spinal cord stimulation versus reoperation for failed back surgery syndrome: A prospective, randomized study design. Acta Neurchir 1995; 64: 106-108). See Evidence Table**.** Kemler MA, Barendse GAM, Kleef VM, deVet HCW, Rijks CPM, Furnee CA, Van Den Wildenberg, NEJM. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med 2000; 343: 618-24. See Evidence Table.

The use of Spinal Cord Stimulators in the treatment of intractable pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/11/2000: MTAC REVIEW
Spinal Cord Stimulators in the Treatment of Intractable Pain
Evidence Conclusion: In the intention to treat analysis, this new RCT did not find a difference in functional status improvement between the two groups. There was significantly greater improvement in the SCS group in two outcome measures (pain score as measured by a visual-analogue scale, global perceived effect of intervention), but not in health-related quality of life. A substantial proportion of patients experienced complications.
The study had several limitations, which include: The choice of physical therapy as the comparison intervention. All patients in the study had already failed 6 months of physical therapy. This may have biased the study towards finding improved outcomes with the SCS intervention, which had not yet been attempted with these patients. Potential bias towards more positive responses on self-report measures among patients who received the SCS intervention (a new and more intensive intervention, patients were not blinded). The difference in scores between groups on the pain measure, although statistically significant, has unclear clinical significance. The analysis that compared patients who actually received SCS to those assigned to physical therapy is subject to selection and observation biases. The analysis is biased towards finding a positive outcome in the SCS group since only patients shown to benefit from SCS during the test period were included and the comparison group included patients previously found to receive no sustained benefit from physical therapy. Due to the above factors the new evidence is not sufficient to permit conclusions about the effects of spinal cord stimulation on health outcomes for patients with reflex sympathetic dystrophy
Articles: The search yielded 184 articles. Many of these were reviews or opinion pieces, were on related procedures or evaluated SCS for indications other than pain relief. There were 4 new RCT publications, but none of these was a new study comparing SCS to an alternative intervention. The new articles consisted of an additional publication on the Kemler 2000 data previously reviewed by MTAC, two studies that compared different SCS techniques (two types of electrodes in North, 2002 and two ways to adjust stimulation in North, 2003), and one study that compared two types of drugs given to patients who had SCS implanted (Harke, 2001). No new large case series or cohort studies were identified. There was no new evidence to critically appraise.

The use of Spinal Cord Stimulators in the treatment of intractable pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/04/2006: MTAC REVIEW
Spinal Cord Stimulators in the Treatment of Intractable Pain
Evidence Conclusion: *Spinal cords stimulation (SCS) in complex regional pain syndrome (CRPS) and refractory neuropathic back and leg pain/failed back surgery syndrome (FBSS)* Kemler et al, studied the effect of SCS plus physical therapy versus physical therapy alone, in the treatment of 54 patients with resistant chronic reflex sympathetic dystrophy. The trial was randomized and controlled, and the patients were followed up for 24 months. However, the patients and providers were not blinded, and the primary outcomes were mainly self-reported and subject to bias. There was no comparison arm with a sham treatment to exclude the placebo effect and reduce bias. The SCS therapy was compared to physical therapy, which is not the ideal control as the study participants were those who did not have a sustained response to standard treatment including physical therapy. The results of the trial show that patients randomized to receive SCS plus PT (ITT analysis) or those who actually received a permanent SCS implant plus PT had statistically greater improvement in the two self-reported outcome measures (pain score as measured by a visual-analogue scale, global perceived effect of intervention). No statistical difference between two groups in the functional status was observed. There was s significant improvement in the QoL among patients who actually received the SCS implant plus PT vs. PT alone. The SCS therapy was associated with side effects among all patients who received it, and 38% needed a reoperation related to the implant. North and colleagues' (2005) RCT evaluated the use of spinal cord stimulation versus reoperation for the treatment of patients with failed back surgery syndrome (FBSS). The investigators included 50 patients with pain refractory to conservative treatment, with concordant neurological, tension, and/or mechanical signs and imaging

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findings of neural compression. The follow-up duration was 2 years, and the study outcomes were the frequency of crossover to alternative procedure, pain control and patient satisfaction. The results show that significantly more patients in the SCS group achieved ≥50% pain relief compared with those who underwent reoperation (37.5 % vs. 12 %, p= 0.02). They also required significantly less opioid analgesics. The rate of cross over to the other treatment was significantly less among those randomized to spinal cord stimulation. The trial had several exclusion criteria, which may limit generalization of the results. *Spinal cord stimulation for the management of refractory angina pectoris:* The published studies on the use of SCS for the treatment of refractory angina were all conducted in Europe. In the ESBY trial, 104 patients at high risk for coronary artery bypass surgery were randomized to SCS or CABG. The follow-up duration was 4.8 years, and the primary outcome was the effect of treatment on angina. The trial was randomized, controlled, and had clinically important outcomes. However, due to the nature of the intervention it was unblinded, it was relatively small, and may have had insufficient power to detect statistically significant differences between the two intervention groups. No comparison was made to a sham treatment, thus the placebo effect of the SCS cannot be ruled out. The results of the study show that there was a significant improvement in the quality of life in the two treatment groups when compared to baseline. The differences in the observed improvement in quality of life and survival were not significant between the two interventions. The study was not designed as equivalence study, and the absence of significant difference does not necessarily indicate that the two treatments were comparable or equivalent. The SPiRiT trial compared the effects of SCS versus percutaneous myocardial laser revascularization, on treadmill exercise time, among patients with refractory angina pectoris. The trial was randomized and controlled. However, it was unblinded, with an intermediate primary outcome, and short follow-up duration. Its results show that that there were no significant differences between the two treatment groups in the exercise tolerance at 3 and 12 moths (primary outcome). Also, no significant differences were observed in the 2 or more points improvements on the Canadian Cardiovascular Society angina class, or quality of life. Patients in the SCS group had a significantly higher event rate mainly angina or system related. A placebo effect may contribute to the improvement in anginal symptoms after SCS. The only sham controlled RCT conducted was a very small trial (n=25) that implanted the SCS in all patients but was left it inactivated for 6 weeks in the control group. The study was too small, had only 6 weeks of follow-up, and other limitations. *Spinal cord stimulation for the management of critical leg ischemia (CLI)* The published studies on the use of SCS for the treatment of critical leg ischemia were also conducted in European countries. The three meta-analyses published by Ubbink and colleagues (2004, 2005, and 2006) pooled data from 5 RCTs and one nonrandomized controlled trial. The sample sizes in these trials varied from 37 to 120 with a total of 444 participants. All suffered from inoperable CLI with ischemic rest pain or ulcers < 3cm in diameter. In these trials, the patients received standard control treatment with or without SCS, and the primary outcome was limb salvage (no amputation of foot or higher within 12 months). The meta-analysis had valid methodology. The trials included were small but were judged by the authors to have good quality. The results of the analysis indicate that highly selected patients with inoperable critical limb ischemia had better outcomes with the SCS therapy compared to those who were treated conservatively. They experienced significantly less amputation rates in 12 months (NNT to salvage a limb was 9) and showed significant clinical improvement (NNT to improve the condition from critical leg ischemia to claudications =3). The procedure was not associated with a difference in mortality or QoL vs. conservative treatment. *Conclusion:* There is insufficient evidence to determine the long-term benefits and safety of SCS therapy among patients with refractory neuropathic back and leg pain, failed back surgery, and chronic reflex sympathetic dystrophy. There is insufficient published evidence to determine the long-term efficacy and safety of SCS in treating patients with chronic refractory angina. There is fair evidence from a meta-analysis of small trials that the addition of SCS to the standard conservative therapy for patients with chronic critical leg ischemia may improve the clinical condition of the leg and lead to less amputation rates.

Articles: The search yielded 199 articles. Many were reviews or opinion pieces, or small case series with no control or comparison groups. *Spinal cords stimulation (SCS) in complex regional pain syndrome (CRPS) and refractory neuropathic back and leg pain/failed back surgery syndrome (FBSS)* The search revealed 2 systematic reviews (Taylor 2004, and Taylor 2006) of studies that used spinal cords stimulation in complex regional pain syndrome (CRPS) and refractory neuropathic back, and leg pain/failed back surgery syndrome (FBSS). It also revealed a RCT on SCS for chronic pain (North 2005), and a more recent publication with a longer-term follow-up for a RCT (Kemler 2000) that was previously reviewed f or MTAC in 2000. Several small case series with no comparison or control groups were also identified. The 2 systematic reviews were conducted by the same principal author and had several limitations. The results of the included RCTs were presented individually without pooling of data, and the results of case series were pooled. The quality of the included case series was poor as judged by the authors; they were heterogeneous, and subject to bias. Due to these as well as other limitations, the meta-analyses ware not presented in evidence tables. Evidence tables were constructed for the North et al RCT, and the more recent publication of Kemler and colleagues' RCT with the 2-year follow-up data. *Spinal cord stimulation for the management of refractory angina pectoris:* The literature search revealed three RCTs and several case series. One RCT compared SCS with coronary artery bypass grafting (ESBY trial), another

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compared it with percutaneous myocardial laser revascularization (SPiRiT), and in the third trial (Hautvast 1998) all patients received the SCS implant, but the stimulator was inactivated in the control group for the 6 weeks of study. This last trial was not critically appraised due to its small sample size (n=25), short follow-up duration as well as other limitations in the trial. The ESBY and SPiRiT trials were critically appraised. *Spinal cord stimulation for the management of critical leg ischemia:* The literature search revealed 5 randomized controlled trials, and one non- randomized comparative study on the use of SCS for the treatment of critical leg ischemia. It also revealed three systematic reviews; all conducted by the same principal authors. These analyses pooled the results of the published RCTs. All three were critically appraised and presented in one evidence table. *The following articles were critically appraised:* Kemler MA, deVet HCW, Barendse GAM, et al. the effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol 2004; 55:13-18. See Evidence Table. North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: A randomized controlled trial. Neurosurg 2005; 56:98-107. See Evidence Table. Ekre O, Eliason T, Norsell H, et al. Long-term effects of spinal cord stimulation and coronary artery bypass grafting on quality of life and survival in the ESBY study. *Eur Heart J* 2002; 23:1938-1945. See Evidence Table. McNab D, Khan SN, Sharples LD, et al. An open label, single –center, randomized trial of spinal cord stimulation vs. percutaneous myocardial laser revascularization in patients with refractory angina pectoris: The SPiRiT trial. *Eur Heart J* 2006;27:1048-1053 See Evidence Table. Ubbink D T, Vermeulen H. Spinal cord stimulation for critical leg ischemia: A review of effectiveness and optimal patient selection. *J Pain Symptom Manage.* 2006;31: S30-S35. See Evidence Table. Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischemia. *The Cochrane Database of systematic reviews* 2005 Issue 3. Art No.:CD00401 DOI:10.1002/14651858.CD004001. pub2. See Evidence Table. Ubbink D T, Vermeulen H, Spincemaille GH, et al. Systematic review and meta-analysis of controlled trials assessing spinal cord stimulation for inoperable critical leg ischemia. *Br J Surg.*2004; 91:948-955. See Evidence Table.

The use of Spinal Cord Stimulators in the treatment of intractable pain, angina or leg ischemia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
HCPC Codes	**Description**
L8679	Implantable neurostimulator, pulse generator, any type

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
04/27/2001	06/01/2010[MDCRPC], 04/05/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/02/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
09/28/2017	Added definition of FBS
04/02/2019	MPC approved to increase pain reduction rate from 50% to 70%

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Clinical Review Criteria
Spinal Fusion

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Criteria

All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	Spinal Fusion Services: Documentation Requirements (A53975) See also the following Medicare Technology Center article - Spinal Fusion for the Treatment of Low Back Pain Secondary to Lumbar Degenerative Disc Disease
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Spinal Fusion," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Effective until November 1, 2022

LUMBAR SPINE

Spinal Fusion may be indicated for **ONE or more** of the following

1) Spinal fracture (acute) repair indicated by **ONE or more** of the following:
   - Spinal instability due to trauma
   - Neural compression due to trauma
2) Lumbar spinal stenosis treatment indicated by **ALL of the following:**
   - Imaging findings of lumbar spondylolisthesis
   - Spondylolisthesis for spine fusion (> or equal to 4 mm shift in the sagittal plane (viewed from the side) on flexion/extension plain x-rays).
   - Clinically important findings of spinal stenosis indicated by **ONE or more** of the following:
     i. Progressive or severe symptoms of neurogenic claudication or radicular pain requiring treatment as indicated by **ALL of the following**:
        - Significant functional impairment
        - Central, lateral recess or foraminal stenosis demonstrated on imaging (e.g., MRI, CT myelography)
        - Failure of at least 3 months of non-operative therapy
     ii. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
3) Spondylolysis treatment indicated by **ONE or more of the following**:

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- Rapidly progressive spondylolisthesis with severe neurologic compromise (eg, urinary incontinence)
- Spondylolisthesis with significant associated findings, including **ALL of the following**:
  i. Grade 2* or more with (anterior slippage, **not retro slippage as an indicator**) spondylolisthesis demonstrated on plain x-rays, CT or MRI
  ii. Back pain, neurogenic claudication symptoms, or radicular pain from lateral recess or foraminal stenosis
  iii. Significant functional impairment
  iv. Failure of at least 3 months of non-operative therapy

*The Myerding grading system measures the percentage of vertebral slip forward over the body beneath:

Grade	Percentage
grade 1	25 % of vertebral body has slipped forward
grade 2	25 % to 49 % of vertebral body has slipped forward
grade 3	50 % to 74 % of vertebral body has slipped forward
grade 4	75 % to 99 % of vertebral body has slipped forward
grade 5	Vertebral body has completely fallen off (i.e., spondyloptosis)

4) Severe degenerative scoliosis treatment with progression of deformity to greater than 30 degrees or 6mm of slippage (olisthesis) having failed 3 months medical therapy and with **ONE of the following:**
   i. Persistent significant radicular pain or weakness unresponsive to non-operative therapy
   ii. Persistent neurogenic claudication unresponsive to non-operative therapy)
5) Anticipated spinal instability due to **ONE or more of the following**:
   - Planned extensive surgery for dislocation, infection, abscess or tumor
   - Current plan for additional primary or revision spinal surgeries (e.g., laminectomy).
6) Spinal instability due to prior surgery for neural decompression including laminectomy, dislocation, infection, abscess or tumor.
7) Revision fusion surgery due to **ONE of the following:**
   - For adjacent segment disease as indicated by **ALL of the following**:
     i. Radiographic evidence of adjacent segment disease (e.g., neural compression) that correlates with symptoms
     ii. Persistent disabling symptoms (low back pain, radiculopathy)
     iii. Failure of 3 months of non-operative therapy
   - Documented pseudoarthrosis (nonunion of prior fusion) by radiological studies when **ALL of the** following are met:
     i. Previous fusion at least 6 months ago with significant interval improvement
     ii. Persistent daily axial back pain with or without neurogenic claudication or radicular pain
     iii. Significant functional impairment inability to perform activities of daily living, school, and work
     iv. Failure of 3 months of non-operative therapy
   - Recurrent same level disc herniation when **ALL of the following** are met:
     i. Previous disc surgery greater than 6 months ago with interval improvement
     ii. Recurrent neurogenic claudication or radicular pain unresponsive to non-operative treatment for greater than 3 months
     iii. Neural structure compression documented by recent imaging consistent with signs and symptoms.

The following are not considered medically necessary:
   a) A lumbar fusion for a spinal deformity not meeting one of above criteria performed primarily for low back pain.
   b) A lumbar fusion performed for any condition not listed above, including non-radicular pain with common degenerative changes (degenerative disc disease, facet joint arthrosis, etc.) or post-laminectomy low back pain.

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Allograft and autograft use in spinal fusion is covered if the requested procedure meets the criteria above for a spinal fusion procedure, **with the exception of InFUSE™ Bone Graft** (see separate criteria here).

Effective November 1, 2022

LUMBAR SPINE

**All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.*

NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery. For persons with recent nicotine use (unless there is evidence of cord compression, or other indications for urgent intervention, noted below), documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to fusion in patients without progressive neurologic deficit or cord compression

Spinal Fusion may be indicated for **ONE or more** of the following:

1) Spinal fracture (acute) repair indicated by **ONE or more** of the following:
   - Spinal instability due to trauma
   - Neural compression due to trauma
2) Lumbar spinal stenosis with spondylolisthesis due to degenerative disease or congenital spondylolysis. Treatment indicated by **ALL of the following:**
   - Imaging findings of lumbar spondylolisthesis defined as ≥ 4 mm forward shift in the sagittal plane (viewed from the side) on standing flexion/extension plain x-rays **OR** Grade II, III, or IV on the Myerding grading system (see table below)
   - Clinically important findings of spinal stenosis indicated by **ONE or more** of the following:
     i. Progressive or severe symptoms of neurogenic claudication* (see below) or radicular pain/ suspected radiculopathy** (see below) with ALL of the following documented in notes:
        - Significant functional impairment
        - Central, lateral recess or foraminal stenosis demonstrated on imaging (e.g., MRI, CT myelography)
        - Failure of at least 3 months of conservative therapy*** (see below)
     ii. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome

The Myerding grading system measures the percentage of vertebral slip forward over the body beneath:

Grade	Percentage
grade 1	25 % of vertebral body has slipped forward
grade 2	25 % to 49 % of vertebral body has slipped forward
grade 3	50 % to 74 % of vertebral body has slipped forward
grade 4	75 % to 99 % of vertebral body has slipped forward
grade 5	Vertebral body has completely fallen off (i.e., spondyloptosis)

3) Severe degenerative scoliosis treatment with progression of deformity to greater than 30 degrees (and 40 degrees for adolescents) and having failed 3 months of conservative treatment*** (see below) and with **ONE of the following:**
   i. Persistent significant radicular pain** (see below) or weakness unresponsive to non-operative therapy
   ii. Persistent neurogenic claudication unresponsive to non-operative therapy) * (see below)
4) Spinal instability due to prior surgery for neural decompression including laminectomy (must meet criteria of imaging findings of lumbar spondylolisthesis defined as > or equal to 4 mm shift in the sagittal plane (viewed from the side) on flexion/extension plain x-rays; dislocation, infection, abscess, or tumor.
5) Anticipated spinal instability (patient has not had prior fusion) due to **ONE or more of the following**:
   - Planned extensive surgery for dislocation, infection, abscess, or tumor

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- Current plan for revision of prior decompressive surgery with anticipated instability due to wide resection needed

6) Revision fusion surgery (with history of previous fusion surgery) due to **ONE of the following:**
- For adjacent segment disease as indicated by **ALL of the following**:
  - i. Radiographic evidence of adjacent segment disease (e.g., significant neural compression that correlates with symptoms
  - ii. Persistent disabling symptoms (low back pain, radiculopathy** (see below), neurogenic claudication* (see below)
  - iii. Failure of 3 months of conservative therapy*** (see below)

7) Documented pseudoarthrosis (nonunion of prior fusion) **when ALL of the following** are met:
- Radiological studies showing **ONE of the following**:
  - o lucency surrounding the hardware
  - o fracture of the hardware
  - o absence of bridging bony arthrodesis on CT imaging 12 months or more post-operative
- Previous fusion at least 12 months ago
- Persistent daily axial back pain with or without neurogenic claudication* (see below) or radicular** (see below) pain
- Significant functional impairment inability to perform activities of daily living, school, and work
- Failure of 3 months of conservative therapy*** (see below)

8) Recurrent disc herniation in the setting of previous surgical microdiscectomy at the same level when **ALL of the following are met**:
  - i. Previous disc surgery greater than 6 months ago
  - ii. Recurrent neurogenic claudication* (see below) or radicular pain** (see below) unresponsive to 3 months of conservative therapy*** (see below)
  - iii. Neural element compression (central, lateral recess or foraminal stenosis) documented by recent imaging consistent with signs and symptoms

The following are **NOT** considered medically necessary:

a. A lumbar fusion for a spinal deformity not meeting one of above criteria performed primarily for low back pain.
b. A lumbar fusion performed for any condition not listed above, including non-radicular pain with common degenerative changes (degenerative disc disease, facet joint arthrosis, etc.) or post-laminectomy low back pain.

Allograft and autograft use in spinal fusion is covered if the requested procedure meets the criteria above for a spinal fusion procedure, with the exception of InFUSE™ Bone Graft (see separate criteria here).

* Neurogenic claudication defined as: bilateral or unilateral leg pain upon standing and walking that is temporarily relieved by forward flexion or sitting or lying down. The pain of lumbar stenosis is caused by relative ischemia of the lumbar nerve roots when in an upright position.

** Radicular pain/suspected radiculopathy defined as:
- Leg pain is > or equal to back pain present in *nerve root distribution* (e.g., L5, S1, etc.) **PLUS, ONE or MORE**:
  - o Positive supine straight leg raising test - radicular leg pain reproduced when the leg is extended >30°(e.g., if patient reported pain down the posterior thigh and lateral calf, expectation is a positive SLR test would reproduce that pain and not cause nonspecific pain like calf tightness or low back pain) OR
  - o Motor weakness or sensory loss in a radicular distribution (must be in a specific radicular distribution) OR
  - o EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

Effective until March 1, 2023

***Conservative treatment defined as: Patients must have three months of non-operative treatment as demonstrated by a trial of one or more of the following medications:

A. Non-steroidal anti-inflammatory drugs (oral or topical)
B. Acetaminophen
C. Epidural steroid injection of corticosteroids as appropriate

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AND

D. A trial of **All** of the following physical measures:
   i. Supervised Physical therapy, attendance at >75% of sessions
   ii. Flexibility and muscle strengthening exercises
   iii. Reasonable restriction of activities
   iv. If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.

Effective until March 1, 2023

***Conservative treatment defined as: Patients must have three months of non-operative treatment as demonstrated by a trial of one or more of the following medications:

A. Non-steroidal anti-inflammatory drugs (oral or topical)
B. Acetaminophen
C. Epidural steroid injection of corticosteroids as appropriate

AND

D. A trial of **All** of the following physical measures:
   i. Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits
      - At least half of PT must be in person (not virtual)
   ii. Flexibility and muscle strengthening exercises
   iii. Reasonable restriction of activities
   iv. If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.

Allograft and autograft use in spinal fusion is covered if the requested procedure meets the criteria above for a spinal fusion procedure, **with the exception of InFUSE™ Bone Graft** (see separate criteria here).

Minimally Invasive Lumbar Decompression
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Minimally Invasive Sacroiliac Joint Fusion (iFuse Implant System™)
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Axial Lumbar Interbody Fusion System
There is insufficient evidence in the published medical literature to show that this procedure is as safe as standard procedures and/or provides better long-term outcomes than current standard procedure.

If requesting these services, please send the following documentation to support medical necessity:

- Specific procedure(s) requested with related procedure/diagnosis codes and identification of the disc levels for surgery
- Clinical notes to include:
  - History and Physical
    - Duration/character/location/radiation of pain
    - Activity of daily living (ADL) limitations
    - Physical examination
  - Evidence/support of specific prior conservative treatment measure(s) attempted
  - Imaging reports pertinent to performed procedure, including x-ray report of flexion-extension films that demonstrate the presence of lumbar spine instability

**All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.*

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

Chronic lower back pain is a major health problem and cause of disability in Western countries. The cause of the persistent pain is not well understood for the majority of patients. It generally occurs without specific damage or signs that can be revealed by imaging or other neurophysiological techniques. It is believed that the pain starts as acute pain of muscle and connective tissue and persists among approximately one third of the patients (Rittweger 2002). Mechanical low back pain may have various causes including degenerative disc disease, degenerative spondylosis, disc herniation, facet arthropathy, and others. Patients with low back pain may also experience reduced lumbar flexibility, reduced flexion-relaxation and static balance. The pain is aggravated by sitting, standing and lifting, which increase axial loading on the spine. Walking may relieve some of the pain, but patients experience more relief by lying down as it unloads the spine and reduces intradiscal pressure (Gose 1998).

Conservative medical care for chronic back pain includes bed rest, steroid injection, anti-inflammatory drugs, muscle relaxants, conventional physiotherapy, exercises, stretching, manipulative techniques, ultrasound treatments, electric stimulation techniques and others. These measures ease the pain for some patients but are ineffective, intolerable, or unsuitable for others. Patients not responding to conservative therapy may be offered conventional or percutaneous surgical procedures such as disc space decompression, epidural blocks, and spinal instrumentation. These interventions play an important role in treating patients with low back pain due to herniated disc and degenerative disc problems. However, surgery may not relieve all the pain, and could permanently disrupt the biomechanical and physiological function of the disc. Moreover, not all patients are candidates for surgery.

In patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). The net benefit of lumbar fusion was moderate compared to standard nonsurgical therapy; however, there was no difference between lumbar fusion and intensive rehabilitation.

Medical Technology Assessment Committee (MTAC)

Allogenic Bone for Spinal Fusions- Allograft Bone

BACKGROUND

Arthrodesis of the spine has been performed for decades for various spinal conditions such as fractures, congenital or developmental deformities, arthritis, degenerative disease, disc lesions, tuberculosis and other infections. With the overall intent to prevent movement in painful bones by permanently joining two or more vertebrae, bone grafting is an integral part of the fusion process. The choice of bone graft is dependent on various factors including patient specific disease, type and location of fusion, the number of levels involved, patient and surgeon preference, as well as, surgeon experience. Non-fusion risks should also be taken into consideration such as patient age, gender, tobacco use and the patient’s health status (Deyo 2004).

Historically, autograft bone harvested from the iliac crest of the patient who is undergoing the procedure has been the gold standard. This type of graft requires an additional incision during operation, lengthening surgery and causing morbidity associated with harvesting the tissue. It is further limited by, inconsistent size, quantity, and quality of tissue. One alternative to autograft is allogeneic bone graft, or allograft bone, which is harvested from cadaver bone. Allograft bone is typically acquired through a bone bank and can be procured in greater quantities than autograft (Ehrler and Vaccaro 2000).

Currently, there are three types of allograft, fresh frozen bone allograft, freeze dried bone allograft and demineralized freeze-dried bone allograft. Allograft bone is available in different shapes and sizes to fit into the area of the spine where it is needed. Allograft materials are difficult to standardize because of the heterogeneity of the donor tissue. In addition, allografts can be prepared in a number of different ways with the characteristics of a particular allograft affected by its method of preparation. Regulations for allograft bone procurement, as well as screening and testing procedures are extensive and enforced by both the American Association of Tissue Banks and the U.S. Food and Drug Administration (FDA).

While allogeneic bone avoids the common complication of donor site morbidity that occurs with autogenic bone grafting the obvious disadvantage is potential disease transfer. Contaminants and pathologies that may be transferred include viral and bacterial infections, malignancy, systemic disorders or toxins. The allograft bone used in spinal fusion procedures is provided by tissue banks (bone banks) which are regulated by the FDA. With

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that said, a retrospective review done by Mroz and colleagues in 2009, examined the safety of allograft bone through data from the FDA, recalls of musculoskeletal allografts data from the Center for Disease Control (CDC), and literature reviews. The review identified 59,476 recalls between 1994 and 2007 citing improper donor evaluation, contamination and infection as the main reasons for recall (Mroz, Joyce et al. 2009). In addition, there have been several reported cases of HIV transmission (Asselmeier, Caspari et al. 1993).

03/04/2014: MTAC REVIEW
Allograft Bone
Evidence Conclusion: *Efficacy* - A meta-analysis of autograft versus allograft in anterior cervical discectomy and fusion (ACDF) was conducted in 2000 by Floyd and Ohnmeiss and concluded that it was not possible to ascertain whether autograft is clinically superior to allograft. When the data from all four studies were pooled, a significantly higher rate of union and a lower incidence of collapse was found with autograft for both one- and two-level fusions. Patient satisfaction and clinical outcomes were not adequately addressed in all of the studies and although autograft has a higher fusion rate than allograft, the clinical results did not rely solely on radiographic results (Floyd and Ohnmeiss 2000). [Evidence Table Allograft bone1] In a comparison of allograft versus autograft in multilevel ACDF with instrumentation, Samartzis et al reported fusion rates of 94.3% and 100% for allograft and autograft, respectively. In this study, nonunion occurred in patients with allograft but this difference was not statistically significant. Excellent and good clinical outcomes were noted in 88.8% of patients. These results should be interpreted with caution as the study was retrospective in nature and only included 80 non-blinded patients. With that said, the authors mention that meticulous surgical technique and patient selection were more important than graft type for successful outcome (Samartzis, Shen et al. 2003). [Evidence Table Allograft bone2] Samartzis and colleagues completed an additional and similar study in 2005 which demonstrated a fusion rate of 100% and 90.3% for allograft and autograft, respectively, in one-level ACDF. Clinical outcomes in relation to graft-type were also analyzed with no statistical differences detected (P>0.05). The study took place at a single institution and was retrospective in nature including only 66 non-blinded participants. (Samartzis, Shen et al. 2005). [Evidence Table Allograft bone3] In a prospective randomized study, Gibson and colleagues reported similar clinical results in 69 patients who received either fresh-frozen allograft or autograft during instrumented posterolateral lumbar fusion. The groups were very similar before operation in terms of back pain and leg pain scores, but the allograft group showed a slightly higher overall pain score, which was statistically significant. After one year, however, the scores from the questionnaire were significantly different in that the group that had received allograft bone seemed to have done better in terms of back pain than those who had received the autograft bone (Gibson, McLeod et al. 2002). [Evidence Table Allograft bone4]
Safety - Both the Gibson et al., and the 2005 Samartzis et al. studies reported no complications associated with allograft bone use, however, it is unclear how systematic they were in collecting this information (Gibson, McLeod et al. 2002; Samartzis, Shen et al. 2005). None of the other studies reported on the safety or adverse events of allogeneic bone grafts when used in spinal fusions. While it appears that allografts have comparable fusion rates with autografts, proper evaluation of the efficacy and safety is difficult to make as the risk of bias throughout the studies was high, especially concerning small population sizes and retrospective, non-randomized or non-blinded studies. Patient risk factors, including body mass index, smoking, age and sex also contribute to the diversity of the study groups. As mentioned previously, surgical technique may have as much influence on fusion as the choice of graft and the contributions of factors such as nutrition, sex, age, bone metabolic factors, and smoking on the success of autograft versus allograft. These variations of standard procedures make it difficult to define the true effectiveness of grafts. Moreover, the absence of standardized fusion criteria and inconsistent outcome reporting creates heterogeneity of studies making it difficult to compare and contrast autograft and allograft across studies. Beyond the question of efficacy, the potential risk of disease transmission is the large concern which, on the whole, did not seem to be adequately addressed by the literature. The use of allograft bone in spinal fusion surgery warrants further clinical studies.
Conclusions:
- There is low quality evidence to support the effectiveness of allogeneic bone grafts for ACDL.
- There is insufficient evidence to determine the effectiveness of allogeneic bone grafts in lumbar surgery.
- There is insufficient evidence to determine the safety of allogeneic bone grafts in both cervical and lumbar spinal fusions.

Articles: The literature search revealed just over 100 studies many of which were case reports examining the performance of allograft for spinal fusion, but very few have been prospectively designed and well conducted. Selection of articles relied on the comparison of allograft to autograft. Studies that combined allograft bone with other materials and studies that compared allograft bone to other spinal fusion techniques were excluded.
The following publications were selected for critical appraisal: Floyd, T and Ohnmeiss, D. A meta-analysis of autograft versus allograft in anterior cervical fusion. European Spine Journal 2000; 9:398-403. [Evidence Table Allograft bone1] Samartzis D, Shen FH, Matthews DK, Yoon T, et al. Comparison of allograft to autograft in

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

multilevel anterior cervical discectomy and fusion with rigid plate fixation. The Spine Journal 2003; 3:451-459. [Evidence Table Allograft bone2] Samartzis D, Shen FH, Goldberg EJ, An HS. Is autograft the gold standard in achieving radiographic fusion in one-level anterior cervical discectomy and fusion in one-level anterior cervical discectomy and fusion with rigid anterior plate fixation? 2005;30(15):1756-1761. [Evidence Table Allograft bone3] Gibson S, McLeod I, Wardlaw D, Urbaniak S. Allograft versus autograft in instrumented posterolateral lumbar spinal fusion. Spine 2002;27(15):1599-1603. [Evidence Table Allograft bone4]

The use of allograft bone for spinal fusion does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Spinal Fusion

09/2011: MTAC REVIEW

Evidence Conclusion: The 2009 APS guideline recommends that clinicians discuss risks and benefits of surgery as an option for patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms; however, they also note that there was no difference between lumbar fusion and intensive rehabilitation (weak recommendation, moderate-quality evidence). The 2009 NICE guideline also recommends considering a referral for an opinion on spinal fusion for patients who have completed an optimal package of care, including a combined physical and psychological treatment program and still have severe non-specific low back pain for which they would consider surgery.
Articles: The literature search did not reveal any new studies that addressed the safety or effectiveness of lumbar fusion for the treatment of chronic low back pain. NICE 2009 Consider referral for an opinion on spinal fusion for people who: Have completed an optimal package of care, including a combined physical and psychological treatment program AND Still have severe non-specific low back pain for which they would consider surgery. American Pain Society (Chou) 2009 In patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). The net benefit of lumbar fusion was moderate compared to standard nonsurgical therapy; however, there was no difference between lumbar fusion and intensive rehabilitation. The literature search revealed several studies published after the 2009 guidelines that addressed the safety or effectiveness of lumbar (spinal) fusion compared to non-surgical interventions for the treatment of chronic low back pain; however, none of these were selected for review because of severe methodological limitations (small sample size, power was not assessed, high level of crossover, etc.). PubMed was searched from July 2008 (NICE literature search date) or November 2006 (APS/ACP literature search date) through July 2011 with the search terms acupuncture, back pain, spinal manipulation, meditation, massage, mindfulness-based stress reduction, multidisciplinary rehabilitation, physical therapy, sacroiliac joint injections, corticosteroid injections, epidural steroid injections, spinal injections, spinal fusion, and surgery with variations. Searches were limited to English-language studies of human subjects. Only randomized controlled trials (RCTs), meta-analyses, and clinical trials were included in the review. Reference lists and the related articles function in PubMed were used to identify additional publications. Studies were excluded if they had severe methodological limitations (e.g. small sample size, power and/or ITT analysis were not performed, etc.) or if pain or functional disability was not a primary or secondary outcome.

Reviewed by the content of care committee and not MTAC.

AxiaLIF

12/16/2013: MTAC REVIEW

Evidence Conclusion: *Efficacy* The literature search revealed five case series that report on outcomes associated with AxiaLIF. The largest, published in 2011, was a retrospective analysis of 156 patients from 4 clinical sites in the US. Ultimately, the mean pain and ODI scores improved by approximately 63% and 54% respectively (P<0.001) and the overall radiographic fusion rate at 2 years was 94%. The study did not report any adverse events. The patient population was reported to be homogenous, however, the variable nature and progression of the disease compromises the reliability of this claim. Limitations of this study include the retrospective analysis, industry funding as well as selection bias. Outcome measures were not all objective and relied on patient reporting. Only half of the patients were accounted for in the preoperative and postoperative ODI outcome (Tobler, Gerszten et al. 2011). Several smaller case series were also identified and are summarized in a table 1. Ultimately, all of the studies report similar results and conclusions but are subject to the bias of any retrospective series. Further limitations include a lack of control subjects, potential for selection bias as only one of the studies enrolled consecutive patients and unclear study objectives. All studies, with the exception of the publication by Patil and colleagues, received industry funding from TranS1 (Patil, Lindley et al. 2010; Gerszten, Tobler et al. 2012; Marchi, Oliveira et al. 2012). *Safety* Two publications addressed the safety of AxiaLIF with conflicting results. The first study was a 5-year surveillance study of 9,152 patients (Gundanna, Miller et al. 2011)

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and the second, a retrospective review of 68 patient records (Lindley, McCullough et al. 2011). Gundanna and colleagues reported minimal complications (1.3%) in their study while Lindley et al. reported high complication rates (23.5%). The observed adverse events across both the studies included pseudoarthrosis, superficial infection, sacral fracture, pelvic hematoma, failure of wound closure, and rectal perforation. Although both studies were designed to be systematic in their investigation, neither study had a control group for comparison and the results are dependent on either spontaneous reporting or the accuracy of medical records. In addition, both of the studies are subject to a variety of bias due to patient selection and industry funding.
Conclusion: There is insufficient evidence to determine the efficacy of AxiaLIF compared to standard fusion procedures. There is insufficient evidence to establish whether the AxiaLIF is as safe as standard fusion procedures.
Articles: Currently, there are no randomized control trials that compare the AxiaLIF with other approaches to lumbosacral interbody fusion. The literature related to the safety and efficacy is primarily comprised of case series.
The following studies were selected for review: Tobler WD, Gerszten PC, Bradley WD, Raley TJ, Nasca RJ and Block JE. Minimally invasive axial presacral L5-S1 interbody fusion. *Spine* 2011;**36**(20): E1296-E1301. See Evidence Table. Gerszten PC, Tobler W, et al. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. *Journal of Spinal Disorders & Techniques* 2012;**25**(2):E36-E40.See Evidence Table. Marchi L, Oliveira L, et al. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow up. *Journal of Neurosurgery: Spine* 2012;**17**(3):197-192. See Evidence Table. Patil S, Lindley E, et al. Clinical and radiological outcomes of axial lumbar interbody fusion. *Orthopedics* 2010;**33**(12). See Evidence Table Aryan H, Newman C, et al. Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. *Minimally Invasive Neurosurgery* 2008; 51:225-230. See Evidence Table.

The use of AxiaLIF does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Lumbar Spine –
Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for

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	decompression), single interspace and segment; each additional interspace and segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
22842	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
22846	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

Allograft and Autograft (except for InFUSE bone graft)- Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)

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20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/04/2011	11/01/2011[MDCRPC], 09/04/2012[MDCRPC], 06/04/2013[MDCRPC], 11/05/2013[MDCRPC], 04/01/2014[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	10/17/2022

[MPC] Medical Policy Committee

Revision History	Description
12/06/2016	Added clarification to indication: Spondylolisthesis for spine fusion (> or equal to 4 mm)
7/26/2017	Removed spinal decompression codes 22867-22870
05/29/2020	Updated links to related criteria; removed minimally invasive sacroiliac joint fusion codes and deleted codes
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare: spondylolisthesis > or equal to 4mm on flexion/extension x-rays; inclusion of the Myerding scale and detailed documentation requirements. Linked to InFUSE Bone Graft criteria as a non-covered allograft.
06/07/2022	MPC approved to adopt updates to criteria to include indications for smoking-cessation, BMI and Spondylisthesis grading and definitions
10/04/2022	MPC approved to include quantifying number of 3 visits for physical therapy of conservative treatment. 60-day notice required.
10/17/2022	Updated applicable codes.

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Clinical Review Criteria
Sports Hernia Surgery

- Athletic Pubalgia Surgery

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Sports Hernia Surgery*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Surgical treatment of groin pain in athletes (also known as athletic pubalgia, Gilmore groin, osteitis pubis, pubic inguinal pain syndrome, inguinal disruption, slap shot gut, sportsmen groin, footballers groin injury complex, hockey groin syndrome, athletic hernia, sports hernia, or core muscle injury) is unproven and not medically necessary due to insufficient evidence.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The incidence of groin pain among athletes is estimated to be from 2% to 20%; however, the incidence in the general population is unknown. Groin hernias and hip joint pathologic findings are common and often considered; once ruled out by physical examination with or without imaging, the differential diagnoses and workup of groin pain is confounding to many practitioners. This ambiguous nature of non-hernia, non-hip groin pain is understandable because routine physical examination often only reveals groin tenderness, and imaging may or may not have abnormalities. Most of the literature written about the subject are case series or opinions. Many of these case series only involve professional male athletes, and the reported end points are often: return to sport, time to return to sport, or level of sport. Thus, the level of evidence of the studies is low quality, and the findings may not be applicable to the general population.

In the acute setting, pain is treated with rest (2-8 weeks) and nonsteroidal anti-inflammatory drugs. If pain continues, the mainstay of initial therapy is physical rehabilitation. Nonoperative, exercise-based therapy has

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been suggested to be an effective first-line therapy, with treatment success ranging from 40% to 100%. Some report that among individuals with greater than 2 months of pain, resolution is unlikely without surgery. Multiple operative approaches have been used. Although there are numerous single-center case series and several meta-analyses, there are no high-quality trials evaluating operative approaches.

Reference
Zuckerbraun BS, Cyr AR, Mauro CS. Groin Pain Syndrome Known as Sports Hernia: A Review. *JAMA Surg.* 2020;155(4):340–348. doi:10.1001/jamasurg.2019.5863. Retrieved May 19, 2020.

Applicable Codes

Considered Not Medically Necessary - experimental, investigational or unproven:

CPT® Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
06/02/2020	06/01/2021[MPC], 06/07/2022[MPC] , 06/06/2023[MPC]	06/02/2020

[MPC] Medical Policy Committee

Revision History	Description
06/02/2020	MPC approved to adopt a new policy of non-coverage. Requires 60-day notice, effective 10/1/2020.

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Clinical Review Criteria
Standers

- Adult Standers
- Pediatric Standers

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Durable Medical Equipment Reference List (280.1) *Per NCD - Standing Tables are not covered because they are not primarily medical in nature.*
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare

Kaiser Permanente has elected to use the Standing Frame (A-0996) MCG* for medical necessity determinations. This service is not covered per MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Supported standing programs are routinely used by therapists as part of a postural management approach in children with severe developmental disabilities (e.g. cerebral palsy, spinal cord injuries, meningomyelocele, osteogenesis imperfecta) as they are unable to stand or walk by themselves due to poor motor control. These programs use assistive devices or adaptive equipment, eg. standers or standing frames that provide external adjustable support, to facilitate an upright position. Standers allow weight bearing activities which are believed to increase bone mineral density (BMD), manage contractures, increase muscle strength and postural control, as well as improve visuals and oral motor skills and social communication. These in turn, may prevent or reduce the children's musculoskeletal problems, increase their independence, and enhance their functional abilities (Gudjonsdottir 2002, Caulton 2003).

Medical Technology Assessment Committee (MTAC)

Pediatric Standers

10/16/2012: MTAC REVIEW

Evidence Conclusion: The is insufficient evidence to date to determine the efficacy of standers in reducing risk of fractures among children who are unable to stand independently due to severe developmental disabilities. The published pilot RCT did not study the effect of stander equipment but examined the effect of increasing standing time in children with cerebral palsy who are already involved in a standing program. In addition, it used bone

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mineral density, an intermediate outcome, as the primary end point. A more important clinical outcome would be the effect of the program on reducing the risk of bone fracture. Larger RCTs with long-term follow-up are needed to determine the long-term safety and efficacy of standers on reducing the risk of fractures in children severe developmental disabilities.
Articles: There is very limited published literature on the use of standers for non-ambulant children due to significant developmental disabilities. The search identified a small pilot randomized controlled trial (RCT) that examined the effect of increasing the duration of a standing program on bone mineral density (BMD) in children with cerebral palsy, and another also very small pilot RCT (N=20) that examined the effect of standing on BMD in children with disabling conditions. There was also a number of published small case series with twenty or less participants each that examined the short-term effect of standing frames or prolonged standing on gait, muscle contracture, or BMD in children with cerebral palsy. The following RCT was critically appraised in the 2012 review. Caulton JM, Ward KA, Alsop CW, et al. A randomized controlled trial of standing program on bone mineral density in non-ambulant children with cerebral palsy. Arch Dis Child. 2004;89;131-135. See Evidence Table.

The use of use of standers to reduce fracture risk does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Pediatric Standers

02/11/2013: MTAC REVIEW

Evidence Conclusion*:* There is insufficient evidence to date to determine the efficacy of standers in reducing risk of fractures among children who are unable to stand independently. The published pilot RCT by Caulton and colleagues (2004), did not study the effect of stander equipment, but examined the effect of increasing standing time in children with cerebral palsy who are already involved in a standing program. In addition, it used bone mineral density, an intermediate outcome, as the primary end point. A more important clinical outcome would be the effect of the program on reducing the risk of bone fracture. Ward and colleagues' (2004) RCT included children who were able to stand independently but had limited mobility due to their disability (autism, involuntary movements, limb deformity, and spasticity). 20 children 4-19 years of age were randomized to standing on active (vibrating platform) or placebo devices for 10 minutes/day, 5 days/week for 6 months. The primary outcome was proximal tibial spinal bone mineral density (vTBMD). The compliance rate was only 44%, and the 6 months results showed a net benefit of treatment equal to +15.72 mg/ml (17.7%; p =0.0033) for proximal tibial BMD and + 6.72 mg/ml, (p = 0.14) for the spine, compared with placebo. Larger RCTs with long-term follow-up, and patient oriented outcomes, are needed to determine the long-term safety and efficacy of standers on reducing the risk of fractures in children with developmental disabilities.
Articles: There is very limited published literature on the use of standers for non-ambulant children due to significant developmental disabilities. The search identified a small pilot randomized controlled trial (RCT) that examined the effect of increasing the duration of a standing program on bone mineral density (BMD) in children with cerebral palsy, and another also very small pilot RCT (N=20) that examined the effect of standing on BMD in children with disabling conditions. There was also a number of published small case series with twenty or less participants each that examined the short-term effect of standing frames or prolonged standing on gait, muscle contracture, or BMD in children with cerebral palsy. The following RCT was critically appraised in the 2012 review. Caulton JM, Ward KA, Alsop CW, et al. A randomized controlled trial of standing program on bone mineral density in non-ambulant children with cerebral palsy. *Arch Dis Child.* 2004;89;131-135. See Evidence Table.

The use of standers to improve pulmonary function does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Adult Standers

BACKGROUND
Standing frames also known as standers, standing devices, standing systems, or standing aids, are assistive devices that enable non-ambulatory individuals to achieve and maintain an upright posture. These may be used by patients with mild to severe disabilities such as spinal cord injury, traumatic brain injury, cerebral palsy, muscle dystrophy, or other neuromuscular conditions that do not enable the individual to stand independently. They can be used at home, in the workplace, extended care units, assisted living centers, nursing homes, and rehabilitation facilities. Prolonged standing has been investigated over the years for its possible benefits for patients with spinal cord injuries and other disabilities. It is suggested that standing and weight bearing activities may increase bone mineral density and muscle strength, reduce abnormal muscle tone and spasticity, improve circulation, reduce lower limb swelling, improve bowel and bladder function, prevent pressure sores, as well as other potential benefits. Many of these benefits, however, are not supported by good quality evidence (Eng 2001, Bagley 2004, Bernhardt 2012).
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There are a variety of standing systems. The common types include sit to stand, prone, upright, prone, multi-positioning standers, and standing wheelchairs. Some systems can be changed by the user from a sitting to a standing position; others require the assistance of another person to change its position. Standing systems can generally be divided into three groups: 1. Passive or static standers that remain in one place and cannot be self-propelled, 2. Mobile or dynamic standers that can be propelled by the user if he/she has the ability to do so, and 3. Active standers that can create reciprocal movements of the arms and legs while the patient is standing.

08/17/2015: MTAC REVIEW
Adult Standers
Evidence Conclusion: There is insufficient evidence to date, to determine the efficacy of standing devices on health outcomes of patients with disabilities or health conditions that render them unable to stand independently. The published RCT conducted by Bagley and colleagues (2005) (Evidence table 1) evaluated the effectiveness of the Oswestry Standing Frame for severely disabled stroke patients. The trial included 140 inpatients in a stroke rehabilitation unit. In addition to undergoing the usual stroke care, the patients were randomized in a 1:1 ratio to receive 14 consecutive treatment with the use of Oswestry standing frame, or to receive 14 consecutive treatments but without access to the Oswestry standing frame. The primary outcome of the trial was the change in the Rivermead Mobility Index (RMI) from baseline to 6 weeks post stroke. The results of the trail showed no statistically significant difference between the study groups in any of the primary or secondary outcome measures or for resource savings. Larger RCTs with long-term follow-up and patient-oriented outcomes are needed to determine the long-term safety and efficacy of standing devices or systems among adults with different health conditions and/or disabilities that do not enable them to stand on their own.
Articles: There is very limited published literature on the use of standers for non-ambulatory adults with mild to severe physical disability. The literature search identified one RCT (Bagley et al, 2005) that evaluated the Oswestry standing frame for patients after stroke, and another very small pilot RCT (Allison et al, 2007) that assessed the impact of additional supported standing practice on the functional ability post stroke in 14 patients. The following trial was selected for critical appraisal: Bagley P, Hudson M, Forster A, Smith J, et al. A randomized trial evaluation of the Oswestry Standing Frame for patients after stroke. *Clin Rehabil*. 2005 June; 19(4):354-364.See Evidence Table 1.

The use of Adult Standers does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
E0637	Combination sit-to-stand frame/table system, any size including pediatric, with seat lift feature, with or without wheels
E0638	Standing frame/table system, one position (e.g., upright, supine or prone stander), any size including pediatric, with or without wheels
E0641	Standing frame/table system, multi-position (e.g., 3-way stander), any size including pediatric, with or without wheels
E0642	Standing frame/table system, mobile (dynamic stander), any size including pediatric

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
03/05/2013	03/05/2013[MDCRPC], 01/07/2014 [MPC], 11/04/2014 [MPC], 09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	10/06/2020

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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
10/28/2015	Added NCD link
10/06/2020	MPC approved the MCG 24th ed. guideline for Standing Frame: A-0996

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Patient Referral Guidelines
Stem Cell Transplant/Bone Marrow Transplant

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Stem Cell Transplantation Formerly 110.8.1 (110.23)
Local Coverage Determinations (LCD)	
Local Coverage Article	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease, and Myelodysplastic Syndrome (MM9620)
Kaiser Permanente Medical Policy - **Stem Cell Transplant for Orthopedic Conditions**	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Stem Cell Transplant for Orthopedic Conditions," for medical necessity determinations. Use the Non-Medicare criteria below.

For Federal Members:

Please refer to the member contract for specific diagnoses and types of stem cell transplants that are covered**.**

For all other Non-Medicare Members

Stem Cell Transplant for Orthopedic Conditions	Mesenchymal stem cell therapy is considered **investigational** for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue or joint.

Stem Cell Storage:
Per Kaiser Permanente policy, stem cell storage is only covered for members who are scheduled to receive a stem cell transplant. Medically indicated storage is reviewed by Clinical Review on a case-by-case basis.

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for Blood and Marrow Transplantation. It is important to note that these are guidelines and should be applied together with careful clinical judgment.

1. **GENERAL PRINCIPLES**
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Uncontrollable active infection is a contraindication to transplant.
   c. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. Exceptions may be made on a case-by-case basis.

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d. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
e. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
f. Patient must have a caregiver or caregivers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
g. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
    a. Evidence of such non-adherence may be, failure to keep appointments failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
h. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. GENERAL CONSIDERATIONS

a. Blood and Marrow Transplantation will be considered for patients with fatal hematologic, malignant, and metabolic conditions for whom other medical therapy is not as likely to be curative, or to prolong disease-free and overall survival, or to prevent progressive disability.
b. Patients are encouraged to participate in clinical studies supported by the National Cancer Institute, Clinical Trials Network (CTN), or other cooperative groups in which National Transplant Services (NTS) transplant centers are participating entities.
c. The indications for cord blood and haploidentical transplant are the same as for allogeneic and matched unrelated donor transplant.
d. The indications for autologous transplant overlap, but are not identical to, those for allogeneic transplant.
e. The decision to recommend blood and marrow transplantation and the choice of stem cell product is complex and dependent upon multiple factors including the disease, stage, response to treatment, remission status, risk factors, performance status and physiological condition of the patient, availability of a donor, availability of other therapies, institutional practices and preferences, etc. It is beyond the scope of these guidelines to outline the specific factors that might be considered in an individual case. It is the role of the transplant physician to carefully evaluate the patient and recommend the appropriate treatment using best available published evidence and consensus guidelines from national professional organizations such as the National Comprehensive Cancer Network (NCCN), American Society of Hematology (ASH), American Society of Clinical Oncology (ASCO), and the American Society of Blood and Marrow Transplantation (ASBMT).

INDICATIONS FOR BLOOD & MARROW TRANSPLANT [1]

GUIDELINES FOR BMT CANNOT LIST EVERY POSSIBLE INDICATION ALTHOUGH THE MAJOR ONES ARE LISTED BELOW. IN THE RARE CASES WHERE THE GUIDELINES DO NOT SPEAK TO A PARTICULAR CONDITION, A CALL TO A NETWORK TRANSPLANT CENTER MAY BE INDICATED.

a. Leukemias, Lymphomas, and other Blood Cancers
    i. Acute myelogenous leukemia (AML)[2]
        1. Intermediate and poor risk cytogenetics in first complete remission (CR)
        2. Poor risk molecular markers in first CR (based on emerging data)
        3. Induction failure
        4. Second or subsequent complete remission (CR2)
        5. Relapsed AML (selected cases; treatment on investigational protocols encouraged)
        6. Secondary AML
    ii. Acute lymphocytic leukemia (ALL)
        1. Immediate or High Risk in first CR (based cytogenetics, WBC count at diagnosis, and/or failure to achieve CR within 4 weeks of initial treatment)
        2. Extra medullary disease
        3. Induction failure
        4. Second or subsequent complete remission
        5. Relapsed ALL (selected cases; treatment on investigational protocols encouraged)
    iii. Chronic myelogenous leukemia (CML)
        1. Chronic phase: only if failure to achieve adequate response and/or development of intolerance to tyrosine kinase inhibitors

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2. Accelerated phase
3. Blast crisis

iv. Chronic lymphocytic leukemia (CLL)
1. High risk cytogenetics or molecular markers
2. Resistant to initial therapy
3. Short initial response
4. Fludarabine-resistant
5. Richter's transformation

v. Biphenotypic leukemia

vi. Juvenile myelomonocytic leukemia

vii. Hodgkin's lymphoma
(Note: chemo sensitive disease is required for autologous stem cell transplant)
1. Induction failure
2. Second or subsequent complete or partial remission

viii. Follicular non-Hodgkin's lymphoma
(Note: chemo sensitive disease is required for autologous stem cell transplant)
1. Resistant to initial therapy
2. Initial duration of response <12 months
3. First relapse
4. Transformation to diffuse large B cell lymphoma

ix. Diffuse large cell lymphoma/high grade NHL/T cell lymphoma
(Note: chemo sensitive disease is required for autologous stem cell transplant)
1. Induction failure
2. Second or subsequent complete or partial remission
3. High risk features in first complete remission

x. Mantle cell lymphoma
1. First CR
2. Second or subsequent complete or partial remission

b. Multiple Myeloma and other Plasma Cell Disorders
i. Symptomatic and/or with evidence of end organ damage
1. After initial therapy
2. At first progression
ii. Special Note: Tandem autologous or allogeneic transplant is generally not indicated as front-line therapy.

c. Myelodysplastic Disorders
i. Advanced intermediate or high risk by IPSS
ii. Progressive disease after treatment by hypomethylating agents

d. Myeloproliferative Disease (Neoplasm)
Special note: a heterogenous group of disorders including idiopathic (primary) myeloproliferative neoplasm and other rarer conditions. (Note: CML is covered in 2.1.3 in these guidelines). The complexity of this group of diseases does not lend itself to establishing a uniform set of guidelines. Consultation with a transplant physician is recommended when there is uncertainty regarding best treatment approach.
i. High risk disease (based on age, symptoms, splenomegaly, cell counts, blast percentage, cytogenetics)
ii. Poor response to treatment or progressive disease

e. Severe aplastic anemia and other bone marrow failure states
i. Severe aplastic anemia:
1. In patients >40 years, immunotherapy should be considered first
2. Pediatric patients with HLA matched sibling donor
3. Disease unresponsive to immunosuppressive therapy
ii. Fanconi's anemia
iii. Dyskeratosis congenital with transfusion dependent cytopenias
iv. Schwachmann-Diamond syndrome with cytopenias and/or dysplastic marrow changes
v. Paroxysmal Nocturnal Hemoglobinuria
vi. Constitutional red cell aplasia
vii. Amegakaryocytosis /congenital thrombocytopenia

f. Immune system disorders
i. Severe combined immunodeficiency disease (SCID)
ii. Wiskott-Aldrich syndrome
iii. Chronic-granulomatous disease
iv. Chediak-Higashi syndrome

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v. Infantile genetic agranulocytosis – refractory to GCSF
vi. Severe leukocyte adhesion defect
vii. Other – rare disorders to be considered on a case by case basis

g. Hemoglobinopathies
   i. Thalassemia major
      1. Matched related donor with HLA matched sibling
      2. Matched unrelated donor – select cases
   ii. Sickle cell disease
      1. Recurrent pain crises, acute chest syndrome, high stroke risk, or other life-threatening complications
      2. Appropriate stem cell source at the discretion of the KP physician and COE

h. Metabolic and other non-malignant genetic disorders
   i. Hurler's Syndrome
   ii. Adrenoleukodystrophy
   iii. Mucopolysaccharidosis after consultation with local genetics
   iv. Infantile osteopetrosis
   v. Kostmann's Syndrome

i. Familial erythrophagocytic lymphohistiocytosis and other histiocytic disorders

j. Solid Tumors (autologous)
   i. Neuroblastoma [3] – high risk disease, upfront tandem transplant should be considered unless specified by the COE
   ii. Germ cell neoplasms – chemo sensitive relapse and high-risk disease
   iii. Relapsed Wilm's tumors – high risk, chemo sensitive disease, lung only
   iv. Malignant brain tumors in young children
   v. Ewing's sarcoma – chemo sensitive relapse

k. Systemic Sclerosis (Autologous):
   i. Adults (18-70) and select pediatric patients at discretion of COE
   ii. Referrals should be made to centers with multidisciplinary teams (rheumatology, cardiology, nephrology, and pulmonology) who have inclusion and exclusion criteria based on SCOT trial experience.[4,5]

CONTRAINDICATIONS FOR BLOOD & MARROW TRANSPLANT

a. Myeloablative Conditioning Regimens
   i. Irreversible decreased organ function
   ii. Class III or IV heart failure
   iii. Heart EF <45%
   iv. Lung FEV1 <50% or DLCO <50% predicted
   v. Kidney
      1. Creatinine clearance of <60 ml/min
      2. Except patients with multiple myeloma and primary systemic amyloidosis in which autologous transplants may be performed if <60 ml/min.
      3. For pediatric patients creatinine clearance <60 ml/min/1.73m^2
   vi. Liver bilirubin >3.0, and transaminase >3x upper limit of normal.
   vii. Liver cirrhosis

   *Patients with borderline organ function may still be eligible based on COE standards

b. Non-Myeloablative/Reduced Intensity Conditioning Regimens

   Requirements for heart, lung, kidney, and liver function may be less stringent than myeloablative conditioning regimens.

[i] Organized by disease classification rather than stem cell source.

[ii] Also known as acute myeloblastic leukemia or acute myelogenous leukemia.

[iii] Adamson, Blaney, O'Connor, Hendricks, Devidas & Alonzo (2015). Update for ANBL0532, Phase III Randomized Trial of Single vs. Tandem Myeloablative Consolidation Therapy for High-Risk Neuroblastoma, Children's Oncology Group: The Children's Hospital of Philadelphia.

[iv] Sullivan KM, Goldmuntz EA, Keyes-Elstein L, McSweeney PA, Pinckney A, Welch B, Mayes MD, Nash RA, Crofford LJ, Eggleston B, Castina S, Griffith LM, Goldstein JS, Wallace D, Craciunescu O, Khanna D, Folz RJ, Goldin J, St Clair EW, Seibold JR, Phillips K, Mineishi S, Simms RW, Ballen K, Wener MH, Georges GE, Heimfeld S, Hosing C, Forman S, Kafaja S, Silver RM, Griffing L, Storek J, LeClercq S, Brasington R, Csuka ME, Bredeson C, Keever-Taylor C, Domsic RT, Kahaleh MB, Medsger T, Furst DE; SCOT Study Investigators. Myeloablative Autologous Stem-Cell Transplantation for Severe Scleroderma. N Engl J Med. 2018 Jan 4;378(1):35-47.

[v] City of Hope. Division of Hematology and Hematopoietic Cell Transplantation: POLICY & PROCEDURE HEMATOPOIETIC CELL TRANSPLANT CLINICAL MA

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Evidence and Source Documents

Allogeneic Bone Marrow Transplantation (BMT) in Low-Grade Lymphoma (LGL) and Chronic Lymphocytic Leukemia (CLL)
Autologous Stem Cell Transplant (SCT)/Bone Marrow Transplant for Chronic Myeloid Leukemia (CML)
High Dose Chemotherapy with Autologous Stem Cell Rescue for Treating Multiple Sclerosis
High-Dose Chemotherapy with Stem Cell Transplant for Breast Cancer
Multiple Myeloma
Nonablative SCT for Renal Cell Carcinoma and Melanoma
Scleroderma
Stem Cell Transplantation for Amyloidosis
Stem Cell Transplantation for Autoimmune Diseases

Background

A stem cell transplant is the infusion of healthy stem cells into your body. A stem cell transplant may be necessary if the bone marrow stops working and doesn't produce enough healthy stem cells. Stem cell transplantation is necessary following high dose chemotherapy/radiation for several types of cancers. Stem cells are a type of cell that divide and develop into one of the three main types of cells found in the blood; red blood cells, white blood cells, and platelets.

Although the procedure generally is called a stem cell transplant, it's also known as a bone marrow transplant or an umbilical cord blood transplant, depending on the source of the stem cells. Stem cell transplants can use cells from your own body (autologous stem cell transplant) or they can utilize stem cells from donors (allogenic stem cell transplant).

The first step in the process of stem cell transplantation is the collection of stem cells from a patient or a donor. When a patient's own stem cells are used, they are frozen and stored until needed. Stem cells can be collected from a donor when they are needed. The patient then receives high-dose chemotherapy and the stem cells are infused into the patient's bloodstream. The stem cells travel to the bone marrow and begin to produce new blood cells, replacing the normal cells lost during high-dose chemotherapy.

Medical Technology Assessment Committee (MTAC)

Autologous Stem Cell Transplant (SCT)/Bone Marrow Transplant for Chronic Myeloid Leukemia (CML)

BACKGROUND

Chronic myelogenous leukemia (CML) also referred to as chronic myeloid leukemia, chronic myelocytic leukemia, and chronic granulocyte leukemia, is a malignant disease of the hematopoietic stem cells. Most cases occur in adults, with a median age of approximately 50 years. CML has three stages: Chronic phase, accelerated phase, and blast phase, which is always fatal. Transition from one phase to the other occurs gradually over a period of one year or more however it may take place abruptly and is called the blast crisis. The average survival of CML is 42 months, however after the development of the accelerated phase, survival is usually less than a year, and only a few months after blastic transformation.

There are many treatment options available, yet management of CML remains unsatisfactory. Currently accepted therapies for the chronic phase range from relatively non-toxic oral medications, to alpha interferon-based therapy or aggressive high-dose chemotherapy with allogenic stem transplantation. Conventional chemotherapy usually does not produce a lasting complete remission, nor does it prevent or delay transformation of the disease from an indolent chronic phase to an accelerated phase and blast crisis. High dose therapy, at concentrations much higher than conventional therapy, is highly toxic to the bone marrow and may be able to alter the haematopoietic environment to favor regrowth of normal stem cells. The most effective treatment of CML is high dose chemotherapy with allogenic bone marrow transplantation, which may result in long-term disease-free survival in the majority of patients who receive transplants early in the chronic phase (Meloni 2001). Unfortunately, allogenic

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stem cell transplantation is limited by donor availability and toxicity of graft-versus-host disease (GVHD), especially in the elderly. Transplant of stem cells derived from a patient's own marrow or peripheral blood (autologous transplant) avoids the need for an HLA-matched donor, has less complications, and shorter hospital stay than allogenic transplantations. Autologous bone marrow transplantation was started at the University of Colorado in 1977 and has been successful in other hematological malignancies.

10/9/2002: MTAC REVIEW
Autologous Stem Cell Transplant (SCT)/Bone Marrow Transplant for Chronic Myeloid Leukemia (CML)
Evidence Conclusion: The studies reviewed do not provide sufficient evidence to determine the efficacy and outcome of stem cell/ bone marrow transplantation for CML patients. Results of these studies suggest that this treatment modality has a potential to lead to hematologic and cytogenic response, as well as prolonging survival of younger patients in the first chronic stage. However, the reviewed studies are limited by their design, size, length of follow-up, and lack of a control or comparison group. Their results should be interpreted cautiously. Prospective randomized clinical trials with larger patient sizes, and longer follow-up is needed to assess and compare efficacy of autologous transplantation for CML with other approaches.
The search yielded 79 articles. Articles were selected based on study type. The majority were reviews, opinion pieces, editorials, letters, and commentaries. Some used different adjunct therapies for conditioning, treatment or immunotherapy.
Articles: The literature search did not reveal any randomized controlled trials, or meta-analyses. A study that pooled data from 8 marrow transplant center, and four case series with patients who underwent an autograft after intensive chemotherapy, were identified. The studies with the larger size and/ or better methodology were selected for critical appraisal. Khouri IF, Kantarjian HM, Talpaz M, et al. Results of high dose chemotherapy and unpurged autologous stem cell transplantation in 73 patients with chronic myelogenous leukemia. The MD Anderson experience. *Bone marrow transplantation* 1996; 17:1775-779. See Evidence Table McGlave PB, De Fabritis P, Deisseroth A, et al. Autologous transplants chronic myeloid leukemia: results from eight transplant groups. *Lancet* 1994; 34:1486-1488. See Evidence Table Singer IO, Franklin IM, Clark RE, et al. Autologous transplantation in chronic myeloid leukemia using peripheral blood stem cells. *British Journal of Haematology* 1998; 102:1359-1362. See Evidence Table

The use of autologous SCT/BMT in the treatment of CML does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

High Dose Chemotherapy with Autologous Stem Cell Rescue for Treating Multiple Sclerosis
BACKGROUND
Multiple Sclerosis (MS) is a progressive debilitating neurological disorder with a relapsing and remitting course of symptoms including tremor. MS is caused by a progressive and selective destruction of myelin that is thought to occur as a result of an autoimmune reaction. It is typically treated with anti-inflammatory and immunosuppressive agents such as high-dose steroids, cyclophosphamide and as a last resort, beta-interferon. The symptomatic improvement seen following immune suppression led investigators to propose treating MS by destroying the immune system with high dose chemotherapy and then restoring immune function by replacement of the patients own stem cells. Patient's stem cells are mobilized by administering cyclophosphamide and then harvested for later reinfusion. High doses of chemotherapeutic agents are then used to destroy the patient's immune system. The previously harvested stem cells are then re-infused and, in most cases, restore normal immunologic function.

8/11/1999: MTAC REVIEW
High Dose Chemotherapy with Autologous Stem Cell Rescue for Treating Multiple Sclerosis
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1995-1999 using terms multiple sclerosis, hematopoietic stem cell transplant, stem cells, and transplantation. The author of the largest case series was contacted to ascertain if there were any studies published which had not been previously identified.
Articles: The best, published scientific evidence consists of a case series of 15 patients with a history of progressive MS for a median of 6 yrs and severe disability. Most of the patients were observed for only a few months after treatment; only 3 of the 15 patients were followed for a year or more. Six months after treatment, 3 of 13 patients had improved by at least 1.5 points on the Kurtzke Disability Status Scale (0=normal to 10=death from MS) and 1 patient had worsened by 1 point. The mean improvement was less than 1 point at 6 months. Using the Scripps Neurological Rating Scale (0-100) eight of 13 patients improved by 20 points or more at 6 months. The mean improvement was 22.5 points at 6 months. Transplant-related complications included sepsis and anaphylactic shock. This case series does not prove that high dose chemotherapy with stem cell rescue is an effective treatment for MS. Because some patients who carry the diagnosis of progressive MS may experience neurologic improvement without treatment, one cannot be certain that the clinical improvement documented in

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this study was the result of the therapeutic intervention. Fassas A, et al. Peripheral blood stem cell transplantation in the treatment of progressive multiple sclerosis: first results of a pilot study. *Bone Marrow Transplantation* 1997; 20:631-8 See Evidence Table

The use of stem cell transplantation in the treatment of multiple sclerosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

High-Dose Chemotherapy with Stem Cell Transplant for Breast Cancer

BACKGROUND

The success of high-dose chemotherapy (HDC) for some hematologic cancers stimulated hope that high doses might also improve survival for patients with metastatic breast cancer. The usual approach for the use of high-dose chemotherapy in breast cancer treatment involves the delivery of maximally tolerable doses of a combination of chemotherapy drugs supported by autologous stem or bone marrow cells. In the last 10 years, dozens of phase I and II studies have been reported. There is agreement that HDC is highly toxic, with treatment-related mortality rates in the range of 5% to 30%. There has been serious disagreement, however, about whether existing evidence establishes that the treatment is effective in improving survival and whether the benefits, if they exist, outweigh the harms. The strongest "evidence" of the efficacy of this treatment came from the work of a South African researcher, Dr. Bezwoda. He recently admitted falsifying data in a randomized controlled trial (RCT) in which he had reported that HDC, done in conjunction with bone marrow transplantation, prolonged the lives of some women with advanced breast cancer. None of the other peer-reviewed RCTs have shown a statistically significant advantage for HDC with stem-cell support over conventional chemotherapy. The current Kaiser Permanente clinical indications include using high-dose chemotherapy for breast cancer treatment. The purpose of this review is to critically appraise the existing literature in order to evaluate the efficacy of this treatment regimen.

6/14/2000: MTAC REVIEW

High-Dose Chemotherapy with Stem Cell Transplant for Breast Cancer

Evidence Conclusion: A critical appraisal of the existing evidence strongly suggests that high-dose chemotherapy with stem or bone marrow cell support is not beneficial in breast cancer treatment. Studies that have shown some benefit, even in a subset of patients, have numerous threats to validity, including selection bias, small sample sizes, and confounding. Furthermore, the procedure is associated with significant morbidity and mortality, a high rate of relapse, and potentially irreversible long-term effects. The available evidence therefore does not permit conclusions about the effectiveness of this treatment. The final results of large, multi-center, randomized trials may help determine the role of HDC in the management of breast cancer.

Articles: Articles were selected based on study type. There were four randomized controlled trials (RCTs) comparing HDC with "standard treatment" as well as several prospective studies, and meta-analyses. Since the results from the randomized trials were essentially similar (except for studies by Dr. Bezwoda), evidence tables were created for one randomized controlled trial and one prospective phase II trial– 1 each with favorable and unfavorable findings (attached). Reviews, editorials, and comments were reviewed, but no evidence tables were created. *The articles (RCT) selected for critical appraisal include* Nieto et al. Phase II trial of high-dose chemotherapy with autologous stem cell transplant for Stage IV Breast Cancer with Minimal Metastatic Disease. Clinical Cancer Research 1999 July; 5:1731-1737. See Evidence Table Staudmauer et al. Conventional-dose chemotherapy compared with high-dose chemotherapy plus autologous hematopoietic stem-cell transplantation for metastatic breast cancer. NEJM 2000; 342:1069-76. See Evidence Table

The use of high-dose chemotherapy followed by stem-cell transplant treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* (fails criteria 2).

Multiple Myeloma

BACKGROUND

Multiple myeloma (MM) is a plasma cell neoplasm that accounts for almost 10% of hematologic malignancies, and about 1% of all cancer related deaths. There are approximately 50,000 patients with MM in the United States, and it is estimated that there are more than 15,000 new cases per year. The median age at onset is 66 years, and only 2% of patients are younger than 40 years at diagnosis. Their median survival is around 3 years, but some patients can live longer than 10 years (Hari 2006, Terpos 2005, Levy 2005, Rajkumar 2005). High dose chemotherapy (HDT) with autologous stem cell transplant (ASCT) is regarded as the standard of care for newly diagnosed myeloma in patients less than 65 years of age. This can prolong remission duration, progression free survival, and overall survival in a significant proportion of patients. However, the therapy is not curative, and survivors eventually experience relapse or progression of the disease. Only a few patients who undergo the procedure are free of the disease for more than 10 years. Recurrences are primarily due to the failure of

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chemotherapy to eradicate all myeloma cells. Once relapse has occurred, survival is limited despite the use of novel drugs and salvage regimens (Terpos 2005, Hari 2006, Gerull 2005, Bruno 2007). Researchers have found that allogenic hematopoietic cell transplantation, following high dose conditioning may lead to lower relapse rates and longer remissions, and possibly cure of MM. This is presumably due to the graft versus myeloma effects, in addition to the advantage of a tumor-free graft. However, only a small percentage of patients are candidates for allogenic transplants because of age, availability of an HLA-matched sibling donor, and adequate organ function. Conventional allogenic transplantation is also limited by the high transplant-related morbidity and mortality associated with myeloablative conditioning regimens, and graft versus host disease (GVHD). The risk of treatment-related mortality (TRM) could be as high as 30-60% (Bruno 2007, Gerull 2005). Reduced intensity (non-myeloablative) conditioning was thus developed to decrease toxicity and treatment related mortality while maintaining the graft versus tumor effect. However, relapses are frequent when non-myeloablative allogenic transplantation is used in patients with a relapsed or refractory disease (Harousseau 2005). In the past few years, researchers have been studying the efficacy and feasibility of performing non-myeloablative allogenic transplantation after one or two procedures of high dose therapy and ASCT. This concept combines the advantage of cytoreduction achieved with the high-dose autologous transplant with the graft versus myeloma effect of the non-myeloablative allogenic transplant in order to eradicate the minimal residual disease with a goal of long-term disease control, and hopefully cure of MM (Maloney 2003, Hari 2006).

04/10/2002: MTAC REVIEW
Multiple Myeloma
Evidence Conclusion: The case series reviewed do not provide sufficient evidence to determine the efficacy and outcome of mini stem cell transplantation, for multiple myeloma. In addition to the small sample size of the study reviewed, and the relatively short follow-up, case series provide the lowest grade of evidence; they lack a control or comparison group and are prone to selection bias, and confounding.
The search yielded 59 articles. Articles were selected based on study type. Most of the articles were reviews, opinion pieces, editorials, letters, and commentaries. The literature did not reveal any randomized controlled trials, or meta-analyses. There was only one case series on MM patients who had mini-stem transplantation.
Articles: *The following article was critically appraised:* Badros A, et al. High response rate in refractory and poor-risk multiple myeloma after transplantation using a nonmyeloablative conditioning regimen and donor lymphocyte infusions. *Blood* 2001; 97:2574-9. See Evidence Table

The use of mini stem cell transplant in the treatment of multiple myeloma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/05/2005: MTAC REVIEW
Multiple Myeloma
Evidence Conclusion: Gerull and colleagues (2005) reported the outcomes of 52 MM patients who received non-myeloablative allogenic transplantation between September 1999 and June 2003, at the University of Heidelberg, Germany. The ages of the patients ranged from 36 to 68 years, and they were followed up for a median of 567 days, (479 days for survivors). At the time of analysis only 24 patients (46%) were alive. The results show that the estimated overall survival at 18 months was 41%, and the estimate progression free survival also at 18 months was 29.4%. 38% developed GVDH grade II-IV, and 70% developed chronic GVHD. This study only presents an analysis of a retrospective data of a heterogeneous group of patients treated at one center, followed up for a relatively short time, and the treatment was not compared to an alternative therapy or no treatment.
Articles: Compiled data in Djulbegovic's systematic review on 103 patients with MM show complete response rate of 37%, acute GVHD among 59%, and chronic GVHD among 18% of the patients.
Gerull S, Goerner M, Benner A, et al. Long-term outcome of nonmyeloablative allogenic transplantation in patients with high –risk multiple myeloma Bone Marrow Transplant 2005;doi: 10.1038/sj.bmt.1705161 See Evidence Table

The use of non-myeloablative stem cell transplantation (mini-stem cell transplantation) in the treatment of hematologic malignancies, acute myeloid leukemia, myelodysplastic syndrome, multiple myeloma, lymphomas, renal cell carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/06/2007: MTAC REVIEW
Multiple Myeloma
Evidence Conclusion: To date, there is no high-quality evidence on the safety and efficacy of mini stem cell transplantation with a preceding autologous hematopoietic cell transplantation for the treatment of multiple myeloma. There are no published randomized controlled trials that compare allografting with non-myeloablative
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conditioning following a cytoreductive autograft to double (tandem) autologous stem cell transplantation, or to an alternative therapy. The best published evidence to date consists of one nonrandomized controlled trial (Bruno 2007) and another study that compared two series of patients (Garban 2006). Bruno and colleagues' study (2007) recruited 245 patients < 65 years old with stage II or III multiple myeloma, from five centers in Italy. 199 of the participants had at least one sibling, and only 104 received treatment. The patients were not randomized to the treatment groups. Those with an HLA-identical sibling (n=58, 56%) received a myeloablative autograft followed by a nonmyeloablative allograft transplantation, and patients without an HLA identical sibling (n=46, 44%) received two consecutive myeloablative doses conditioning, each followed by an autologous stem cell transplant. The primary endpoints of the study were overall survival and event-free survival. After a median follow-up of 45 months, the overall survival and event free survival were significantly longer in patients who completed the autograft-allograft treatment versus those who completed the high-dose, double autograft treatment. The results of the study also show that there was no significant difference between the two groups in the treatment related deaths, but the autograft-allograft transplantation was associated with high rates of acute and chronic GVHD (43% and 64% respectively). Thechronic GVHD was extensive among 36% of the patients in that treatment group. Garban and colleagues (2006) compared the results of two multicenter trials (IFM99-03 and IFM99-04). The studies recruited patients <65 years old with newly diagnosed MM, and with two adverse prognostic factors. After 3-4 cycles of induction regimens, the participants received their first ASCT. Then, according to the availability of an HLA-identical sibling, they either received an allograft with a nonmyeloablative conditioning (IFM99-03 trial) or a second allograft with or without anti-IL-6 monoclonal antibody (IFM99-04 trial). After a relatively short follow-up period (median 24 months) the authors compared the outcomes from both studies. The results showed no significant difference between the two strategies in terms of overall survival or event free survival. Patients were not randomized to one of the two transplantation protocols, and the study was not powered to detect any significant difference between these two treatments. The two studies have their limitations, and it is hard to compare their results because different regimens were used for conditioning, and different intensities of immune suppression drugs were used. Moreover, the participants in Garban's study had a high-risk myeloma unlike those in Bruno's study who were at intermediate or good risk. Large randomized controlled trials would provide higher quality evidence the efficacy and safety of allografting with nonmyeloablative conditioning following a cytoreductive autograft, to other alternative therapies e.g. the tandem autograft used in these non-randomized studies.
Articles: The search yielded around 140 articles. Several were not related to the current review, and many others were review articles. There were two nonrandomized studies with comparison groups, and several prospective and retrospective case series. The two trials with comparison groups were selected for critical appraisal.
Bruno B, Rotta M, Patriarca F, et al. A comparison of allografting with autografting for newly diagnosed myeloma. NEJM 2007; 356:1110-1120. See Evidence Table. Garban F, Attal M, Michallet M, et al. Prospective comparison of autologous stem cell transplantation followed by dose-related allograft (IFM99-03 trial) with tandem autologous stem cell transplantation (IFM99-04 trial) in high risk de novo multiple myeloma. Blood 2006; 107:3474-3480 See Evidence Table.

The use of mini stem cell transplant in the treatment of multiple myeloma meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

Nonablative SCT for Renal Cell Carcinoma and Melanoma

BACKGROUND
Considerable morbidity and mortality are consequences of the myeloablative chemoradiotherapy utilized in conventional allogenic marrow transplantation. This has generally restricted such potentially curative treatment to patients <50-55 years with normal organ function. Recent studies indicate that purine-analogue based non-myeloablative regimens are sufficiently immunosuppressive to facilitate allogeneic donor cell engraftment. Non-ablative (non-myeloblative) bone marrow transplantation involves engrafting an HLA-matched donor's marrow into a host to obtain a graft versus tumor effect. Engraftment is done with just immunosuppressive therapy (not high dose chemotherapy) initially and then is stopped. This procedure is not FDA-approved, but Dr. Feldman states that FDA approval is not necessary.

10/11/2000: MTAC REVIEW
Nonablative SCT for Renal Cell Carcinoma and Melanoma
Evidence Conclusion: Given the limitations of the studies presented (small sample sizes, potential selection bias, and possible toxicity associated with the procedure) there is insufficient evidence at this time to determine the efficacy of non-myeloblative allogeneic peripheral-blood stem-cell transplantation. As stated by one of the investigators "non-myeloblative allogeneic peripheral-blood stem-cell transplantation should remain an investigational approach for the treatment of metastatic renal-cell carcinoma.

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Articles: Articles were selected based on study type. There was one prospective study and one case series. Evidence tables were created for these 2 studies (attached). Review articles and commentaries were reviewed, but no evidence tables were created. *The articles selected for critical appraisal include* Childs et al. Regression of metastatic renal-cell carcinoma after non-myeloblative allogeneic peripheral-blood stem-cell transplantation. NEJM 2000; 343: 750-758. See Evidence Table Grigg et al. "Mini-allografts" for hematological malignancies: an alternative to conventional myeloblative marrow transplantation. Aust NZ J Med 1999; 29:308-314. See Evidence Table

The use of Non-ablative Stem Cell Transplantation for Melanoma and Renal Cell Carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* (fails criteria 2 for effectiveness).

12/05/2005: MTAC REVIEW
Nonablative SCT for Renal Cell Carcinoma and Melanoma
Evidence Conclusion: Peccatori and colleagues (2005), analyzed data from 70 patients who received reduced intensity stem cell transplantation for advanced renal cell carcinoma in nine European transplant centers from 1999 to 2003. The authors selected ten variables and entered them in a univariate analysis. Those significantly correlated with survival were entered in a multivariate regression analysis, which suggested three prognostic parameters according to which the authors categorized the study patients as high or low risk groups. After a median follow-up of ten months the median survival (according to Kaplan Meier estimates) was 23 months for the low-risk group, and 3.5 months for the high-risk group. The study population was a highly selected group of patients, and the therapy was not compared to an alternative strategy or to no treatment.
Articles: Peccatori J, Barkholt, Demirer, et al. Prognostic factors for survival in patients with advanced renal cell carcinoma undergoing nonmyeloablative allogenic stem cell transplantation. Cancer 2005; 104:2099-2103. See Evidence Table

The use of nonmyeloablative stem cell transplantation (mini-stem cell transplantation) in the treatment of hematologic malignancies, acute myeloid leukemia, myelodysplastic syndrome, multiple myeloma, lymphomas, and renal cell carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Non-Myeloablative Stem Cell/Bone Marrow Transplant (Mini Transplant)

BACKGROUND

Myeloablative combination of high-dose chemo-radiotherapy followed by allogenic hematopoietic stem-cell transplantation (HSCT) is an effective treatment for various hematological malignancies resistant to conventional doses of chemotherapy. Conventional allogenic HSCT involves the use of maximally tolerated myeloablative chemotherapy and/or radiotherapy conditioning regimens to eradicate the underlying disease, while the allograft serves to rescue patients from marrow aplasia induced by the treatment (Georges 2002). However, high-dose chemo/radiotherapy with allogenic HSCT is associated with significant morbidity and mortality due to toxicity of the preparative regimen, the accompanying immunodeficiency, and graft versus host disease (GVHD). The associated toxicity and mortality have limited the use of allogenic HSCT to young medically fit patients. Many patients who may potentially benefit from the treatment are not eligible for the procedure due to age, co-morbid illnesses, poor organ function, or extensive previous chemotherapy. Several hematologic malignancies e.g. acute myelogenous leukemia, chronic myelogenous leukemia, and myeloblastic syndromes peak in the seventh decade of life, which limits the options for these older patients to palliative chemotherapy (Burroughs 2004). There are indications that the main therapeutic effect of allogenic HSCT may not be solely due to the physical elimination of all tumor cells by the high doses of conditioning regimen, but also to T-cell-mediated graft-versus tumor (GVT) or graft versus leukemia (GVL) effect. Researchers also found that donor lymphocyte infusions (DLIs) can re-induce remissions in patients who have relapsed following allogenic transplantation. This has led to the exploration of non-myeloablative allogenic stem cell transplantation (NST) as a safer alternative to conventional high-dose transplant regimens, and as a means to exploit the GVD effect to cure malignancies with elimination of the need for hazardous conditioning. Conditioning regimens are referred to as non-myeloablative if they are not given at a dose that will result in permanent marrow aplasia i.e. will not completely eradicate host hematopoiesis and immunity. They have a potent immunosuppressive effect but are only mildly myelodepressive and commonly result in induction of mixed chimerism (Shimoni, 2002). A truly nonmyeloablative regimen is defined as a regimen that allows relatively prompt hematopoietic recovery (in less than 28 days) without a transplant and upon engraftment mixed chimerism should occur (Khouri, 2004). Clinical data indicate that NST lowers the incidence and severity of GVHD which is main cause of treatment related mortality. NST regimens were originally designed for older patients or any patient ineligible for standard conditioning due to other co-morbidities or risks. Now, they may also be considered for patients where high-dose chemo/radiotherapy is unnecessary. Reduced intensity regimens usually consist of purine analogues e.g. fludarabine combined with alkylating agents such as busulfan, or cyclophosphamide. A second approach which is nonablative, consists of 2 Gy total body irradiation either alone

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or combination with fludarabine. Mini stem cell transplant was reviewed by MTAC on 4/10/2002, and 6/11/2003 and did not pass MTAC criteria. They study reviewed were all small case series with short follow-up and no control or comparison groups.

06/11/2003: MTAC REVIEW
Non-Myeloablative Stem Cell/Bone Marrow Transplant (Mini Transplant)
Evidence Conclusion: There is insufficient published literature to provide evidence on the use of non-myeloablative stem cell/bone marrow transplant for cervical cancer, myeloproliferative disease, HIV patients, severe combined immunodeficiency, Wiskott-Aldrich syndrome, amyloidosis, or other metabolic disorders. There is also insufficient evidence to determine the efficacy and outcome of mini stem cell/ bone marrow transplantation in treating hematological diseases. In addition to the small sample sizes of the series reviewed, and the relatively short follow-up duration, case series provide the lowest grade of evidence; they lack a control or comparison group and are prone to selection and observation bias.
Articles: The search yielded almost 600 articles. The majority were reviews, opinion pieces, or dealt with the technical aspects of the procedure. The literature search did not reveal any randomized controlled trials, or non-randomized comparative studies. All were small case series or case reports with small sample sizes. The search did not reveal any studies or reports on non-myeloablative transplantation for cervical cancer, amyloidosis, or other metabolic disorders. There were very few case reports with 1-8 patients each on PNP deficiency, Wiskott-Aldrich syndrome, ADA severe combined immunodeficiency, DiGeorge syndrome, and HIV infection. The search also revealed a series of 50 patients with Fanconi's anemia conditioned with a non-myeloablative regimen before the transplantation, and with six years of follow-up. Most of the series published were on leukemias, lymphomas, and multiple myeloma (MM). Mini transplant for MM was reviewed by the committee in 4/10/2002 and did not pass MTAC criteria. The case series on the individual leukemias and lymphomas were too small. The two largest series that included older patients and/or patients with other co-morbid conditions, with a variety of hematological diseases were selected for critical appraisal, as well as the series on Fanconi's anemia. *The following articles were critically appraised:* McSweeney PA, Niederwieser D, Shizuru JA, et al. Hematopoietic cell transplantation in older patients with hematologic malignancies: replacing high-dose toxic therapy with graft-versus-tumor effects. *Blood* 2001; 97:3390-3400. See Evidence Table Niederwieser D, Maris M, Shizuru JA, et al. Low-dose total body irradiation (TBI) and Fludarabine followed by hematopoietic cell transplantation (HCT) from HLA-matched or mismatched unrelated donors and postgrafting immunosuppression with cyclosporine and mycophenolate mofetil (MMF) can induce durable complete chimerism and sustained remissions in patients with hematological diseases. *Blood* 2001; 101:1620-1629. See Evidence Table Socie G, Devergie A, Girinski T, et al. Transplantation for Fanconi's anemia: long-term follow-up of fifty patients transplanted from a sibling donor after low-dose cyclophosphamide and thoraco-abdominal irradiation for conditioning. *British Journal of Hematology* 1998; 103:249-255. See Evidence Table

The use of non-myeloablative stem cell/bone marrow transplant in the treatment of cervical cancer, myeloproliferative disease, HIV patients, severe combined immunodeficiency, Wiskott-Aldrich syndrome, amyloidosis, or other metabolic disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/05/2005: MTAC REVIEW
Non-Myeloablative Stem Cell/Bone Marrow Transplant (Mini Transplant)
Evidence Conclusion: Hematological malignancies Djulbegovic and colleagues' systematic review included 25 case series with a total of 603 patients with a wide range of hematologic malignancies. Only 4 studies included more than 10 patients with the same malignancy. The authors compiled some extractable data from the heterogeneous studies included, but apparently, they did not use standard meta-analysis techniques. The studies had different inclusion/exclusion criteria, used different conditioning, treatment, and immunosuppression regimens, and the patients had variable co-morbid conditions. The authors did not discuss any evaluation of the quality of the studies, or how they pooled the data. The results of the compiled data showed that 44% of the patients had complete response to the treatment, and that 51% developed acute GVHD, and 23% developed chronic GVHD. Some analyses were done for specific diseases. Three recent studies (Alyea 2005, Sorror 2004, and Diaconescu 2004) compared the outcomes of transplantations after nonablative and ablative regimens in different centers in the US. They were not randomized rather retrospective analysis of cohorts of patients selected to receive the nonablative conditioning regimens, and matched controls conditioned with myeloablative regimens. The results of these analyses showed that patients who received the nonablative conditioning had lower transplant related mortality, nonrelapse mortality rates, and experienced less or comparable grade II to IV toxicities despite the fact that they were older, had more advanced diseases, and more co-morbidities. The three studies had specific questions, defined inclusion/exclusion criteria, and comparison groups, yet they were only observational, and subject to bias and confounding. Randomization would have been ideal but is not an option as
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patients conditioned with nonablative regimen are not candidates for the standard ablative conditioning. Specific hematologic diseases: AML Sayer et al's article (2003) reported on 113 patients with AML treated at ten German transplant centers between February 1998 and December 2000, using reduced intensity conditioning regimens. Their ages ranged from 16-67 years, and the survivors had a median follow-up of 12 months (range 46-937 days). The authors analyzed the outcomes of this retrospective series of patients and did not include a control group. There were multiple baseline variations in the patient and disease characteristics, and according to the authors, inclusion criteria differed between centers, with no clear or accurate definition for who is or is not eligible for the standard conditioning regimen. The results of the analysis show that the estimated 2-year overall survival, and event free survival after the procedure were 32% and 29% respectively. The rate of acute GVHD grades II-IV was 42%, and that of chronic GVHD was 32.7%. The latter was extensive among 6.5% of the patients. The compiled data in Djulbegovic's systematic review (N=62) showed a 66% complete response rate, 36% acute GVHD, and 23% chronic GVHD. AML/MDS De Lima and colleagues (2004) compared the outcomes of 94 patients with AML or MDS treated with either a reduced intensity or a nonablative conditioning regimen. The average ages were 61 and 54 years in the two regimens respectively, and the median duration of the follow-up was 40 months. It was a retrospective analysis and there were several baseline variations in the patients' and disease characteristics among the recipients of the two regimens, as well as some variations in the source of transplant received. The analysis had the advantage of comparing two regimens but the disadvantage of non-randomization, which is a potential source of selection bias. The regimens were not compared to the conventional ablative regimen. Overall, the results of the study indicate a 3-year actuarial progressive free survival rate of 34%, and overall survival of 27% with no statistically significant difference between the two groups. The rate of acute GVHD grade II-IV was 36%, and that of chronic GVHD was 34% for all patients. Ho and colleagues (2004) presented the results of 62 patients who received a reduced intensity allogenic hematopoietic stem cell transplant for MDS, and AML with multilineage dysplasia, in one center in UK. The donors were either siblings or unrelated volunteers. The ages of the patients ranged from 5-60 years with a median of 53 years, and they were followed up for a median of 348 days (range 37-1,495 days). The overall survival was 89% at 100 days, 80% at 200 days, and 74% at one year. The corresponding disease-free survival rates were 84%, 67% and 62% respectively, and the nonrelapse mortality at one year was 15%. None of the related recipients, and 9% of the unrelated recipients developed acute GVHD. Extensive chronic GVHD developed in only 3% of the population. The nonmyeloablative transplantation was not compared to any other therapeutic strategy, or to no treatment. Multiple myeloma Gerull and colleagues (2005) reported the outcomes of 52 MM patients who received nonmyeloablative allogenic transplantation between September 1999 and June 2003, at the University of Heidelberg, Germany. The ages of the patients ranged from 36 to 68 years, and they were followed up for a median of 567 days, (479 days for survivors). At the time of analysis only 24 patients (46%) were alive. The results show that the estimated overall survival at 18 months was 41%, and the estimate progression free survival also at 18 months was 29.4%. 38% developed GVDH grade II-IV, and 70% developed chronic GVHD. This study only presents an analysis of a retrospective data of a heterogeneous group of patients treated at one center, followed up for a relatively short time, and the treatment was not compared to an alternative therapy or no treatment. Compiled data in Djulbegovic's systematic review on 103 patients with MM show complete response rate of 37%, acute GVHD among 59%, and chronic GVHD among 18% of the patients. NHL Khouri and colleagues (2004) reported on the results of a prospective cohort of patients treated with nonmyeloablative stem cell transplantation for advanced recurrent NHL after a prior response to conventional treatment study, in one center in Texas. Their ages ranged from 21 –68 years with a median of 55 years. 20 (41%) patients dad follicular lymphoma, 15 (31%) had transformed or de novo diffuse large cell lymphoma, and 14 (28%) had mantle cell lymphoma. All had received a prior treatment with a range of 1-4 chemotherapy regimens (median 4), and 17% had failed a previous autologous transplant. The results of the analysis show that hematopoietic recovery occurred within 25 days (median 11 days), 22% had a persistent or progressive disease after transplantation, 20% developed acute GVHD, and 36% developed chronic extensive GVHD. 2% of the patients died within 100 days and 6% after 100 days. The study was small, with potential biases, and no comparison group. Compiled data from Djulbegovic's systematic review on patients with NHL (N=103) show complete response rate of 31%, acute GVHD among 50%, and chronic GVHD among 12% of the patients. Renal cell carcinoma: Peccatori and colleagues (2005), analyzed data from 70 patients who received reduced intensity stem cell transplantation for advanced renal cell carcinoma in nine European transplant centers from 1999 to 2003. The authors selected ten variables and entered them in a univariate analysis. Those significantly correlated with survival were entered in a multivariate regression analysis, which suggested three prognostic parameters according to which the authors categorized the study patients as high or low risk groups. After a median follow-up of ten months the median survival (according to Kaplan Meier estimates) was 23 months for the low-risk group, and 3.5 months for the high-risk group. The study population was a highly selected group of patients, and the therapy was not compared to an alternative strategy or to no treatment. Conclusion: The results of the published studies do not provide strong evidence on the efficacy of nonmyeloablative stem cell transplants in improving the net health outcomes of patients with hematopoietic malignancies. The studies were all observational case series with different selection criteria. Those with comparison groups were retrospective and
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Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

nonrandomized. There were significant differences in patients' characteristics, disease characteristics and stages, and other co-morbid conditions. Moreover, there was no clear or accurate definition for who is or is not eligible for the standard conditioning regimen. Multiple conditioning regimens, treatments, and GVHD prophylaxis regimens were used. Randomized controlled trials might not be an option among these patients who are not candidates for transplantation with the conventional conditioning regimens. Overall, the results of existing published studies, with their limitations, indicate good overall survival and disease-free survival rates, and reduced regimen-related toxicities with the nonmyeloablative stem cell transplantations despite the older age of the patients and presence of more co-morbid conditions and/or organ dysfunctions.
The search yielded more than 600 articles. The majority were reviews, opinion pieces, or dealt with the technical aspects of the procedure. The literature did not reveal any randomized controlled trials. One systematic review of case series was identified. Other published studies were small prospective or retrospective case series or case reports, and most lacked control groups. Most studies included patients with a wide range of hematologic malignancies, and only a few included cohorts of patients with a specific disease. Hematological malignancies: The search identified several case series with population sizes ranging from six patients to just over 100. There was one systematic review with some compiling of the results of smaller studies, and several other prospective and retrospective series. The systematic review, and the studies with comparison groups were selected for critical appraisal. *Specific disease results:* Acute myeloid leukemia and myelodysplastic syndrome (AML/ MDS)
The search revealed few studies on patients with AML or MDS. The series with comparison groups, large number of patients, and published in full text were reviewed.
Articles: The literature search for articles published on MM after the last review revealed a recent case series with 52 patients (Gerull 2005), and smaller series with less than 25 patients. Gerull's study was selected for critical appraisal. Lymphoma: Hodgkin's disease (HD) and Non-Hodgkin's lymphoma (NHL):
There were few small case series on either HD, and /or NHL. The largest series with 49 patients was selected for the review. Other hematopoietic diseases Studies on other hematologic conditions included small number of patients and were not critically appraised. Renal cell carcinoma (RCC): There were several reports on small case series (sizes ranging from 6-18) of patients with RCC treated with nonmyeloablative stem cell transplantation. Very recently a larger analysis of 70 patients with advanced RCC was published. The latter was critically reviewed. *The following articles were selected for critical appraisal:* Alyea EP, Kim HT, Ho V, et al. Comparative outcome of nonmyeloablative and myeloablative allogenic hematopoietic cell transplantation for patients older than 50 years of age. Blood 2005; 105:1810-1814. See Evidence Table Diaconescu R, Flowers CR, Storer B et al. Morbidity and mortality with nonmyeloablative compared with myeloablative conditioning before hematopoietic cell transplantation from HLA-matched related donors. Blood 2004; 104:1550-1558. See Evidence Table de Lima M, Anagnostopoulos A, Munsell M, et al. Nonablative versus reduced intensity conditioning regimens in the treatment of acute myeloid leukemia and high-risk myelodysplastic syndrome: dose is relevant for long-term disease control after allogenic hematopoietic stem cell transplantation. Blood 2004; 104:865-872. See Evidence Table Djulbegovic B, Seidenfeld J, Bonnel C, Kumar A. Nonmyeloablative allogenic stem-cell transplantation for hematologic malignancies. A systematic review. Cancer Control. 2003 10:17-41. See Evidence Table Gerull S, Goerner M, Benner A, et al. Long-term outcome of nonmyeloablative allogenic transplantation in patients with high –risk multiple myeloma Bone Marrow Transplant 2005;doi: 10.1038/sj.bmt.1705161 (advance online publication) See Evidence Table Ho AYL, Pagliuca A, Kenyon M, et al. Reduced intensity allogenic hematopoietic stem cell transplantation for myelodysplastic syndrome and acute myeloid leukemia with multilineage dysplasia using fludarabine, busulphan, and alemtuzumab (FBC) conditioning. Blood 2004; 104:1616-1623. See Evidence Table Khouri IF, and Champlin RE Nonmyeloablative stem cell transplantation for lymphoma. Seminars in Oncology 2004; 31:22-26. See Evidence Table Peccatori J, Barkholt, Demirer, et al. Prognostic factors for survival in patients with advanced renal cell carcinoma undergoing nonmyeloablative allogenic stem cell transplantation. Cancer 2005; 104:2099-2103. See Evidence Table Sorror ML, Maris MB, Storer B et al. Comparing morbidity and mortality of HLA-matched unrelated donor hematopoietic cell transplantation after nonmyeloablative and myeloablative conditioning: influence of pretransplantation comorbidities. Blood 2004; 104:961-968. See Evidence Table Sayer HG, Kroger M, Beyer J, et al. Reduced intensity conditioning for allogenic hematopoietic stem cell transplantation in patients with acute myeloid leukemia: disease status by marrow blasts is the strongest prognostic factor. Bone marrow transplant 2003; 31:1089-1095. See Evidence Table

The use of nonmyeloablative stem cell transplantation (mini-stem cell transplantation) in the treatment of hematologic malignancies, acute myeloid leukemia, myelodysplastic syndrome, Melanoma and Renal Cell Carcinoma, Multiple Myeloma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Scleroderma

BACKGROUND
Scleroderma is a rare multi-system autoimmune disease notable for a pathologic fibrotic thickening of the skin and abnormalities of the vasculature and visceral organs. It is progressive, debilitating, and often fatal. There is

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no cure and treatment usually involve anti-inflammatory and immunosuppressive agents such as high dose steroids. The symptomatic improvement seen following immune suppression led investigators to propose treatment of scleroderma by destroying the immune system with high-dose chemotherapy and then restoring immune function by infusing the patient's own stem cells. The patient's stem cells are mobilized by administering cyclophosphamide and then harvested for later reinfusion. High doses of chemotherapeutic agents are then used to destroy the patient's immune system. The previously harvested stem cells are then re-infused and, in most cases, restore normal immunologic function.

8/11/1999: MTAC REVIEW
Scleroderma
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1995-1999 using terms multiple sclerosis, hematopoietic stem cell transplant, stem cells, and transplantation. The author of the largest case series was contacted to ascertain if there were any studies published which had not been previously identified.
Articles: The best, published scientific evidence consists of a case series of 15 patients with a history of progressive MS for a median of 6 yrs. and severe disability. Most of the patients were observed for only a few months after treatment; only 3 of the 15 patients were followed for a year or more. Six months after treatment, 3 of 13 patients had improved by at least 1.5 points on the Kurtzke Disability Status Scale (0=normal to 10=death from MS) and 1 patient had worsened by 1 point. The mean improvement was less than 1 point at 6 months. Using the Scripps Neurological Rating Scale (0-100) eight of 13 patients improved by 20 points or more at 6 months. The mean improvement was 22.5 points at 6 months. Transplant-related complications included sepsis and anaphylactic shock. This case series does not prove that high dose chemotherapy with stem cell rescue is an effective treatment for MS. Because some patients who carry the diagnosis of progressive MS may experience neurologic improvement without treatment, one cannot be certain that the clinical improvement documented in this study was the result of the therapeutic intervention. Fassas A, et al. Peripheral blood stem cell transplantation in the treatment of progressive multiple sclerosis: first results of a pilot study. *Bone Marrow Transplantation* 1997; 20:631-8 See Evidence Table

The use of stem cell transplantation in the treatment of multiple sclerosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Stem Cell Transplantation for Amyloidosis
BACKGROUND
Amyloid is a protein that is made by plasma cells in bone marrow. There are several forms of amyloid; one form is lighter than the others. A disease called amyloidosis occurs when too much of the light form of amyloid is produced and the proteins are deposited in the body's organs and tissues. The most common form is primary (AL) amyloidosis that mainly affects the heart, lungs, skin, tongue, nerves and intestines. The accumulation of amyloid causes progressive disruption of the normal tissue structure and ultimately leads to organ failure. Signs and symptoms of amyloidosis are generally nonspecific and are seen in a small proportion of patients. Many patients have multi-system involvement at diagnosis. The natural history of amyloidosis is that it is fatal within 2 years in about 80% of patients. It is a rare condition, affecting approximately 3000 people in the United States per year (United Kingdom Myeloma Forum, 2004; Gertz & Rajkumar, 2002; Mayoclinic.com). The standard treatment for AL amyloidosis is oral melphalan. However, this has a clinical response rate of only about 20% and is not effective for rapidly progressive disease (Dispenzieri et al., 2004; Skinner et al., 2004). The use of high-dose intravenous melphalan, followed by autologous stem cell transplantation was first described in the literature in 1996. Stem cells are collected from the patient's bone marrow before high-dose chemotherapy is administered. Early case series found a substantially higher procedure-related mortality than for patients with multiple myeloma. There is also significant risk associated with stem cell mobilization in patients with AL amyloidosis. However, positive results have been reported in patients who survive the treatment. A United Kingdom guideline does not recommend high-dose chemotherapy and stem cell transplantation for patients with any of the following: over 70 years old, more than two organ systems involved, symptomatic cardiac neuropathy or autonomic neuropathy, dialysis-dependent renal failure or a history of GI bleeding due to amyloid (United Kingdom Myeloma Forum, 2004).The amyloid patients who are eligible for high-dose chemotherapy and stem cell transplantation are a highly select group. Researchers at the Mayo Clinic reviewed their records and found that fewer than 20% of their amyloidosis patients would have theoretically been eligible for the treatment. The researchers point out that, due to the better prognosis of this group compared to other amyloidosis patients, a randomized controlled trial or study with a matched control group is needed to determine efficacy (Gertz & Rajkumar, 2002).

10/13/2004: MTAC REVIEW
Stem Cell Transplantation for Amyloidosis

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Evidence Conclusion: There is evidence from a matched case-control study (Dispenzieri) that high-dose chemotherapy and autologous stem cell transplantation improves survival in patients with amyloidosis. Two-year survival in the Dispenzieri study was 70% in the cases and 40% in controls. Matching reduces but does not eliminate the potential for selection bias. The evidence is weaker than that provided by a randomized controlled trial which can control for group differences on unmeasured characteristics. There were no appropriate randomized controlled trials or other matched studies. Experts in amyloidosis have stressed the need for randomized or matched studies because of the better prognosis of patients with amyloidosis who are eligible for high-dose chemotherapy and stem cell transplantation. The Skinner study was a descriptive analysis of one institution's experience over 8 years. It did not match patients and is therefore subject to selection bias.
The searched yielded 112 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the treatment or addressed similar treatments or diseases. There was one randomized controlled trial. In the RCT, both groups received high-dose chemotherapy and stem cell transplantation, one initially and the other after two rounds of oral chemotherapy. Since there was no comparison to a different treatment, this study was not reviewed.
Articles: The best, most relevant, evidence was a matched case-control study comparing patients who did and did not receive high-dose chemotherapy and stem cell transplantation. This was critically appraised, along with the largest case series. *The two studies reviewed were:* Dispenzieri A, Kyle RA, Lacy MQ et al. Superior survival in primary systemic amyloidosis patients undergoing peripheral blood stem cell transplantation: a case-control study. *Blood* 2004; 103: 3960-3963. See Evidence Table Skinner M, Sanchorawala V, Seldin DC et al. High-dose melphalan and autologous stem-cell transplantation in patients with AL amyloidosis: An 8-year study. *Ann Intern Med* 2004; 140: 85-93. See Evidence Table

The use of stem cell transplantation in the treatment of amyloidosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Stem Cell Transplantation for Autoimmune Diseases

BACKGROUND
Autoimmune diseases (ADs) encompass a heterogeneous group of chronic systemic disorders with different genetic, environmental, and individual etiological factors, as well as different prognoses. They are highly prevalent, have a significant morbidity and mortality, and a considerable economic cost to the patients and the community. For most ADs the exact pathophysiology remains unclear and may vary from one disease to another. It is known however, that some immunogenic predisposition combined with environmental triggers is required to initiate most ADs (Gratwohl 2005, Tyndall 2005). Among the categories of autoimmune diseases are neurological disorders, rheumatological disorders, vasculitis, hematological immunocytopenias, gastrointestinal and others. Multiple sclerosis, systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis are the most commonly encountered ADs. Multiple sclerosis (MS) is a chronic inflammatory disease that affects the central nervous system. It is the most frequent cause of neurologic disability in young adults in Western countries. MS is thought to be an autoimmune disease, but there are other views for its origin. The disease causes gradual demyelination and axonal degeneration in the brain and spinal cord. The clinical course of MS is widely variable ranging from isolated episodes with no clinical significance to impaired mobility, disability, and reduction of life expectancy in more severe cases (Saccardi 2005). Several therapies have been utilized, but currently immunosuppression and immunomodulation are the only recognized forms of therapy. Systemic lupus erythematosus (SLE) is a chronic multisystem autoimmune disease that affects predominantly young women and may range from a relatively mild condition to a severe life-threatening disease involving major organs such as the kidney, brain, lung, or the hematopoietic system. Renal involvement is the most common severe manifestation; it occurs in 30-50% of patients and. and has a 9-25% rate of end-stage renal failure. Lupus has no cure, but in the majority of cases it is responsive to treatment with immunosuppression and steroids. It was reported that more than half of the patients have permanent organ damage, much of which is due to, or increased by corticosteroids (Petri 2006). The disease often pursues a relapsing or refractory course that results in poor quality of life and reduced survival (Jayne 2004). Systemic sclerosis (SSc) also known as scleroderma, is a clinically heterogeneous autoimmune disease characterized by excessive collagen deposits in the skin and internal organs. It was found that rapidly progressive SSc, both in the cutaneous and diffuse forms, has a 5-year survival rate of 20-80%, and a 10-year survival rate of 15-65% (Farge 2004). Various treatments were tried, but none has been proven effective in preventing disease progression or reversing fibrosis. Rheumatoid arthritis (RA) is a chronic systemic inflammatory autoimmune disease of undetermined etiology that affects about 1% of the population (Snowden 2004). It primarily involves the synovial membranes and articular structures of multiple joints leading to substantial pain, joint destruction, and loss of mobility. RA often affects extra-articular tissues throughout the body including the skin, blood vessels, muscles, heart, and lungs. It is a disorder for which there is no cure, and current treatment methods focus on relieving pain, reducing inflammation, slowing joint damage and improving function, and sense of well-being. Patients with severe diseases however may not be controlled by the conventional

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methods used. In general, immunosuppression and immunomodulation are the basic therapeutic strategies for autoimmune diseases and are usually successful. However, certain patients do not respond to these therapies, and require more toxic drugs to achieve or maintain remissions (Gratwohl A, 2005). The ability to use immunosuppressive or cytotoxic therapy over longer periods of time is limited due to infections, bone marrow toxicity, and secondary malignancy. In the last decade, hematopoietic stem cell transplantation (HSCT) after intense immunosuppression has been proposed as a possible strategy for the treatment of severe or refractory autoimmune diseases. HSCT is a short name for a complex multi-step treatment aimed at resetting the dysregulated immune system of patients with severe autoimmune diseases. Various protocols have been tried depending on the underlying disease and experience of the transplant centers. The majority were based on autologous HSCT which a 3-step procedure is involving collection of hemopoietic stem cells (HSCs), treating the patient with a conditioning regimen to eliminate self-reacting lymphocytes within the body, and finally re-infusion of the previously frozen autologous stem cells. The source of stem cells may be bone marrow, cord blood, or peripheral blood. Peripheral blood stem cells harvest contains more progenitor and mature lymphocytes and gives more rapid hematological and immunological reconstitution. It is also simpler to collect than bone marrow harvests, and do not require general anesthesia (Tyndall 2005). Once mobilized, the stem cells are harvested, manipulated, and may be cryopreserved. The conditioning regimens used are designed to specifically target the lymphocytes (lymphoablative regimens) or to destroy the entire hematopoietic bone marrow compartment (myeloablative regimen). However, the goal of autologous HSCT for AD is to generate new self-tolerant lymphocytes after elimination of self or autoreactive lymphocytes within the patient, rather than ablate and reconstitute the entire hematopoietic compartment (Burt 2006). A major difference between lymphoablative and myeloablative regimens is the use of total body irradiation. The latter may have deleterious effects among patients especially those with SSc as radiation can cause microvascular damage. After conditioning the patient, the graft is thawed and infused. Hematological reconstitution occurs in 10-12 days, and immunological reconstitution takes longer. HSCT for autoimmune diseases is still in its experimental stages, it has a learning curve, and some researchers are concerned that it might not be feasible, or too toxic in immunosuppressed patients with organ involvement from the underlying AD.

04/2/2007: MTAC REVIEW
Stem Cell Transplantation for Autoimmune Diseases
Evidence Conclusion: The use of hematopoietic stem cell transplantation in the treatment of severe refractory autoimmune diseases is still in the experimental phase. All published studies were case reports or small case series that assessed the feasibility, tolerance, and efficacy of the transplant for patients with ADs. None included a control or comparison group. These cases were registered in databases, the largest of which is The European Bone Marrow transplant/European league against Rheumatism (EBMT/EULAR) registry. Gratwohl, and colleagues (2005), analyzed the data recorded in the EBMT registry up to 2003. It included records for 473 patients treated in 110 transplant centers in 21 countries in Europe and Australia. This has the advantage of studying the efficacy and safety of the procedure in a larger series of patients but has several limitations including the variations between these centers in the eligibility criteria, patient characteristics, autoimmune disorders and stage of the disease, protocol and techniques of the transplant, and experience in performing the procedure as well as others. Moreover, the analysis did not include a control or comparison group that received an alternative or no treatment. The results of the analysis show that the overall treatment mortality was 7% and with large differences between the ADs (20% for immune thrombocytopenia, 14% for SLE, and 2% for rheumatoid arthritis). The results also show that the more aggressive conditioning regimen was statistically associated with slowing down of the disease progression but was also associated with a significantly higher treatment related mortality. In conclusion the published studies to date do not provide sufficient evidence to determine the efficacy and safety and long-term net health outcome of stem cell transplantation in the treatment of autoimmune diseases.
All studies on HSCT published to date are phase I-II clinical trials (only case series with no controls). Phase III RCTs are underway in US and Europe, and none has been completed and reported to date. The published reports are mostly on one or two individual cases or small case series that either included patients with a specific autoimmune disease or grouped patients with different ADs who underwent an autologous HSCT. The inclusion/exclusion criteria, patient characteristics, protocol, and technique of the procedure, as well as the population size and duration of follow-up varied between the trials. The population sizes of the case series ranged from as low as 8 patients with miscellaneous ADs in one study with 12 months of follow-up, to 50 patients with systemic lupus erythematosus who were followed up for a mean of 29 months. The majority of the published reports collected their data from databases and had overlapping population. The largest database is The European Bone Marrow transplant/European League Against Rheumatism (EBMT/EULAR) International Stem Cell Project database. Other databases for stem transplantation include the International Bone Marrow Transplantation (IBMTR) registry, and the Autologous Blood and Marrow Transplant Registry (ABMTR) in the US, the Sylvia Lawry Center, Munich, Germany database, and the International Autoimmune Diseases stem cell Database in Basel, Switzerland.
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Articles: There is insufficient literature on reduced intensity conditioning and allogenic HSCT. The article (Gratwohl 2005) that analyzed data on the efficacy and toxicity of HSCT recorded in the EBMT database was critically appraised. Gratwohl A, Bocelli-Tyndall C, Fassa A, et al. Autologous hematopoietic stem cell transplantation for autoimmune diseases. Bone Marrow Transplantation 2005; 35:869-879. See Evidence Table

The use of stem cell transplantation in the treatment of autoimmune disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Allogeneic Bone Marrow Transplantation (BMT) in Low-Grade Lymphoma (LGL) and Chronic Lymphocytic Leukemia (CLL)

BACKGROUND

Low grade lymphomas (LGL) are indolent malignancies with a high rate of initial response to treatment and median survival duration of 7-10 years. Radiation therapy or the combination of radiation and chemotherapy can produce durable remissions in some patients with stage I, II, or III disease. Patients with an advanced, recurrent or refractory disease have a poor prognosis. The use of myeloablative therapy and autologous BMT showed positive results among patients with recurrent disease, but not among those with an extensive bone marrow involvement or refractory disease. Allogenic BMT is viewed as an attractive option to treat younger patients with refractory or recurrent disease, with the idea that donor lymphoid cells can potentially mediate a graft versus lymphoma (GVL) effect and achieve a long-term disease control. Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in Europe and North America. Although it is generally considered a disease of the elderly, it is increasingly recognized in younger patients. CLL is characterized by the heterogeneity in clinical behavior and life expectancy for those affected by it. Treatment options for CLL are the use of steroids, alkylating agents, or observation. Bone marrow transplantation is not a standard therapy, but autologous and allogeneic transplants are increasingly being used. BMT which induces high remission rates, yet a small percentage of durable remissions, is an appealing treatment strategy for younger patients. The use of tumor free grafts constitutes an obvious advantage of allogeneic over autologous bone transplantation. The allogeneic transplantation, however, has considerable treatment-related complications and mortality, particularly graft-versus-host disease (GVHD) and infections. Other reasons for the infrequent use of allogeneic BMT are the frequent lack of a matched sibling donor and the higher cost of care. Many questions regarding patient selection, efficacy and outcome are still unresolved. Description: Before BMT, patients are conditioned with total body irradiation (TBI) containing regimens, which may also include cyclophosphamide. After the infusion of the bone marrow, immune suppression is generally used for GVHD. The bone marrow source is human leukocyte antigen (HLA) matched sibling, syngeneic donor, or HLA matched unrelated donor.

12/12/2001: MTAC REVIEW

Allogeneic Bone Marrow Transplantation (BMT) in Low-Grade Lymphoma (LGL) and Chronic Lymphocytic Leukemia (CLL)

Evidence Conclusion: The case series reviewed do not provide sufficient evidence to determine the efficacy and outcome of allogenic bone marrow transplantation, for low-grade lymphoma, and chronic lymphocytic leukemia. Case series provide the least grade of evidence; they lack a control or comparison group and are prone to selection bias, and confounding. The search yielded 161 articles. Articles were selected based on study type. Most of the articles were reviews, opinion pieces, editorials, letters, and commentaries.

Articles: The literature did not reveal any randomized controlled trials, or meta-analyses, only clinical reports and case series. Evidence tables were created for the following articles: van Besien, K; et al. Allogeneic bone marrow transplantation for low-grade lymphoma. Blood 1998; 92: 1832-6 See Evidence Table Toze CL, Shepherd JD, et al. Allogeneic bone marrow transplantation for low-grade lymphoma and chronic lymphocytic leukemia. Bone Marrow Transplantation 2000; 25: 605-612. See Evidence Table

The use of allogenic bone marrow transplantation in the treatment of low-grade lymphoma, and chronic lymphocytic leukemia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
38204	Management of recipient hematopoietic progenitor cell donor search and cell acquisition

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38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38242	Allogeneic lymphocyte infusions
S2140	Cord blood harvesting for transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and posttransplant care in the global definition

Stem Cell Storage (long-term) – Considered not medically necessary unless patient is scheduled for transplant

CPT® or HCPC Codes	Description
No specific codes for storage - often submitted as *86999 Unlisted transfusion medicine procedure*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
5/1996	05/04/2010 MDCRPC, 03/01/2011 MDCRPC, 01/03/2012MDCRPC, 11/06/2012MDCRPC ,09/03/2013MPC,07/01/2014MPC, 05/05/2015MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC , 10/02/2018MPC, 10/01/2019MPC , 10/06/2020MPC , 10/05/2021MPC , 10/04/2022MPC	10/17/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
02/06/2018	MPC approved criteria for Mesenchymal Stem Cell Therapy for orthopedic conditions
05/29/2018	Added coverage language for Medicare members to use Kaiser Permanente criteria for stem cell use for orthopedic conditions

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05/07/2019	MPC approved to adopt KP National Criteria for Bone & Marrow Transplant
03/03/2020	MPC approved the proposed changes from KP National Transplant Services.
06/18/2020	Removing CPT codes 30206 and 30207; adding CPT codes 38206 and 38207
04/06/2021	Per National Transplant Guidelines: 1.2 added “active”
12/16/2021	Added stem cell storage policy language to criteria.
01/10/2022	MPC approved the proposed changes from KP National Transplant Services. 60-day notice is not required.
10/17/2022	Updated applicable codes

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Clinical Review Criteria

Stereotactic Radiation (Radiosurgery/Focused Beam/Gamma Knife)

- CyberKnife Robotic Radiosurgery System
- Fractionated Stereotactic Radiotherapy
- Multiple Brain Metastatic Lesions (5 or more brain metastatic lesions)
- Stereotactic Body Radiation Therapy for Prostate Cancer

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	01/15/2021 Noridian retired Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151).These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34151 for determining medical necessity.
Local Coverage Article	None

For Non-Medicare Members

Effective Until 06/01/2023

Kaiser Permanente has elected to use the Stereotactic Radiosurgery (KP-0423) MCG* for medical necessity determinations for the following indications*: trigeminal neuralgia, arteriovenous malformation, essential tremor, glomus jugulare tumor, intracranial meningioma, pituitary adenoma, vestibular schwannoma, and tumors of the prostate. This list does not include all indications covered in the criteria. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Effective 06/01/2023

For Non-Medicare Members

Kaiser Permanente has elected to use the Stereotactic Radiosurgery (KP-0423 06012023) MCG* for medical necessity determinations for the following indications*: trigeminal neuralgia, arteriovenous malformation, essential tremor, glomus jugulare tumor, intracranial meningioma, pituitary adenoma, vestibular schwannoma, and tumors of the prostate. This list does not include all indications covered in the criteria. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

MCG*are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

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If requesting this service, please send the following documentation to support medical necessity:

- Most recent medical oncology notes
- Most recent radiation oncology notes
- Most recent imaging (i.e. CT/MRI)

Service	Criteria Used
▪ Multiple Brain Metastatic Lesions (5 or more brain metastatic lesions)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
▪ For solitary lung metastases (from any primary)	Send all cases to MD review and possible further radiation oncology consultation

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Radiosurgery can be defined as the stereotactic (precision) delivery of multiple cross-fired radiation beams to a point or volume within a configured space (Chang 2003). Stereotactic radiosurgery may also be described as a method to destroy targets using single high doses of focused ionizing radiation, administered using stereotactic guidance (Niranjan 2001). It is a combination of minimally invasive technologies administered by a multidisciplinary team consisting of surgeons, oncologists, medical physicists, and engineers.

Stereotactic radiosurgery (SRS) was originally designed to produce functional lesions in the brain. It then evolved to target benign tumors and vascular malformations in surgically inaccessible locations. These indications are continuously expanding with the rapidly evolving technology of radiosurgical systems. Currently it has become an alternative to microsurgery and conventional radiation therapy in the treatment of many lesions in the base of the skull. It is used for vascular, tumor, and functional brain surgery, including arteriovenous malformations, pituitary adenomas, acoustic neuromas, and meningiomas, as well as brain metastases. Radiosurgery was initially limited to the brain because of the requirement of a stereotactic frame attached to the skull to provide a coordinate system for tumor localization. Recent advances, however, allow radiosurgical treatment throughout the body without such frames.

A variety of methods have been developed to provide a reference system for the localization study to determine the target coordinates, including fixed frame and frameless systems, removable frame systems, and rigid masks.

Treatment can be repeated any number of times with equal precision as the target is calculated from the position of gold markers. Regardless of the number of sessions, these procedures consist of the following components:

- Head position stabilization (attachment of a frame or frameless)
- Imaging for localization (CT, MRI, or angiography, etc.)
- Computer assisted tumor localization
- Treatment planning – number of isocenters, number, placement and length of arcs, beam size and weight, etc.
- Isodose distributions, dosage prescription and calculation
- Setup and quality assurance testing
- Simulation of prescribed arcs or fixed portals
- Stereotactic intervention or treatment itself

Gamma knife, the prototype of stereotactic radiosurgery was first clinically used in 1967. It developed rapidly from the earlier A-units to B units, and in 1999 to Model C that has a robotic engineering. With the gamma knife, the patient's head is placed within a large metal collimator consisting of a dome-shaped shell with holes that transmit the radiation to the center point. A stereotactic frame is anchored to the skull with four screws that penetrate the outer table to position the head so that the desired target is at the center of the collimator. The use of the frame limited the use of the gamma knife to head lesions, and to patients who could tolerate the rigid frame fixation.

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Moreover, the use of fractionated treatments that extended for several days was impractical with the frame fixation (Giller 2005).

The CyberKnife is a recently developed frameless stereotactic system that consists of a modified linear accelerator mounted on a robotic arm that moves slowly around the patient. It delivers several beams of radiation at each of many stopping points while minimizing radiation exposure of surrounding tissue (Quinn 2001). Stereotactic precision is achieved without a rigid frame by means of two diagnostic x-ray cameras mounted in the CyberKnife vault and are used to acquire real-time images of the patient's internal anatomy during treatment. Any patient motion is detected by these images, and the information is used by the robot to compensate and keep the linear acceleration on target. Treatment time ranges from 45-60 minutes and can be given in one fraction, or several fractions with smaller doses given over several days, depending on the condition being treated and the size of the affected area.

The use of the CyberKnife for radiosurgery of organs other than the brain is more challenging and requires several technical refinements. When used for spinal lesions for example, it requires the placement of internal small 2-mm stainless steel screws in the spinal lamina adjacent to the target site as "fiducial markers" (Giller 2005).

Radiosurgery has its advantages as well as risks. It is non-invasive, and can treat poor surgical candidates, and tumors inaccessible to surgery, Moreover, it can safely deliver higher doses of radiation than those used in conventional radiotherapy, while sparing the surrounding tissues from the high levels of radiation. It can thus be more effective in treating radioresistant and recurrent tumors and may be used as a boost to conventional radiotherapy. On the other hand, it was reported that its efficacy is lower and risk of complications higher in larger tumors, or those that were previously treated with radiation. Another limitation is the sensitivity of the optic nerve and chiasma to radiosurgical doses. There is also the risk of radionecrosis which is a combination of cytotoxic and microvascular tissue injury within the treated field due to radiation. This may be delayed for months, asymptomatic, severe, and /or persistent (Giller 2005).

The CyberKnife was cleared by the FDA in October 2001for radiosurgery for lesions, tumors, and other conditions in any anatomical site.

Trigeminal neuralgia (tic douloureux) is a disorder of the fifth cranial (trigeminal) nerve that causes episodes of intense, stabbing pain (separated by pain-free periods) in the areas of the face where the branches of the nerve are distributed.

The general approach to treating this disorder is to begin treatment with pharmacological agents and to initiate surgical treatment if medical treatment fails. There are 3 categories of surgical options: 1) Percutaneous procedures (glycerol injection commonly used at GHC); 2) Microvascular decompression; 3) Focused beam radiosurgery (gamma knife, LINAC). According to the MRU, GHC patients currently referred for radiosurgery on a case-by-case basis).

In gamma knife radiosurgery, magnetic resonance imaging (MRI) is used to identify the trigeminal nerve root. Subsequently, a single 4-mm isocenter of radiation is delivered to the trigeminal nerve root (just posterior to the pons). The radiation dose is 70-90 Gy. No surgical incisions are made.

Evidence and Source Documents

Gamma Knife in the treatment of Trigeminal Neuralgia
CyberKnife Robotic Radiosurgery System
Gamma Knife in the treatment of five or more brain metastatic lesions
Stereotactic Body Radiation Therapy (SBRT) for Prostate Cancer

Medical Technology Assessment Committee (MTAC)

Gamma Knife in the treatment of Trigeminal Neuralgia

04/12/2000: MTAC REVIEW

Evidence Conclusion: Since this topic was last reviewed in 1997, there have been two moderately sized case series articles published examining gamma knife radiosurgery on trigeminal neuralgia. A substantial proportion of patients improved after treatment with low rates of adverse outcomes. Case series have numerous threats to validity and provide weak evidence. If patients with trigeminal neuralgia are known to uniformly experience unrelenting pain, however, the improvement reported in these papers is more suggestive of efficacy. Even in this

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situation, it is not known whether alternate treatments might be as or more effective than gamma knife radiosurgery. If pain episodes tend to occur infrequently, case series results are less impressive because many patients would likely have been in remission during the initial follow-up period.

Articles: Articles were selected based on study type. For gamma knife therapy, there were no randomized control trials or meta-analyses. Several case series were sub-sets of subsequent case series. The largest and most comprehensive case series that had not been previously reviewed for the 1997 CPC evaluation were selected for critical appraisal and evidence tables were created (Kondziolka, D, Perez, B, Flickinger, JC, Habeck, M, Lunsford, D. Gamma knife radiosurgery for trigeminal neuralgia. Arch Neurol 1998; 55: 1524-1528. Young, RF, Vermeulen, S, Posewitz, A. Gamma knife radiosurgery for the treatment of trigeminal neuralgia. Stereotact Funct Neurosurg 1998; 70 (suppl 1): 192-199). The search on LINAC did not yield any additional articles. One book chapter on LINAC was located. This reported on a case series with 10 patients and was not included in this review due to the small sample size. Young, RF, Vermeulen, S, Posewitz, A. Gamma knife radiosurgery for the treatment of trigeminal neuralgia. Stereotact Funct Neurosurg 1998; 70 (suppl 1): 192-199. See Evidence Table. Kondziolka, D, Perez, B, Flickinger, JC, Habeck, M, Lunsford, D. Gamma knife radiosurgery for trigeminal neuralgia. Arch Neurol 1998; 55: 1524-1528. See Evidence Table.

The use of Gamma Knife in the treatment of Trigeminal Neuralgia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

CyberKnife Robotic Radiosurgery System

06/05/2006: MTAC REVIEW

Evidence Conclusion: CyberKnife; There were no published meta-analyses or randomized controlled trials on the CyberKnife radiosurgery system. There were only case reports and small case series with no control or comparison groups. Case series have numerous threats to validity and provide the weakest grade of evidence, Chang, et al reported on their experience with radiosurgical treatment with the CyberKnife among 61 patients treated in their center at Stanford University over 3 years, and who had at least 36 months of follow-up. The treatment was not compared to an alternative therapy. Data were collected both prospectively and retrospectively, and the main outcome was the tumor response and hearing preservation. The authors did not discuss any inclusion/exclusion criteria, included a heterogeneous group of patients, and two fractionation regimens for the therapy were used. After 36 months of observation, the tumor size decreased among 48% of the patients, was stable among 50%, and increased in size in 2%. Ninety percent of those with those with measurable hearing maintained their hearing level after treatment. Gerszten and colleagues reported their experience with CyberKnife radiosurgery for spinal lesions among 115 patients with several variations in their baseline characteristics and indications for the treatment. It was also a case series with no control or comparison group and potential selection and observation biases. The median follow-up duration was 18 months, and the outcome was
improvement in pain, and tumor control. The results of the series indicate that 94% of the patients presenting with significant pain described an improvement in their pain using a 10-point scale after one month of the treatment. The condition did not progress among those who received the therapy as the primary treatment modality or those who had undergone previous surgery. In conclusion the published literature to date does not provide sufficient evidence to determine the efficacy of CyberKnife for stereotactic radiosurgery for lesions or tumors in various anatomical sites.

Articles: The search yielded 71 articles. There were no meta-analyses or randomized control trials on CyberKnife robotic surgery. There were several small case reports and series that dealt with the technology for the treatment of several lesions in different parts of the body including pituitary tumors, extracranial lesions, metastatic brain tumors, acoustic neuromas, trigeminal neuralgia, spinal lesions, lung, renal, and prostate cancer. Gerstzen et al, published two articles on the same series of patients. The largest and most comprehensive case series, and/or the series with long-term follow-up were selected for critical appraisal. Chang SD, Gibbs IC, Sakamoto GT. Staged stereotactic irradiation for acoustic neuromas. Neurosurgery. 2005; 56:1245-1263. See Evidence Table. Gerszten PC, Ozhasoglu C, Burton SA, et al. Evaluation of CyberKnife frameless real-time image-guided stereotactic radiosurgery for spinal lesions. Stereotact Funct Neurosurg. 2003; 81:84-89. See Evidence Table. Gerszten PC, Ozhasoglu C, Burton SA, et al. CyberKnife frameless stereotactic radiosurgery for spinal lesions: Clinical experience in 125 cases. Neurosurgery. 2004; 55:89-99. See Evidence Table.

The use of CyberKnife Robotic Radiosurgery System in the treatment of lesions, tumors, and other conditions in any anatomical site does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gamma Knife in the treatment of five or more brain metastatic lesions

02/09/2015: MTAC REVIEW

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Evidence Conclusion: To date, there is no direct evidence from randomized controlled trials to determine that stereotactic radiosurgery alone or in combination with WBRT for patients with more than 4 brain metastases leads to better or equivalent outcomes to those of WBRT as regards overall survival, local recurrence, need for salvage therapy, neurological functioning, quality of life, or other outcomes. The best published evidence consists of a recent large prospective observational study of patients with one to 10 brain metastases (Yamamato et al, 2014), two case-matched studies conducted by the same principal author and colleagues, that compared SRS treatment results for patients with 1-4 versus ≥ 5 tumors and 2-9 vs. >10 brain metastases (Yamamato et al, 2013 & 2014 respectively), and a number of retrospective analyses of patients for multiple brain metastases treated with SRS used alone or in conjunction with surgical excision or WBRT. The prospective study conducted by Yamamato and colleagues (2014, Evidence table 1) included 1,194 patients with 1-10 newly diagnosed brain metastasis, with a maximum lesion volume <15 mL, and a Karnofsky performance status (KPS) score of ≥70. All patients received standard stereotactic radiosurgery and the primary outcome was overall survival for which the non-inferiority margin for the comparison of outcomes in patients with two to four brain metastases with those of patients with five to ten brain metastases was set as the value of the upper 95% CI for a hazard ratio (HR) of 1.30. The results of the analysis showed a median overall survival after stereotactic radiosurgery of 13.9 months in the patients with one brain metastasis, 10.8 months for those with 2-4 metastases, and 10.8 months among those with 5-10 lesions). Overall survival did not differ between the patients with two to four vs. those with 5-10 lesions (HR 0.97, 95% CI 0.81-1.18). This was less than the value of non-inferiority margin set by the authors a prior. The same group of investigators performed two retrospective case matched-studies to examine whether treatment results of SRS alone for patient with five or more brain metastases differ from those for patients with 1-4 metastases in one study, and for patients with 2-9 versus 10 or more lesions in the other study (Yamamato et al 2013, 2014). Overall the analysis comparing outcomes of SRS in patients with more than 5 metastases versus 1-4 showed a minimal, but statistically significant higher survival in patients with 1-4 versus ≥ 5 metastases. There were no significant differences between the subgroups in other outcomes including death due to progression of brain disease, need for salvage WBRT, salvage surgery, repeat SRS for new tumors, neurological deterioration, or SRS-related complications. Generally similar results were observed with the comparison of outcomes among patients with 2-9 versus 10 or more brain metastases. The studies had their shortcomings including the inherent limitations of retrospective studies, as well as limitations in analyses performed. The great majority of published observational retrospective studies suggest that the number of brain metastases (exceeding one lesion) had no statistically significant impact on overall survival among patients treated with SRS given alone or in combination with WBRT. These retrospective studies include the largest series (Karlsson et al 2009) with data for 1,885 patients with 1-8 metastases treated over 30 years. The results of the analysis indicate that the median overall survival did not differ significantly between those with 2, 3-4, 5-8 or >8 brain metastatic lesions; but patients with one brain metastasis survived longer than those with multiple brain metastases. Prospective randomized controlled trials are needed to determine the efficacy of SRS with or without surgery for multiple brain metastases compared to WBRT alone or following surgical excision of the lesions. A randomized controlled study of neurocognitive outcomes in patients with five or more brain metastases treated with radiosurgery or whole-brain radiotherapy is underway. The primary aim of this study is to compare the change in neurocognitive function outcome between baseline and 6 months in WBRT versus SRS treatment groups. Conclusion: There is insufficient evidence to determine that SRS with or without whole brain radiation therapy (WBRT) has non-inferior, equivalent, or superior outcomes to WBRT in the management of patients with five or more brain metastases. There is insufficient direct evidence to determine that the outcomes of SRS in patients with five or more brain metastases are non-inferior or equivalent to those in patients with 1-4 brain metastases.

Articles: The literature search revealed over 400 articles on the use of SRS for brain metastases. The majority of published articles were studies evaluating the use of the technology for one to four brain lesions, studies comparing different radiation doses, and articles on the technical aspects of the technology. The search did not identify any randomized controlled trial (RCT) that compared SRS with or without WBRT versus WBRT. Almost all the studies that examined the efficacy of SRS in patients with five or more brain lesions were retrospective, observational studies with no comparison groups. There was one recently published prospective, observational study conducted in Japan (Yamamato, et al, 2014) among patients with up to 10 brain metastases, and two case-matched retrospective studies conducted by the same group of principal authors comparing the SRS results for patients with 1-4 versus ≥ 5 tumors in one study, and 2-9 versus 10 or more lesions in the other .The Prospective study and the case matched study comparing outcomes of SRS for 1-4 versus ≥ 5 brain metastases were critically appraised. The results of the retrospective studies published in the last 8 years were summarized and presented in Table 3. Yamamoto M, Serizawa T, Shuto T, et al, Stereotactic radiosurgery for patients with multiple brain metastases (JLGK0901): A multi-institutional prospective observational study. Lancet Onclo. 2014 April; 15(4): 387–395. Evidence tables 1 and 2. Yamamoto M, Kawabe T, Sato Y, et al. A case-matched study of stereotactic radiosurgery for patients with multiple brain metastases: comparing treatment results for 1-4 vs ≥ 5 tumors: clinical article. J Neurosurg. 2013 Jun; 118(6):1258-1268. Evidence tables 1 and 2.

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The use of Gamma Knife in the treatment of five or more brain metastatic lesions does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Stereotactic Body Radiation Therapy (SBRT) for Prostate Cancer

BACKGROUND

Prostate cancer is one of the most common cancers, and the second leading cause of cancer death in men in the US. There are many treatment options for a localized disease, and each has its advantages and side effects. The choice of intervention should be considered carefully, balancing the benefits and harms as they relate to the patient's age, overall health, and personal preferences. External beam radiation therapy (EBRT) is one of the standard treatment options for localized prostate cancer and research shows that there is a dose response for biochemical relapse-free survival. However, the increase in radiation dose to the prostate also results in an increase in exposure to the adjacent organs at risk (namely the bladder, urethra, and rectum). The National Comprehensive Cancer Network (NCCN) Prostate Cancer Guideline (2014) states that doses of 75.6–79.2 Gy in conventional fractions to the prostate are appropriate for patients with low-risk cancers, and that patients with intermediate- or high-risk disease should receive doses up to 81.0 Gy. Several advanced techniques have been developed within the last two decades to deliver these high doses of radiation to the prostate while sparing the surrounding normal tissues. Currently intensity-modulated radiation therapy (IMRT) is the most common EBRT modality used for the treatment of localized prostate cancer. IMRT involves the external delivery of multiple beams of radiation that conform to the shape of the tumor, and where the intensity of each beam can be modulated in order to spare the surrounding healthy tissue. IMRT is typically delivered in 38-45 fractions (treatment sessions) and requires 7-9 weeks of treatment (Parthan 2012, Yamazaki 2014, NCCN 2014). Slowly proliferating prostate cancer cells are thought to have a unique radiobiology that is characterized by a low α /β ratio (around 1.5 Gy as opposed to about 10 Gy for other cancers). This assumption was first promoted in 1999 by Brenner and Hall, based on their observation of 367 patients from two centers. They noted that this low α /β ratio of prostate cancer is comparable or lower than that for late-responding normal tissue (experiments on rodents suggest that α /β ratio for the rectum is 4-6 Gy). This suggests that prostate cancer cells have a high degree of sensitivity to dose per fraction, and that the use of fewer high-dose per fraction radiation treatments (hypofractionation) would improve local tumor control. This theory is controversial, supported by some investigators and questioned by others, yet it provided the biologic rationale in favor of hypofractionated radiotherapy for localized prostate cancer (Brenner 1999, Freeman 2011, McBride 2012, Bolzicco 2013, Cabrera 2013, Katz 2013, Oliai 2013, Mangoni 2014, Tan 2014). Hypofractionation may be defined as moderate (2.4-4 Gy per fraction) or extreme (6.5-10 Gy per fraction). Extreme hypofractionation with high-dose-rate brachytherapy (HDR-BT) has been used in some centers for the treatment of prostate cancer, either as a monotherapy or in combination with EBRT. HDR-BT therapy, however, is not widely adopted due to its relatively invasive nature, need for hospitalization, anesthesia, resources, and technical expertise for the planning and delivery of therapy. It also requires prolonged bed rest that increases the risk of infection and thromboembolism (Jabbari 2012, Fukudo 2014, Koh 2014). Stereotactic radiation therapy refers to non-surgical techniques that deliver precisely-targeted (within a few millimeters) external beam photon radiotherapy. Stereotactic techniques are often used to deliver much higher doses per treatment (in only a single or few treatments), compared to traditional radiation therapy. Stereotactic radiosurgery (SRS) was initially developed to treat small brain tumors and functional abnormalities of the brain. Stereotactic body radiotherapy (SBRT) has recently emerged, and is highly marketed, as a non-invasive alternative to HDR-BT for delivering hypofractionated radiotherapy to the prostate. The term 'stereotactic' means precise positioning of the target within three-dimensional space, and the term 'body' is used to distinguish the technique from the current terminology of SRS used for brain tumors. SRS and SBRT rely on several technologies: 1. Three-dimensional imaging and localization techniques that determine the exact coordinates of the target within the body, 2. Systems to immobilize and carefully position the patient and maintain it during therapy, 3. Highly focused gamma-ray or x-ray beams that converge on a tumor or abnormality, and 4. Image-guided radiation therapy to improve the precision and accuracy of the treatment (Freeman 2011, Radiology Info.org, Aneja 2014, Tan 2014). SBRT for prostate cancer delivers the entire course of therapy in 4-5 visits over 2-2.5 weeks, compared with up to 45 fractions over 9 weeks with conventional fractionation. Thus, it may be more convenient to patients, potentially improve their adherence to therapy, reduce staff and machine burden, and according to a number of analyses (based on modeling), may be less costly than EBRT. However, the use of SBRT for prostate cancer is an area of controversy in the radiation oncology community and is still regarded by many as an experimental treatment. The mechanism of cell kill with large hypofractionated doses is not fully understood in vivo, and many radiation oncologists have concerns over the potential toxicity of the very high ablative doses delivered per fraction, as well as the risk of disease recurrence (Hodges 2012, Parthan 2012, Cabrera 2013, Seison 2013, Tan 2014). CyberKnife® (Accuray Incorporated, Sunnyvale, CA) is one of the devices used for delivering SBRT. It is a non-gantry-based frameless robotic stereotactic radiation delivery system that consists of a 6MV linear accelerator mounted on a robotic arm, with two orthogonal X-ray imagers to track the inserted gold fiducial markers (GFM) and perform real-time corrections for target repositioning during

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treatment. CyberKnife delivers hundreds of individualized circular beams with a targeting error of less than 1 mm. allowing the safe delivery of highly conformal treatment plans. To date, CyberKnife has been used to treat tumors of the head and neck, lung, kidney, liver, pancreas, and prostate. The CyberKnife SBRT treatment protocol has two principal phases; treatment planning and treatment delivery. The treatment planning phase involves the implanting of three to four gold fiducial markers (GFMs) in the apex, intermediate lateral zone, and base of the prostate using TRUS for image guided positioning and motion tracking, followed by treatment planning using CT to differentiate the prostate and proximal seminal vesicles from the surrounding tissue. Treatment is then delivered to the prostate by the CyberKnife system in four or five fractions to a total of 34 -39 Gy, given on consecutive or alternating days, according to the study protocol (Freeman 2011, Chen 2013, Seisen 2013). CyberKnife was previously reviewed by MTAC in 2006 for the treatment of lesions or tumors in any anatomical site and did not meet MTAC evaluation criteria. The current review is limited to the use of CyberKnife SBRT for the treatment of prostate cancer, based on a request for coverage of the technology.

10/20/2014: MTAC REVIEW
Stereotactic Body Radiation Therapy (SBRT)
Evidence Conclusion:
Conclusion: Overall the results of the published small observational phase I and II trials indicate that SBRT has favorable outcomes in terms of short-term biochemical control, and with acceptable toxicity. However, the literature does not provide sufficient evidence to determine the comparative effectiveness of SBRT to other conventional radiotherapy techniques, or the durability of the observed biochemical control and low toxicity associated with the treatment beyond 3-5 years. The published studies did not examine the long-term safety of SBRT or its clinical effects in terms of disease-free survival, metastases-free survival, or overall survival. Larger trials with longer follow-up duration are required to evaluate the long-term safety and effects of SBRT, especially that late toxicity could be worse with extreme hypofractionation compared to the conventional hypofractionation. A number of RCTs involving extreme hypofractionation are underway and may provide more evidence on the safety and efficacy of SBRT compared to conventional therapies for the treatment of localized prostate cancer. However, it will be several years before the results of these trials are published. These ongoing studies are: PACE (Prostate Advances in Comparative Evidence) is an ongoing international randomized phase III study comparing SBRT using CyberKnife, radical prostatectomy, and IMRT (78 Gy in 39 fractions) for low and intermediate risk prostate cancer. HYPO-RT-PC (Hypofractionated radiotherapy of intermediate risk localized prostate cancer) is a Swedish phase III trial that will compare 78Gy in 39 fractions delivered with IMRT over 8 weeks vs. SBRT 42.7 Gy in 7 fractions of 6.1 Gy over 2.5 weeks. RTOG 0938 is a randomised phase II trial that compares the health related side effects of 2 hypofractionation regimens (36.25 Gy delivered twice weekly for a total of 5 treatment sessions (7.25Gy /session) over 15-17 days versus 51.6 Gy delivered in 12 daily treatment sessions (4.3Gy per session) over 16-18 days) for low-risk patients.
Articles: The literature search revealed over 200 articles, the majority of which were reviews, description of hypofractionation radiation therapy, or studies that were unrelated to the current review. No randomized controlled trials (RCTs) comparing SBRT to conventional EBRT regimens or low dose brachytherapy for low-risk prostate cancer were identified. The published empirical studies on the use of the technology for prostate cancer were only phase I and phase II feasibility trials conducted in a number of centers in US and overseas. The search also revealed a pooled analysis (King et al, 2013) of the results of the phase II trials conducted in 8 institutions participating in a consortium for prostate SBRT, as well as a number of published systematic reviews (with no meta-analyses) for hypofractionation therapy in general, or SBRT for the treatment of localized prostate cancer. The pooled analysis by King and colleagues, and the larger phase II trials with the longest follow-up duration were selected for critical appraisal: King CR, Brooks JD, Gill H, et al. Long-term outcomes from a prospective trial of stereotactic body radiotherapy for low-risk prostate cancer. Int J Radiat Oncol Biol Phys. 2012; 82:877-882. See Evidence Table 1. King CR, Freeman D, Kaplan I, et al. Stereotactic body radiotherapy for localized prostate cancer: pooled analysis from a multi-institutional consortium of prospective phase II trials. Radiother Oncol. 2013; 109:217-221. See Evidence Table 1 . King CR, Collins S, Fuller D, et al. Health-related quality of life after stereotactic body radiation therapy for localized prostate cancer: results from a multi-institutional consortium of prospective trials. Int J Radiat Oncol Biol Phys. 2013;87(5):939-45. See Evidence Table 1 Chen LN, Suy S, Uhm S, et al. Stereotactic body radiation therapy (SBRT) for clinically localized prostate cancer: the Georgetown University experience. Radiat Oncol. 2013;8: 58.doi: 10.1186/ 1748-717X-8-58. See Evidence Table 2

Katz AJ, Santoro M, Diblasio F, et al. Stereotactic body radiotherapy for localized prostate cancer: disease control and quality of life at 6 years. Radiat Oncol. 2013;8: 118.doi: 10.1186/1748-717X-8-118. See Evidence Table 2. Oliai C, Lanciano R, Sprandio Bet al. Stereotactic body radiation therapy for the primary treatment of localized prostate cancer. J Radiat Oncol. 2013; 2:63-70. See Evidence Table 2.

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The use of Stereotactic body radiation therapy (SBRT) for Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion
61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)
61800	Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)
61781	Stereotactic computer-assisted (navigational) procedure; cranial, intradural (List separately in addition to code for primary procedure)
61782	Stereotactic computer-assisted (navigational) procedure; cranial, extradural (List separately in addition to code for primary procedure)
61783	Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
G0339	Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment
G0340	Image guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
1992	06/01/2010[MDCRPC], 04/05/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 05/07/2013[MDCRPC],11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC], 12/07/2021[MPC],12/06/2022[MPC]	01/10/2023

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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34136 and added L34151
02/06/2018	MPC approved criteria for prostate cancer
4/28/2020	Added list of covered indications from KP-0423 criteria as clarification for searching
03/09/2021	Updated criteria to include clarifying language: *For cognitive sparing, an alternative consideration could be whole brain radiation therapy with hippocampal sparing and memantine.*
01/10/2023	MPC approved to adopt the revised changes to the SRS criteria to include indications for brain metastasis. Requires 60-day notice effective 06/01/2023.

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Clinical Review Criteria
Subtalar Arthroereisis for the Treatment of Pes Planus (Flat Feet)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual (MBPM) Chapter 15 section 290 – Foot Care, B. Exclusions from Coverage *This service is not covered per Medicare criteria.*
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Flatfoot is a progressive developmental or acquired deformity characterized by plantar medial rotation of the talus, decrease in the medial arch height, and supination and abduction of the forefoot. The posterior tibial tendon may weaken and tear and the talo-navicular capsule, the tibio-navicular ligament, the spring ligament, the long and short plantar ligaments and the plantar aponeurosis may become stretched. There is a shift in the load from lateral column to the medial column, which may cause the medial arch to flatten further (Arangio 2007).

Flexible flatfoot is also referred to as “collapsing pes valgo planus” in which collapsing refers to the flexibility of the deformity, pes refers to the foot, planus refers to the flattened arch, and vulgus refers to the everted calcaneus (Forg 2001). It is one of the most common foot deformities in adults and can cause pain, fatigue, night cramps, and abnormal gait.

A vast majority of flexible flatfeet can be controlled with functional orthoses, but the worst deformities may require surgical intervention to reconstruct the foot deformity and reduce posterior tendon dysfunction. Many surgical procedures as tendon and muscle lengthening, osteotomies, arthrodesis, and arthroereisis have been described (Saxena 2007).

Arthroereisis was developed more than 30 years ago to be used in combination with other bone and soft tissue procedures. It involves placing various shaped implants beneath the talus to limit excessive eversion while preserving inversion. The implants are intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation. They do not replace reconstructive surgery but are used in conjunction with other operative soft-tissue and bony procedures (Needleman 2006, Saxena 2007).

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The operative procedure includes inserting the arthroereisis implant after correcting all parts of the flatfoot deformity and associated conditions in sequence; ankle, hindfoot, midfoot and forefoot. To date there are at least four cylindrical metallic implants (composed of titanium alloys) designed to be placed under the talus in the tarsal canal and sinus tarsi lesion. They range from 6 -14 mm in width, and 12-18 mm in length. The Futura Biomedical Subtalar Peg Implant, the Maxwell-Brancheau Arthroereisis (MBA) Sinus Tarsi Implant, the Kalix device, and the HyProCure Sinus Tarsi implant are all approved by the Food and Drug Administration for use as an internal support to primary surgical interventions in the treatment of flatfoot. The devices are contraindicated in cases of active local infection, allergic reactions to foreign bodies, poor or insufficient bone stock, the presence of clinical or functional abnormalities that would prevent the potential of achieving good results, or other conditions that may place the patient at risk.

Medical Technology Assessment Committee (MTAC)

Subtalar Arthroereisis

06/04/2007: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of Arthroereisis in the treatment of flexible flatfeet in adults. The published studies on the technology are only small case series with no comparison groups to compare the outcomes of the intervention to alternative therapies.
Articles: The search revealed around twenty articles on subtalar arthroereisis for the correction of flatfeet in adults. There were no randomized or non-randomized controlled trials that compared the procedure with an alternative therapy. The majority of the published articles reported on experimental studies performed on cadavers. The reports on human adult patients were either case reports or case series with less than 25 patients. The largest were two case series (Needleman 2006, and Viladot 2003) with 23 and 21 patients respectively, and each on a different arthroereisis implant. Both were critically appraised. Needleman RL. A surgical approach for flexible flatfeet in adults including a subtalar arthroereisis with MBA Sinus tarsi Implant. Foot &Ankle International 2006; 27:9-18. See Evidence Table. Viladot R, Pons M, Alvarez F, et al. Subtalar arthroereisis for posterior tibial tendon dysfunction. A preliminary report. Foot & Ankle International 2003; 24:600-606. See Evidence Table.

The use of Subtalar Arthroereisis in the treatment of Pes Planus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
0335T	Insertion of sinus tarsi implant
S2117	Arthroereisis, subtalar
0510T	Removal of sinus tarsi implant
0511T	Removal and reinsertion of sinus tarsi implant

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
06/26/2007	04/06/2007[MDCRPC], 02/07/2011 [MDCRPC], 12/04/2012 [MDCRPC], 10/01/2013 [MPC], 08/05/2014[MPC],06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	04/6/2011

[MDCRPC] Medical Director Clinical Review and Policy Committee

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MPC Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Pressure Reducing Support Surfaces

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Hospital Beds NCD 280.7
Local Coverage Determinations (LCD)	LCD L33830 Pressure Reducing Support Surfaces Group 1 LCD L33642 Pressure Reducing Support Surfaces Group 2 LCD L33692 Pressure Reducing Support Surfaces Group 3
Local Coverage Article	Pressure Reducing Support Surfaces - Group 1 - Policy Article (A52489) Pressure Reducing Support Surfaces - Group 2 - Policy Article (A52490) Pressure Reducing Support Surfaces - Group 3- Policy Article (A52468)

For Non-Medicare Members

Group 2 Pressure Reducing Support Surfaces:
Alternating Pressure and Low Air Loss Mattresses and Overlays

A group 2 support surface is considered medically necessary DME if the member meets **ONE of the following:**

A. The member must meet **ALL of the following:**
   The member has multiple stage II (partial thickness skin loss) pressure ulcers located on the trunk or pelvis.
   The member has been on a comprehensive ulcer treatment program† for at least the past month, which has included the use of an appropriate group 1 support surface.
   The member's ulcers have worsened or remained the same over the past month.
B. The member has large or multiple stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure ulcer(s) on the trunk or pelvis; or
C. The member has had a recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days) and has been on a group 2 or 3 support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days).

† The comprehensive ulcer treatment described in criterion 2 above should generally include:

- Appropriate management of moisture/incontinence;
- Appropriate turning and positioning;
- Appropriate wound care (for stage II, III, or IV ulcer);
- Education of the member and caregiver on the prevention and/or management of pressure ulcers;
- Nutritional assessment and intervention consistent with the overall plan of care;
- Regular assessment by the nurse, physician, or other licensed healthcare practitioner (usually at least weekly for a member with a stage III or stage IV ulcer).

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If the member is on a group 2 surface, there should be a care plan established by the physician or home care nurse, which includes the above elements.

When a group 2 support surface is prescribed for a myocutaneous flap or skin graft, continued use is generally considered medically necessary for up to 60 days from the date of surgery.

Use of a group 2 support surface is considered medically necessary until the ulcer is healed or, if healing does not continue, there is documentation in the medical record to show: (i) other aspects of the care plan are being modified to promote healing, or (ii) the use of the alternating pressure mattress is medically necessary for wound management.

A group 2 support surface is considered experimental and investigational when these criteria are not met because of insufficient evidence in the peer-reviewed literature.

For Non-Medicare Members
Group 3 - Pressure Reducing Support Surfaces

An air-fluidized bed is covered only if **All of the following** criteria are met:

1. The patient has a stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure ulcer (Reference ICD-10 Codes that Support Medical Necessity section for applicable diagnoses).
2. The patient is bedridden or chair bound as a result of severely limited mobility.
3. In the absence of an air-fluidized bed, the patient would require institutionalization.
4. The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. The evaluation generally must be performed within one month prior to initiation of therapy with the air-fluidized bed.
5. The course of conservative treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment was rendered. Conservative treatment must include:
    a. Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours); and
    b. Use of a Group 2 support surface to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation; and
    c. Necessary treatment to resolve any wound infection; and
    d. Optimization of nutrition status to promote wound healing; and
    e. Debridement by any means, including wet-to-dry gauze dressings, to remove devitalized tissue from the wound bed; and
    f. Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

    In addition, conservative treatment should generally include:
    g. Education of the patient and caregiver on the prevention and management of pressure ulcers; and
    h. Assessment by a physician, nurse, or other licensed healthcare practitioner at least weekly, and
    i. Appropriate management of moisture/incontinence.

An occlusive barrier is required, when necessary, to maintain a moist wound-healing environment that may otherwise be compromised by the drying action of airflow generated by air-fluidized therapy. If moist dressings are NOT required because of the wound characteristics (e.g. heavily exudative wound, etc.), the occlusive barrier is not required as a condition for reimbursement.

Wet-to-dry dressings when used for debridement do not require an occlusive dressing. Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days will not preclude coverage of an air-fluidized bed. Should additional debridement again become necessary while a patient is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to be denied.

6. A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed

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treatments, and management and support of the air-fluidized bed system and its problems such as leakage.

7. A physician directs the home treatment regimen and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis.

8. All other alternative equipment has been considered and ruled out.

An air-fluidized bed will be denied as not reasonable and necessary under any of the following circumstances:

1. The patient has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);

2. The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material;

3. The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed;
4. Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);

5. Electrical system is insufficient for the anticipated increase in energy consumption; or

6. Other known contraindications exist.

Payment is not included for the caregiver or for architectural adjustments such as electrical or structural improvement.

The continued coverage of an air-fluidized bed as reasonable and necessary must be documented by the treating physician every month. Continued use of an air fluidized bed is covered until the ulcer is healed or, if healing does not continue, there is documentation to show that: (1) other aspects of the care plan are being modified to promote healing, or (2) the use of the bed is reasonable and necessary for wound management.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Pressure relieving support surfaces are designed to prevent or promote the healing of pressure ulcers by reducing or eliminating tissue interface pressure. Most of these devices reduce interface pressure by conforming to the contours of the body so that pressure is distributed over a larger surface area rather than concentrated on a more circumscribed location. This clinical policy is consistent with Medicare DME MAC guidelines.

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Group 2 and 3 - Considered Medically Necessary when criteria in the applicable policy statements listed above are met. Group 1- Medical Necessity Review not required

HCPC Codes	Description
Pressure Reducing Support Surfaces - Group 1	
A4640	Replacement pad for use with medically necessary alternating pressure pad owned by patient

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E0181	Powered pressure reducing mattress overlay/pad, alternating, with pump, includes heavy-duty
E0182	Pump for alternating pressure pad, for replacement only
E0183	Powered pressure reducing underlay/pad, alternating, with pump, includes heavy duty
E0184	Dry pressure mattress
E0185	Gel or gel-like pressure pad for mattress, standard mattress length and width
E0186	Air pressure mattress
E0187	Water pressure mattress
E0188	Synthetic sheepskin pad
E0189	Lambswool sheepskin pad, any size
E0196	Gel pressure mattress
E0197	Air pressure pad for mattress, standard mattress length and width
E0198	Water pressure pad for mattress, standard mattress length and width
E0199	Dry pressure pad for mattress, standard mattress length and width
Pressure Reducing Support Surfaces - Group 2	
E0193	Powered air flotation bed (low air loss therapy)
E0277	Powered pressure-reducing air mattress
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width
E0373	Nonpowered advanced pressure reducing mattress
Pressure Reducing Support Surfaces - Group 3	
E0194	Air fluidized bed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
10/28/2015	11/03/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC] , 06/06/2023[MPC]	06/02/2020

[MPC] Medical Policy Committee

Revision History	Description
7/10/2018	Added criteria for Group 3 mattresses
10/11/2018	Removed Group 3 effective date information
06/02/2020	Added Pressure Reducing Support Surfaces Group 1 HCPC codes

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Clinical Review Criteria
Surgical Treatment of Migraine Headaches

- Surgical Deactivation of Trigger Sites

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Surgical Treatment of Migraine Headache*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Migraine Headache, Surgical Treatment (A-0578) for medical necessity determinations. These procedures are not covered per MCG. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

> **The MCG* are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 2 years of neurology notes
- Most recent clinical note from requesting provider

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Background

Migraine headache is a common primary headache disorders that is characterized by a variety of symptoms such as nausea, vomiting, visual disturbances, and sensitivity to light and sounds. In the United States, approximately 18% of women and 6% of men have experienced at least one migraine in the previous year. Standard treatment for migraine involves identification and avoidance of triggers, and the use of pharmacotherapy to treat acute attacks and prevent further attacks (Goadsby 2010, Silberstein 2004).

Surgical treatment for migraine headache has been proposed for patients who are not receiving adequate benefit from standard treatment options. This approach was originally discovered as an unanticipated benefit of cosmetic

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surgery. The first step to determining whether the patient is a candidate for surgery is to identify trigger sites. Most investigators use Botox to identify the trigger site; however, local nerve blocks can also be used. Patients who experience complete elimination or at least 50% improvement in intensity and/or frequency of headaches are considered candidates for surgery. The surgical approach varies by trigger site and involves removal of certain facial muscles, severing of a facial nerve, and/or surgical modification of the sinuses (Kung 2011).

Medical Technology Assessment Committee (MTAC)

Surgical Deactivation of Trigger Sites for Treatment of Migraine Headaches

02/11/2013: MTAC REVIEW

Evidence Conclusion: A RCT that included 125 subjects evaluated the safety and efficacy of surgical deactivation of migraine headache trigger sites. Patients in the treatment group were injected with Botox to identify trigger sites. Patients were eligible for surgery if they experienced at least 50% improvement in the intensity and/or frequency of headaches from the Botox lasting at least 4 weeks. Ninety-one patients out of the 100 patients in the treatment group underwent surgery. Patients in the control group receive injections of saline. After one year 31 patients in the treatment group and 3 patients in the control group experienced complete elimination. Both groups experienced significant improvement in headache intensity and duration compared to baseline; however, only the treatment group experienced a significant improvement in headache frequency. Compared to the control group, patients who received surgery experienced significantly greater reductions in headache frequency, intensity, and duration at one year. The most common surgical complications were: nasal dryness, rhinorrhea, recurrence of septal deviation, scalp itching, and minor hair loss. This study had several limitations: the inclusion and exclusion criteria were not provided, an ITT analysis was not performed, power was not assessed, the outcome data was self-reported, and it is not stated whether patients were taking pharmacotherapy during the trial (Guyuron 2005).

Headache outcomes at 1 year (Guyuron 2005)

	Treatment	Control	P-value
	Number (%)		
Complete elimination	31 (35)	3 (15.8)	<0.001
Significant improvement*	82 (92)	0 (0)	<0.001
	Mean ± SE		
Frequency (migraine/month)	3.8 ± 0.4	10.2 ± 1.7	<0.001
Intensity (0 to 10, most severe)	4.0 ± 0.3	7.0 ± 0.3	<0.001
Duration (hour)	0.35 ± 0.05	0.99 ± 0.2	0.007

*A t least 50% improvement in intensity, frequency, and/or duration.

Patients in the treatment group were followed for 5-years to determine the long-term safety and efficacy of surgery. Ten patients in the treatment group who underwent additional surgery were excluded from the analysis, leaving 69 patients. Results from this observational follow-up study suggest that the improvements in headache frequency, duration, and intensity that were achieved at 1 year were maintained at 5 years (Guyuron 2011).

Headache outcomes at baseline, 1 year, and 5 years (Guyuron 2011)

	Baseline	Year 1	Year 5
	Number (%)		
		N=89	N=69
Complete elimination	NA	31 (35)	20 (29)
Significant improvement*	NA	82 (92)	61(88)
	Mean ± SD		
Frequency (migraine/month)	10.9 ± 7.5	4.0 ± 6.4	4.0 ± 5.3
Intensity [0 to 10 (most severe)]	8.5 ± 1.2	4.0 ± 3.3	4.5 ± 3.2
Duration (days)	1.4 ± 1.4	0.42 ± 0.8	0.31 ± 0.9

*A t least 50% improvement in intensity, frequency, and/or duration.

A more recent RCT that included 75 subjects also evaluated the safety and efficacy of surgical deactivation of migraine headache trigger sites. Patients underwent injections of Botox to identify the trigger site. Patients who experienced complete elimination or at least 50% improvement in intensity and/or frequency of headaches were candidates for surgery. Patients were then randomized to receive either surgery based on migraine trigger site (frontal, temporal, or occipital) or sham surgery. Twenty-eight (57%) patients who underwent surgery experienced complete elimination compared to 1 (4%) who underwent sham surgery. Both groups experienced significant improvements in headache frequency and intensity from baseline. The treatment group also experienced a significant improvement in headache duration from baseline. The treatment group experienced significantly

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greater reductions in headache frequency and intensity compared to the control group at one year. There was no significant difference between the treatment and the control group in headache duration. The most common adverse events were temporary hollowing and intense itching. This trial had several limitations: it was a small trial and power was not assessed, outcomes were self-reported, and it is not stated whether patients were taking pharmacotherapy during the trial (Guyuron 2009).

Change from baseline to 1 year (Guyuron 2009)

	Treatment	Control	P-Value
	Number (%)		
Complete elimination	28 (57.1)	1 (3.8)	<0.001
Significant improvement*	41 (83.7)	15 (57.7)	0.014
	Mean ± SD		
Frequency (headaches/month)	-7.4† ± 5.8	-3.5† ± 5.4	0.005
Intensity (1 to 10)	-3.0† ± 3.5	-1.3† ± 2.9	0.03
Duration (days)	-0.30† ± 0.46	-0.87 ± 4.5	0.43

*At least 50% improvement in intensity, frequency and/or duration.
†Significant improvement from baseline.

Conclusion: Results from two RCTs with methodological limitations suggest that surgical treatment for migraine headaches may improve migraine headache frequency, intensity, and durations, and results in more patients achieving complete elimination compare to control (not surgery or sham surgery). However, the safety and efficacy of surgical treatment for migraine headaches compared to standard therapy is unknown and there is limited data on the long-term efficacy of this procedure.
Articles: Several observational studies and two randomized controlled trials (RCTs) were identified that evaluated the safety and efficacy of surgical treatment of migraine headaches. The two RCTs and a follow-up study of one of the RCTs were selected for review. All of these studies were conducted by the same investigator.
The following studies were selected for review: Guyuron B, Kriegler JS, Davis J, Amini SB. Comprehensive surgical treatment of migraine headaches. Plast Reconstr Surg. 2005; 115:1-9. See Evidence Table. Guyuron B, Kriegler JS, Davis J, Amini SB. Five-year outcome of surgical treatment of migraine headaches. Plast Reconstr Surg. 2011; 127:603-608. See Evidence Table**.** Guyuron B, Reed D, Kriegler JS, Davis J, Pashmini N, Amini S. A placebo-controlled surgical trial of the treatment of migraine headaches. Plast Reconstr Surg. 2009; 124:461-468. See Evidence Table.

The use of Surgical Deactivation of Trigger Sites for Treatment of Migraine Headaches does not meet *the Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
15824	Rhytidectomy; forehead
15826	Rhytidectomy; glabellar frown lines
21299	Unlisted craniofacial and maxillofacial procedure
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
30801	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); superficial
31200	Ethmoidectomy; intranasal, anterior
31201	Ethmoidectomy; intranasal, total
31205	Ethmoidectomy; extranasal, total
31254	Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)
31255	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)
64732	Transection or avulsion of; supraorbital nerve
64734	Transection or avulsion of; infraorbital nerve
64744	Transection or avulsion of; greater occipital nerve
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

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With diagnosis codes	
G43.001	Migraine without aura, not intractable, with status migrainosus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.401	Hemiplegic migraine, not intractable, with status migrainosus
G43.409	Hemiplegic migraine, not intractable, without status migrainosus
G43.411	Hemiplegic migraine, intractable, with status migrainosus
G43.419	Hemiplegic migraine, intractable, without status migrainosus
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
G43.601	Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus
G43.609	Persistent migraine aura with cerebral infarction, not intractable, without status migrainosus
G43.611	Persistent migraine aura with cerebral infarction, intractable, with status migrainosus
G43.619	Persistent migraine aura with cerebral infarction, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.A0	Cyclical vomiting, in migraine, not intractable
G43.A1	Cyclical vomiting, in migraine, intractable
G43.B0	Ophthalmoplegic migraine, not intractable
G43.B1	Ophthalmoplegic migraine, intractable
G43.C0	Periodic headache syndromes in child or adult, not intractable
G43.C1	Periodic headache syndromes in child or adult, intractable
G43.D0	Abdominal migraine, not intractable
G43.D1	Abdominal migraine, intractable
G43.801	Other migraine, not intractable, with status migrainosus
G43.809	Other migraine, not intractable, without status migrainosus
G43.811	Other migraine, intractable, with status migrainosus
G43.819	Other migraine, intractable, without status migrainosus
G43.821	Menstrual migraine, not intractable, with status migrainosus
G43.829	Menstrual migraine, not intractable, without status migrainosus
G43.831	Menstrual migraine, intractable, with status migrainosus
G43.839	Menstrual migraine, intractable, without status migrainosus
G43.901	Migraine, unspecified, not intractable, with status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.911	Migraine, unspecified, intractable, with status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
03/05/2013	03/05/2013[MDCRPC], 11/04/2014 [MPC], 09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC],	02/16/2022

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	02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC] , 02/01/2022[MPC] , 02/07/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/01/2022	Adopted Kaiser Permanente policy for Medicare Advantage members.
02/16/2022	Updated applicable codes

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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Targeted Axillary Node Dissection (TAD)

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Criteria

For Medicare Members

Source)	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Targeted Axillary Node Dissection (TAD),*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

A significant proportion of breast cancer women have axillary metastasis which is a crucial factor in determining local and systemic treatment. The standard of care for these women is total axillary lymph node dissection. However, total axillary lymph node dissection results in morbidities (Lucci et al., 2007) including numbness and lymphedema which is an incapacitating swelling of the arm. In addition to the complications, many women undergo chemotherapy (before the total node dissection) which convert them to node-negative status in approximately 40% to 75% of cases (Boughey et al., 2013; Mittendorf et al., 2014). Yet, a high percent of women undergoes extensive surgery which may no longer be necessary. Sentinel lymph node dissection (SLND) which is an alternative to complete axillary lymph node dissection (ALND) is less invasive, is shown to be promising but it has a high false negative rate (Caudle et al., 2015). New surgery, targeted axillary node dissection (TAD), which combines SLND and identification with removal of clipped node has been the center of attention.

Description of procedure: From Shin et al., 2016 (Shin et al., 2016): At the time of diagnosis/biopsy and in patients with node disease limited to axilla, cancerous nodes are clipped. Then patients undergo chemotherapy involving anthracycline-based, taxane-based, or a combination of both. At the completion of chemotherapy, the previously clipped cancerous nodes are identified with ultrasound and 125 I-radiolabeled seeds are placed to localize them. Implantation of seed is performed one to five days before the surgery and is ultrasound-guided. Both lymph node with radioactive seed are identified with gamma probe. During the surgery, the surgeon removes the sentinel

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lymph nodes, which is sentinel lymph node dissection (SLND), and the cancerous clipped nodes. The clipped node is then sent to Pathologist for assessment. Radiography of the specimen during surgery is performed to assure the removal of lymph node and the seed. Eligible patients for TAD include women with N1 or N2 disease. In patients with N3 disease, clip placement is not performed because they need axillary lymph node dissection after chemotherapy.

Medical Technology Assessment Committee (MTAC)

Target Axillary Node Dissection

01/14/2019: MTAC REVIEW

Evidence Conclusion: In patients with biopsy-proven axillary metastasis in whom a clip placement was performed and who underwent chemotherapy, there is insufficient evidence to determine the efficacy and safety of targeted axillary node dissection (TAD) in comparison with complete axillary lymph node dissection (ALND) or Sentinel Lymph Node Dissection (SLND) in patients with axillary metastasis after chemotherapy.

Articles: PubMed was searched through September 19, 2018 with the search terms Targeted axillary lymph node dissection, TAD, clip placement, breast cancer with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded several articles. However, three met the framework and were reviewed. These studies can be found in evidence table 1. Studies with small sample size or feasibility study were excluded. Studies with no assessment of TAD (SLND with clip placement and removal at time of surgery) were not included. See Evidence Table**.**

The use of Target Axillary Node Dissection does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

Date Created	Date Reviewed	Date Last Revised
02/05/2019	02/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC] , 03/07/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt criteria of no coverage for TAD; added 01/2019 MTAC review.

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Clinical Review Criteria
Transanal Endoscopic Resection of Rectal Carcinoma

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "***Transanal Endoscopic Resection of Rectal Carcinoma,***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Transanal Endoscopic Microsurgery (TEM) will be considered medically necessary for **ONE** or more of the following indications:

1. Benign rectal tumors (adenomas)
2. Low-risk Tis and T1 rectal carcinoma
3. Small rectal carcinoids (less than 2 cm in diameter)
4. T2 cancer in someone medically unable to undergo a major operation

Kaiser Permanente Washington does not cover Transanal Endoscopic Microsurgery (TEM) for lesions that do not meet the criteria above.

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Background

Transanal endoscopic microsurgery (TEM) is a minimally invasive surgical technique that was developed to avoid the morbidity of radical surgery for adenomas and early-stage rectal cancer, while still allowing for complete removal of the lesion. TEM requires specialized instrumentation. TEM uses a natural opening (the anus) to reach the target organ, and is a valuable surgical technique with a low complication rate for patients with appropriate rectal lesions. The main advantages of TEM are preservation of the rectum, anus and fecal continence, low complication rates, short operation times, lower blood loss, shorter hospital stays, and shorter recover times. Other advantages include better exposure, magnified stereoscopic view, and greater reach into the middle and upper rectum.

Local excision (LE) alone does not offer the opportunity for lymph node biopsy and, therefore, has been reserved for patients in whom the likelihood of cancerous extension is small. LE can occur under direct visualization for

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rectal tumors within 10 cm of the anal verge and may be most appropriate for small tumors (less than 4cm) confined to the submucosa (T1, as defined by the TNM staging system). TEMS extends local excision ability to the proximal rectosigmoid junction. Adenomas, large rectal polyps (which cannot be removed through a colonoscope), retrorectal masses, small carcinoid tumors, and non-malignant conditions such as strictures or abscesses are amenable to local excision by either method. TEMS can avoid morbidity and mortality associated with major rectal surgery, including the fecal incontinence related to stretching of the anal sphincter, and can be performed under general or regional anesthesia. Use of TEMS for resection of rectal cancers is more controversial.
The most common treatment for rectal cancer is surgery, either open resection or local excision. The technique chosen depends on the size and location of the tumor, evidence of local or distal spread, and patient characteristics and goals. Open, wide resections have the highest cure rate, but may also have significant adverse effects, such as lifelong colostomy, bowel, bladder, or sexual dysfunction. The use of LE in rectal adenocarcinoma is an area of much interest; however, because LE alone does not offer the opportunity for lymph node biopsy it has been reserved for patients in whom the likelihood of cancerous extension is small. Despite this increased risk of local recurrence, local excision may be an informed alternative for patients. TEMS permits local excision beyond the reach of direct visualization equipment.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
03/07/2017	03/07/2017[MPC], 05/02/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description
03/07/2017	MPC approved to adopt criteria for TEMS

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Clinical Review Criteria
Focused Aspiration of Scar Tissue (FAST)

- Tenex
- Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Focused Aspiration of Scar Tissue (FAST)***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies for tendonitis and soft tissue injuries.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Tenex Health TX™ is used for the treatment of tendonitis and soft tissue injuries. This procedure — Fasciotomy and Surgical Tenotomy (may also be referred to as Focused Aspiration of Scar Tissue FAST) – is a minimally invasive, non-surgical approach for eliminating scar tissue, the source of chronic tendon pain. FAST is a minimally invasive treatment designed to remove tendon scar tissue, allowing patients to return to their athletics and active lifestyles. The Tenex system is a surgical instrument that uses ultrasonic energy to perform a percutaneous tenotomy and fasciotomy. It is intended to precisely cut and remove disease and damaged tissue that leads to natural tendon and soft-tissue function.

Hayes Review

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Hayes, Inc. Hayes Health Technology Brief. Tenex Health TX Procedure (Tenex Health) for Treatment of Tendon Pain. Lansdale, PA: Hayes Inc.; 9/2015

Medical Technology Assessment Committee (MTAC)

Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies

BACKGROUND

Tendons are fibrous connective tissues that attach muscles to other body parts, usually bones. They play an important role in the movement by transmitting the contraction force produced by the muscles to the bone they hold. Tendons are anatomically designed to withstand extensive mechanical loading but are prone to injury through a variety of biomechanical and biological mechanisms Tendon disorders have become very common among athletic and non-athletic population and account for a considerable proportion of activity-related diseases of the musculoskeletal system. Different terms have been used to describe tendon pathology including tendinitis, tendinosis, paratendonitis, and tendinopathy. Currently, tendinopathy has become the accepted term to describe a spectrum of changes that occur in damaged and/or diseased tendons. Common tendinopathies include plantar fasciitis, Achilles tendinopathy, medial and lateral elbow epicondylitis, rotator cuff tendinopathy, and others. These are mainly characterized by pain, reduced exercise tolerance, and decreased function (Ahmad 2020, Scott 2015, Steinmann 2020).

Tendinopathy is primarily a diagnosis of clinical suspicion and can be difficult to diagnose. Imaging can be normal in pathological tendon, and asymptomatic tendon can be histologically pathological. It is thus reported that the clinical presentation and prognosis of tendinopathy can be very individualized and require detailed assessment of the extent or nature of pathology and risk factors to diagnose and manage the condition. Treatment of tendinopathy should promote repair and remodeling rather than further injury/inflammation. However, it is reported that there is no good clinical outcome measure for tendon remodeling as there is often a discrepancy between clinical improvement and structural improvement measured with clinical imaging (Ahmad 2020, Scott, 2015).

The first line treatment for a diagnosed tendinopathy consists of conservative measures such as rest and activity modification to allow the tendon to heal, bracing, and individualized rehabilitation exercises to stimulate the cellular activity and increase the blood flow in the tendon. Pharmacological therapies such as non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids may have short-term effect on reducing pain but could have negative or equivocal long-term effect. The majority of individuals will respond to conservative therapy; however, in some patients the tendinopathy is refractory (recalcitrant) to conservative therapy. Corticosteroid injections are commonly used in cases refractory to conservative therapy but have unproven efficacy, can delay healing, and may be associated with potential harms to the tendons (Ahmad 2020, Mattie 2017).

Currently, there is no universally accepted therapeutic modality for recalcitrant tendinopathies. Several non-pharmacological invasive or minimally invasive therapies have been introduced to practice or are being investigated such as laser therapy, shock-wave therapy, therapeutic ultrasound, and thermal modalities (cryotherapy and hyperthermia), platelet rich plasma (PRP) injection, stem cell therapy and others. Many of these therapies were found to have no effect, have only a short-term effect on improving symptoms and /or result in long-term damage to the tendon. Some investigators have advocated re-injuring the tendon through treatments such as intra-tendinous needling and injections, and aggressive soft tissue therapy. These approaches may improve the patient's symptoms in the short-term but could result in long-term damage to the tendon (Mattie 2017, Scott 2015, Stover 2019).

Surgery is often considered as a last option for patients with persistent pain and disability after exhausting all appropriate nonoperative options. Surgery involves the excision of degenerative tendon portions, removal of adhesions, decompression, and/or creation of multiple longitudinal tenotomies. It is reported that ideally surgical treatment of chronic tendinopathy should involve micro-resection of specific regions demonstrating mucoid degenerative tissue. However, traditional surgical techniques are based on gross and not microscopic appearance. Over the years the surgical procedures have evolved from open techniques to more minimally invasive approaches using arthroscopy, or through percutaneous incisions under ultrasound guidance. It is

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reported however, that there is insufficient evidence from high quality RCTs to determine the effectiveness of surgical interventions for the treatment of tendinopathies (Koh 2013, Ma 2020).

Ultrasound-guided percutaneous tenotomy (UGPT) (also known as percutaneous ultrasonic tenotomy [PUT]) is a relatively recent option introduced for the treatment of multiple types of tendinopathy. The therapy is based on the assumption that the removal of the pathological tissues would convert the chronic degenerative process into an acute process that introduces inflammatory growth factors and promotes tendon healing. UGPT combines ultrasound visualization with a small cutting handpiece to allow debridement of the pathological tendon tissue. It is reported however, that ultrasound scanning delivers a 2-dimensional image for a 3-D structure which may result in either failing to remove all the pathologic tissue or removing too much of the healthy tissue. In addition, the pistoning motion of the cutting handpiece can penetrate healthy tendons due to the inadequate visualization provided by the ultrasound probe (Sanchez 2017).

Tenex procedure is an ultrasound-guided percutaneous tenotomy performed with the assistance of proprietary device “TX Tissue Removal System” (Tenex Health; Lake Forest, CA). It uses both diagnostic and therapeutic ultrasound and is intended for ablating, emulsifying and removing diseased or pathologic musculoskeletal tissue to treat chronic tendon and soft-tissue injuries. The Tenex Health TX System is an ultrasonic surgical aspirator that fragments, emulsifies, and removes soft tissue. The system consists of a console, ultrasonic handpiece, inflation cuff and a foot pedal. The console provides control over the user functions including irrigation, aspiration, and ultrasonic fragmentation/emulsification. It has a large, color LCD and employs a touchscreen with a graphical user interface for selection of required settings. The console also houses the irrigation valve, the irrigation pump, and the aspiration pump. The ultrasonic handpiece has a double lumen to allow for concomitant aspiration and irrigation of emulsified tendon tissue. It connects to the console for power, as well as for delivering irrigation fluid directly to the surgical site and for aspirating emulsified tissue by way of integrated tubing set. The handpiece and tubing are single use disposable components of the system. Irrigation fluid is delivered under pressure to the surgical site by operation of an air pump residing in the console. The foot pedal is used to control each of the functions (irrigation, aspiration, ultrasonic fragmentation/emulsification) of the system (FDA website, Batista 2018).

The Tenex procedure is performed in an outpatient setting under sterile condition with local anesthesia and no sedation. A pre-procedure ultrasound is performed to identify the location and extent of the pathology. A small incision (approximately 5 mm) is then made in line with the tendon fiber to allow the introduction of the TX cutting device while limiting any iatrogenic damage to the tendon. The TX ultrasonic cutting device a needle-like point (the TX Micro Tip) is inserted into the area and high-frequency vibrations cuts and debrides the damaged scar tissue and intra-tendinous calcifications that were identified by the pre-procedural ultrasound. Once debridement is complete the skin incision is closed with adhesive bandage, an occlusive film and a compression sleeve. Post procedure protocol limits movement according to the tendon treated. (Chimenti 2019).

Sanchez, et al (2017) reported that that percutaneous ultrasound-guided tenotomy using Tenex device is a surgical procedure associated with complications similar to those of surgery including tendon tear, re-rupture, deep vein thrombosis, and worsening of healing.

10/12/2020: MTAC REVIEW

Evidence Conclusion:

There is insufficient published evidence from well-conducted randomized or non-randomized prospective observational studies to determine the safety and efficacy of Tenex Health TX system for the management of recalcitrant tendinopathies.

Low- to very low strength of evidence suggest that the intervention may lead to some improvement in pain and /or function when compared to baseline symptoms.

Articles:

The literature search did not identify any randomized controlled trials or prospective comparative study that compared the safety and efficacy of percutaneous ultrasound tenotomy, using Tenex Health TX tissue removal system versus a sham therapy or any other intervention used for the treatment of tendinopathy refractory to conservative therapy. The limited published literature consisted of small observational studies and case series the majority of which were retrospective with data obtained from chart reviews.

The use of Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered not medically necessary:

CPT® Codes	Description
23405	Tenotomy, shoulder area; single tendon
23406	Tenotomy, shoulder area; multiple tendons through same incision
24357	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); percutaneous
27000	Tenotomy, adductor of hip, percutaneous (separate procedure)
27306	Tenotomy, percutaneous, single tendon (separate procedure)
27307	Tenotomy, percutaneous, adductor or hamstring; multiple tendons
27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia

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Date Created	Date Reviewed	Date Last Revised
04/04/2017	04/04/2017[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	12/02/2022

[MPC] Medical Policy Committee

Revision History	Description
02/14/2019	Updated criteria set to publish
12/01/2020	Added MTAC report for Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies. MPC approved to retain non-coverage policy. Included additional CPT codes for percutaneous tenotomy for review. Requires 60-day notice, effective date of additional codes 05/01/2021.
12/02/2022	Removed codes 28008 and 28060 fasciotomy codes as they are not applicable to this procedure.

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Date Sent: 6/28/23
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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Therasphere and SIR Sphere for Unresectable Hepatocellular Carcinoma

- SIRT (Selective Internal Radiation Therapy)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Treatment with Yttrium-90 Microspheres (A52950)

For Non-Medicare Members

I. The use of Yttrium-90 (90Y) microsphere radioembolization (SIR-Spheres® or TheraSphere®) is medically necessary if **ONE** of the following is met:
   A. Unresectable metastatic liver tumors from primary colorectal cancer (CRC)
   B. Unresectable liver-only or liver-dominant metastases from neuroendocrine tumors (NET) (e.g. carcinoid, islet cell tumor/pancreatic endocrine tumor) and **ALL** of the following:
      1. The disease is diffuse* and symptomatic (*For this medical policy, the term “diffuse” disease is defined as tumor tissue spread throughout the affected organ (e.g., diffuse liver disease)
      2. Only in persons who have failed systemic therapy with octreotide to control carcinoid syndrome (e.g., debilitating flushing, wheezing and diarrhea)
   C. Unresectable primary hepatocellular carcinoma (HCC)

II. Yttrium-90 (90Y) microsphere radioembolization is not covered for any other indication because its clinical utility has not been established.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Hepatocellular carcinoma (HCC) is the fifth most common cancer in the world, and the third most common cause of cancer-related mortality. It is responsible for more than half a million deaths across the globe each year. Treatment options for patients diagnosed with hepatocellular carcinoma (HCC) are limited. Less than 15% are candidates for surgical resection at presentation, and the use of external beam radiation is limited due to the intolerance of normal liver parenchyma to tumoricidal radiation doses (the dose required to destroy solid tumors (>70 Gy) is much higher than the liver tolerance dose of 35 GY). In addition, systematic chemotherapy was found to have little impact on survival and negative impact on the health-related quality of life due to the toxicity to other

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organs and systems. These limitations have led to the emergence of local and regional treatments such as radiofrequency ablation, local administration of cytostatic drugs like hepatic arterial infusion and isolated hepatic infusion, or intrarterial embolization techniques such as transarterial chemo-embolization and selective intrarterial radioembolization therapy (Steel 2003, Salem 2004, Ibrahim 2008, Bult 2009, Riaz 2009).

Yttrium-90 (90Y) intra-arterial radiotherapy also known as radioembolization, is an emerging technique for the treatment of patients with unresectable primary or metastatic liver tumors. It is a minimally invasive catheter-based therapy that delivers internal radiation via the arterial vessels that feed the tumor. The technology takes advantage of the dual blood supply of the liver as the normal hepatic tissue obtains more than 70% of its blood supply through the portal vein, while intrahepatic malignancies derive their blood supply almost entirely from the hepatic artery i.e. arterial rather than portal circulation. The concept of intra-arterial radioembolization was first explored by injecting yttrium-90 containing microspheres in the hepatic artery of rabbits with liver tumor. The first clinical trial on selected patients was conducted in the mid 1980s, but was discontinued due to the several patient deaths of myelosupressions due to leaching (leakage) of the microspheres (Vente 2009).

In an attempt to overcome the problem of leaching, yttrium containing solid glass microspheres were developed (TheraSphere®, MDS Nordion. Ottawa, Ontario, Canada). These consist of microscopic glass beads 20-30 μ in diameter embedded with the radionuclide yttrium-90. The glass microspheres are delivered into the liver tumor through a catheter placed into the hepatic artery and subsequently get lodged in the microvasculature surrounding the tumor. Their size causes them to be trapped in the tumor capillary bed where they deliver very high irradiation doses to the tumors while sparing the surrounding liver parenchyma. Once inside the liver neither the medical personnel nor the family members can be irradiated. The microspheres are not biodegradable; they have a half-life of 64.1 hours (2.67 days) and emit pure beta-radiation with a mean tissue penetration of 2.5 mm and a maximum of 1 cm. The therapy is given as an outpatient interventional radiology procedure, and lasts from 30 to 40 minutes (Carr 2004, Ibrahim 2008, Bult 2009).

Another 90Y product available for clinical use is SIR-Spheres® (SIRTeX Medical Ltd., Sydney, Australia). These consist of biodegradable resin-based microspheres containing Yttrium-90 (90Y) and have an average size of 35 μ in diameter. Upon administration of the spheres in vivo, they are permanently implanted. Similar to TheraSphere, SIR-Spheres emit pure β-radiation with a half life of 2.67 days. Both types of microspheres have shown to preferentially localize to abnormally vascularized liver tumors, where they exert intense localized radiation, while limiting radiation exposure to the uninvolved hepatic parenchyma (Ibrahim 2008, Bult 2009).

Radioembolization is not without complications; it may lead to post-radioembolization syndrome which includes fatigue, nausea, vomiting, anorexia, fever, abdominal pain and cachexia. More serious adverse events include radiation induced liver toxicity, vascular injury when introducing the catheter, radiation pneumonitis from microspheres shunting around the liver and into the lungs, and gastrointestinal tract ulceration. Absolute contraindications for the use of 90Y microspheres include pretreatment with 99mTc macroaggregated albumin scan demonstrating significant hepatopulmonary shunts, and inability to prevent deposition of the microspheres to the gastrointestinal tract with modern catheter techniques (Ibrahim 2008, Riaz 2009).

TheraSphere (MDS Nordion, Ottawa, Canada) was approved by the FDA in 1999 under the Humanitarian Device Exemption Guidelines for the treatment of unresectable hepatocellular carcinoma.

SIR-Spheres® (SIRTeX Medical Ltd., Sydney, Australia) received FDA premarket approved in 2002 for the treatment of colorectal cancer metastasized in the liver with adjuvant floxuridine administered via the hepatic artery.

Medical Technology Assessment Committee (MTAC)

Therasphere in the Treatment of Unresectable Hepatocellular Carcinoma

04/10/2002: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the effectiveness of Therasphere for the treatment of unresectable hepatocelluar carcinoma (HCC). Many of the empirical studies were done with animals. Only small case series (four studies, each with n<20) with human populations were available.

Articles: The search yielded 24 articles, many of which dealt with technical aspects of the procedure. There were no randomized controlled trials or meta-analyses. There were several case series, all with small sample sizes (n<20). None of the empirical articles were considered of sufficient quality to be evaluated.

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The use of Therasphere in the treatment of unresectable hepatocellular carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/05/2006: MTAC REVIEW
Therasphere in the Treatment of Unresectable Hepatocellular Carcinoma
Evidence Conclusion: The empirical studies published before the previous MTAC review of the TheraSphere in 2002, were very small case series with less than 20 patients. For this review the literature search identified a small comparative non-controlled trial and few additional relatively larger series, many of which were published by the same group of investigators. In the comparative trial 28 patients received either TheraSphere therapy or Cisplatin. The patients were not randomized to the treatment groups, the study was unblinded, and the authors did not discuss how the patients were selected for each of the two therapies. The trial was not powered to detect significant differences between the study groups, had a short follow-up duration, and the 6-months data were available for only 50% of the patients. Its results indicate that patients treated with 90-Yttrium microspheres reported significantly higher scores on physical, functional, and social well-being vs. those treated with cisplatin. There was no significant difference in survival between the two groups according to Kaplan Meier curves.

The other case series reviewed was relatively small, had no control or comparison group, included a heterogeneous group of patients with different comorbidities, and the therapy received was not uniform for all patients. Its results indicate that 47% of the patients and 51% of the lesions had a greater than 50% reduction in size. The median survival was 20.8 months among non-high risk patients, and 11.1 month for those at high risk. In conclusion, the evidence published after the previous review is still insufficient to determine the effectiveness and safety of TheraSphere for the treatment of unresectable hepatocelluar carcinoma (HCC).
Articles: The search yielded 27 articles, many of which dealt with technical aspects of the procedure. No randomized controlled trials or meta-analyses were identified. There was a small non-randomized cohort study that compared TheraSphere treatment with Cisplatin, as well as several small prospective and retrospective case series with sizes ranging from 15 to less than 90 patients. The study with a comparison group, as well as a prospective case series with no patient overlap with the comparative trial, and clinically important outcomes, were selected for critical appraisal. Steel J, Baum A, and Carr B. Quality of life in patients diagnosed with primary hepatocellular carcinoma: hepatic arterial infusion of cisplatin versus 90-Yttrium microspheres (TheraSphere)® Psycho-Oncology 2004;13;73-79. See Evidence Table. Salem R, Lewandowski RJ, Atassi B, et al. Treatment of unresectable hepatocellular carcinoma with use of 90Y microspheres (TheraSphere): safety, tumor response, and survival J Vasc Interv Radiol. 2005;16:1627-1639 See Evidence Table.

The use of Therasphere in the treatment of unresectable hepatocellular carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/06/2010: MTAC REVIEW
Therasphere in the Treatment of Unresectable Hepatocellular Carcinoma
Evidence Conclusion: *TheraSphere* The literature search did not reveal any published randomized controlled trials on TheraSphere after the last 2006 review. At the time the published empirical studies consisted of one small comparative non-randomized trial with 28 patients and a number of case series, many of which were published by the same group of investigators. In the comparative trial, 28 patients received either TheraSphere therapy or cisplatin. The patients were not randomized to the treatment groups, the study was unblinded, and the authors did not discuss how the patients were selected for each of the two therapies. The trial was not powered to detect significant differences between treatments, had a short follow-up duration, and the 6-month data were available for only 50% of the patients. Its results indicate that patients treated with Yttrium-90 microspheres reported significantly higher scores on physical, functional, and social well-being vs. those treated with cisplatin. There was no significant difference in survival between the two groups according to Kaplan Meier curves. The recently published meta-analysis (Vente 2009) pooled the results of the case series with no comparison or control group and do not provide any additional evidence to determine the efficacy and safety of TheraSphere in the treatment of unresectable hepatocellular carcinoma. *Sir-spheres*: The results of the two randomized trials on Sir-Spheres (Gray 2001 and Van Hazel 2004) provide some but insufficient evidence on the benefits of Sir-Spheres combined with regional chemotherapy vs. regional chemotherapy alone in improving the response rate and time to progression. The common toxicities associated with the treatment were generally mild and the rate of grade 3 and 4 toxicities did not differ significantly between the treatment arms in Gray et al's trial. These results, however may not generalized as the chemotherapies use in the trials are not the standard regimens currently used as a first-line treatment, and the response rates in the control arms (0% in Gray et al's trial and 18% in Van Hazel and colleagues trial) were much lower than usually observed. Moreover, the trials were too small, and had insufficient power to determine whether radioembolization has any mortality benefit. *Conclusion:* There is insufficient published evidence to determine efficacy and toxicity of TheraSphere in the treatment of unresectable liver cancer
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when given alone or in combination with systemic or regional chemotherapy. There is insufficient published evidence to determine the efficacy and toxicity of Sir-Spheres in the treatment of liver metastases from colorectal cancer when given alone or in combination with systemic or regional chemotherapy.
Larger RCTs are randomizing patients to first line chemotherapy with or without ^{90}Y microsphere radioembolization are currently underway and may provide more evidence on the benefits of adding radioembolization therapy to first line chemotherapy.
Articles: The literature search yielded around 200 articles; many were review articles or publications that dealt with technical aspects of the procedure. There was one meta-analysis of studies (Vente 2009) on patients with primary or secondary liver malignancies treated with 90Y glass or resin microspheres, and another Cochrane review (Townsend 2009) of RCTs on radioembolization for liver metastases from colorectal cancer. Vente meta-analysis pooled the data from case series but presented a summary result for each of the RCTs separately. The Cochrane review also presented the results of the same 2 trials separately. The search also identified two phase-2 randomized trials conducted by the same research group in Australia that compared Sir-Spheres plus chemotherapy vs. chemotherapy alone for treating patients with liver metastases from primary colorectal cancer. The first published RCT (Gray 2001) compared Sir-Spheres with regional chemotherapy vs. regional chemotherapy alone in 74 patients, and the second (Van Hazel 2004) compared Sir-Spheres combined with systemic chemotherapy vs. systemic chemotherapy alone in 21 patients. The two trials were included in both meta-analyses. The search did not reveal any randomized controlled trials on TheraSphere.
The majority of other published studies were prospective or retrospective case series including patients with HCC or hepatic metastatic colorectal cancer (mCRC). A small number of case series reported on patient with liver metastases secondary to neuroendocrine or breast cancers. The following meta-analysis and the larger RCT were selected for critical appraisal: Vente MAD, Wondergem M, van den Bosch MAAJ, et al. Yttrium-90 microsphere radioembolization for the treatment of liver malignancies: a structured meta-analysis. Europ Radiol 2009;19:951-959. See Evidence Table. Gray B, Van Hazel G, Burton M, et al. Randomized trial of SIR-Spheres® plus chemotherapy vs. chemotherapy alone for treating patients with liver metastases from primary large bowel cancer. Ann Oncol 2001;12:1711-1720. See Evidence Table.

The use of Therasphere in the treatment of unresectable hepatocellular carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of SIRsphere in the treatment of unresectable hepatocellular carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/13/2012: MTAC REVIEW
Therasphere in the Treatment of Unresectable Hepatocellular Carcinoma
Evidence Conclusion: The best evidence published to date, after the last 2010 MTAC review, consisted of one small phase III randomized controlled trial on radioembolization using SIR-Spheres in patients with liver metastatic colorectal cancer, and two comparative efficacy analyses conducted to compare of the safety and efficacy of yttrium 90 (^{90}Y) radioembolization in patients with unresectable hepatocellular carcinoma. In all published series and studies the radioembolization were performed by highly trained professionals in specialized centers.
TheraSphere: Salem and colleagues (2011) recently published a comparative analysis of the outcomes of two relatively large cohorts of patients (total N= 463) with unresectable HCC who were treated in a single center with either transarterial chemotherapy (TACE) or radioembolization using ^{90}Y microspheres (TheraSphere). The study was not a randomized trial, nor designed to determine equivalence between the two therapies. The authors indicated that treatment response and survival were calculated from first treatment, and follow-up duration was longer for TACE. They also explained that patients undergoing TACE were younger and more likely to receive it as a bridge to transplantation. The overall results of the analysis showed longer time to progression with radioembolization using^{90}Y microspheres. There was no significant difference between the two therapies in time to response or survival. The study was not designed as an equivalence study, and lack of significant difference does not indicate that the two therapies are equivalent. An analysis performed by the authors showed that a randomized trial with 1000 patients would be required to establish equivalence in survival. There were no statistically significant differences in major toxicities between the two therapies. Patients treated with chemoembolization were more likely to experience abdominal pain and higher hepatic transaminase elevation. Lance et al's (2011) comparative analysis only included 73 patients treated with either chemoembolization or radioembolization with glass or resin ^{90}Y microspheres. The results did not show survival advantage with radioembolization but found higher rates of hospitalization in the chemoembolization group due to the postembolization syndrome.
Sir-Sphere: Hendlisz and colleagues' (2010), RCT compared the efficacy and safety of intravenous fluorouracil (FU) given alone or with of intra-arterial 90Y-resin microspheres (SirSpheres) in 46 patients with liver-limited
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metastatic colorectal cancer (mCRC) who failed other chemotherapies. The trial was randomized, controlled, and multicenter. However, it was conducted among a highly selected group of patients; it was not blinded and allowed patients in the FU alone group who had documented progression to cross-over to the radioembolization plus FU group at the investigators' discretion. As a result, 70% of those in the FU alone group also received radioembolization, which is significant source of bias, but the authors performed an intention to treat analysis (ITT), ie.analyzed the patients in the groups they were randomized to. The overall results of the study indicate that radioembolization with yttrium 90 resin microspheres in addition to intravenous fluorouracil significantly improved the response to therapy and time to liver progression compared to FU alone among the selected patients included in the trial. Radioembolization was not associated with more toxicity than chemoembolization. The effect on survival was not statistically significant, which could be attributed to the small sample size, especially with the high cross-over that could have improved the outcomes in the FU only group.

Articles: The literature search for studies published after the last review revealed one Phase III trial that compared IV fluorouracil infusion alone or with radioembolization with SIR-Spheres for a specific indication, two retrospective comparative analyses that compared radioembolization with TheraSphere vs. transcathether chemoembolization, and a number of retrospective and prospective single center case series with different population sizes. The largest case series and the larger comparative analyses were published by the same group of authors (Salem et al. 2010, 2011) and had a potential population overlap. The comparative analysis, as well as the Phase III trial, were selected for critical appraisal. Salem R, Lewandowski RJ, Kulik L, et al. Radioembolization results in longer time-to-progression and reduced toxicity compared with chemoembolization in patients with hepatocellular carcinoma. *Gastroenterology.* 2011;140:497-507. See Evidence Table. Hendlisz A, den Eynde M V, Peeters M, et al. Phase III trial comparing protracted intravenous fluorouracil infusion alone or with yttrium-90 resin microspheres radioembolization for liver-limited metastatic colorectal cancer refractory to standard chemotherapy. *J Clin Oncol.* 2010;28:3687-3694. See Evidence Table.

The use of Therasphere in the treatment of unresectable hepatocellular carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of SIRsphere in the treatment of unresectable hepatocellular carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
C2616	Brachytherapy source, nonstranded, yttrium-90, per source
Q3001	Radioelements for brachytherapy, any type, each
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres ****S codes not covered by Medicare***
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
With diagnosis codes	
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
04/10/2002	07/16/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 04/03/2012 MDCRPC, 02/05/2013 MDCRPC ,12/03/2013 MPC, 10/07/2014MPC, 08/04/2015MPC, 06/07/2016MPC, 04/04/2017MPC, 02/06/2018MPC, 01/08/2019MPC, 01/07/2020MPC, 01/05/2021MPC, 01/04/2022MPC, 01/10/2023MPC	02/16/2022

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
02/28/2018	Added Noridian coverage article
02/16/2022	Updated applicable codes

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Tinnitus Masking/Retraining Therapy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"**Tinnitus Masking/Retraining Therapy**"** for medical necessity determinations. Use the Non-Medicare criteria below.

*Codes for auditory assessment and rehabilitation are covered by Medicare.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Tinnitus is the perception of sound in the absence of an acoustic source (Luxon 1993). The perceived sound can vary from simple sounds such as whistling or humming to complex sounds such as music. Tinnitus may be perceived as a single sound or multiple sounds, unilateral or bilateral, within the head or outside the body, and intermittently or constantly. The American Tinnitus Association estimates that 50 million Americans have some degree of tinnitus with about 16 million of those experiencing significant enough symptoms to seek medical care and 2 million of them suffering so much that it ultimately interrupts normal day to day function. Tinnitus can occur at any age but its incidence increases by the age of 40 and peaks between 65 to 79 years (Hobson, Chisholm et al. 2012). The tinnitus experience is consistently higher among men and is strongly related to hearing loss but may be experienced by individuals with normal hearing as well. Acute tinnitus, which can last for days or weeks, may be caused by ear infection, medication, ear wax, exposure to excessive sound or changes in blood pressure. Chronic tinnitus, experienced by 10 to 15% of adults, persists for six or more months and may be caused by almost any disorder involving the outer, middle or inner ear, or the auditory nerve (Davis, Paki et al. 2007). In any

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case, tinnitus can be debilitating because it is difficult to describe, predict and manage and can lead to disruption of sleep, inability to concentrate, and depression.

Tinnitus is not a condition itself, rather, it is a symptom of an underlying condition and, therefore, management should include diagnosis and elimination of the factors precipitating tinnitus. In many cases, the cause of tinnitus cannot be identified warranting treatment of the symptom itself. At present, no universal treatment has been found effective in all patients and options are heavily dependent on the severity and perception of the condition. Treatment might range from counseling and dietary modification to acupuncture and relaxation therapy. Optimal management techniques seek to minimize the detrimental effects on activities of daily life and might include a variety of strategies. The use of medications and surgical interventions are rarely successful.

Tinnitus masking instruments have been clinically employed for alleviating symptoms for decades. These devices are worn behind or in either the same or the opposite ear affected by tinnitus and generate a noise based on the principle of distraction. The idea being that the level of noise, usually white noise, is introduced and can reduce the contrast between the tinnitus signal and background activity in the auditory system, with a decrease in the patient's perception of their tinnitus (Vernon 1977). The characteristics and circumstances of the tinnitus determine the kind of masking noise and instruments that might bring relief. No side effects or significant morbidities have been reported, to date, from the use of maskers or hearing aids as treatment for tinnitus and no substantial risks of sound therapy have been demonstrated.

Tinnitus instruments such as maskers and hearing aids are approved by the Food and Drug Administration (2009) for alleviating the symptoms associated with tinnitus and are classified as a Class III device.

Medical Technology Assessment Committee (MTAC)

Tinnitus Masking Devices

02/10/1999: MTAC Review

Evidence Conclusion: *Masking*: One small randomized controlled crossover study reports no decrease in self report of tinnitus intensity but statistically significant improvement in both specific and nonspecific effects of masking on tinnitus. Another study of patients randomized to masking or hearing aid devices and then allowed to choose which device to continue using demonstrated that 60% chose to continue using a masking device and 20% discontinued the use of any device. *Retraining Therapy*: A single small RCT demonstrated a statistically significant reduction (1-point improvement on a 10-point visual analogue scale) in subjective tinnitus loudness and discomfort following behavioral training as compared to a no treatment control group.
Articles: Erlandsson, S, et. Al. Treatment of Tinnitus: A Controlled Comparison of Masking and Placebo, British *J Audiol*. 1987, 21, 37-44. See Evidence Table Mehlum, D et. Al. Prospective Crossover Evaluation of Four Methods of Clinical Management of Tinnitus, *Otolaringol. Head Neck Surg*. 1984: 92: 448-453 See Evidence Table Scott, B. Et. Al. Psychological Treatment of Tinnitus: An Experimental Group Study. Scand. Audiol. 1985, 14: 223-230 See Evidence Table

The use of Tinnitus Masking Devices for treatment of tinnitus does not meet *Kaiser Permanente Medical Technology Assessment Criteria.*

Tinnitus Masking Devices

6/17/2013: MTAC REVIEW

Evidence Conclusion: Henry et al 2006 study recruited 800 US military veterans via advertisements. Following screening, 172 candidates were enrolled into the study; those not eligible were not convinced that their tinnitus was sufficiently severe, or they were not motivated to comply with the study requirements. A further 49 subjects were excluded in secondary screening resulting in a total of one hundred and twenty-three patients commencing treatment. Candidates were quasi-randomly assigned to a tinnitus masking (TM) device or tinnitus retraining therapy group (TRT). The mean age in the sound therapy group was 61 (SD 9.6) and in the tinnitus retraining group it was 58.7 (SD 10.5). Baseline audiometry was performed and the Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ) and Tinnitus Severity Index (TSI) were administered. Both groups used a combination of noise generators, hearing aids and combination instruments. Audiometry and questionnaires were evaluated at 3, 6, 12 and 18 months. The results show that for patients with 'moderate' problems, sound therapy resulted in a statistically significant improvement in the THQ at six months but tinnitus retraining therapy (TRT) appeared to offer superior results. For patients who described their tinnitus as a 'big' problem, there was an across the board significant improvement in the three instruments at all time points except three months, which is comparable to the TRT group. Looking at the effect sizes, for sound therapy these ranged from 0.18 to 0.59 in

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the 'moderate group and did not show a systematic improvement over time. For those with a 'big' problem, the effect sizes for sound therapy ranged from 0.46 to 0.86 and whereas the THI and TSI improved over time the THQ effect size remained unchanged. For those with a 'very big' problem the effect of sound therapy seemed greater at three months, with a trend of effect sizes becoming progressively smaller through 18 months. Based on effect size, both groups showed considerable improvement overall but whereas the benefits of sound therapy tended to remain constant over time, the effect of tinnitus retraining improved incrementally. Currently, the literature on maskers and/or hearing aids for the treatment of tinnitus in adults is limited. First and foremost, the lack of an established universal tool for baseline and follow-up assessment of outcome measures restricts the ability to produce valid data and make comparisons. Additionally, due to the often "off label" use of hearing aids as tinnitus treatments there has been a dearth of driving forces for undertaking large randomized controlled trials. Henry and colleague's study demonstrate some of these limitations; although the study claims to be controlled, the two groups being investigated do not make an attempt to treat both groups similarly. Different instruments are used across the study, and even within each group, and patient contact time differs by 1.4 hours between the TM and TRT groups. In addition to these limitations, the study was quasi-randomized which allows for a greater risk of selection bias. The study also notes that the devices were more apt to break in the TRT group compared to the TM group and variation in treatment specialists for each method might result in clinician differences. While some of the studies included in the Cochrane Review report that patients experienced a decrease in tinnitus with use of masking devices there is no conclusive evidence to validate the effectiveness. On the whole, the studies included in the review demonstrate either no or limited improvement in tinnitus perception. Furthermore, the quality of the studies is, generally, low. With several different devices employed throughout the studies and marked methodological heterogeneity including numerous measures of evaluation of tinnitus severity and outcome all with different scores, scales, tests and questionnaires, comparisons and further analysis are complicated. Small sample sizes also contribute to the low quality leading to the inability to generalize findings.
Conclusions: Although some patients report a decrease in tinnitus with the use of masking devices, there is no conclusive evidence from randomized trials to demonstrate effectiveness. The limited data from the included studies show that sound therapy on its own is of unproven benefit in the treatment of tinnitus, although the effect may be better than placebo. Thus far, no adverse outcomes or significant morbidity from using sound-generating (masking) devices have been reported, and furthermore, the literature is unable to demonstrate any substantial risks.
Articles: Henry JA, Schechter MA, Zaugg TL, Griest S, Jastreboff PJ, Vernon JA, Kaelin C, Meikle MB, Lyons KS, Stewart BJ. Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Oto-Laryngologica*, 2006;126:64-69. See Evidence Table

The use of Tinnitus Masking Devices for treatment of tinnitus does not meet *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour
92627	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)
92630	Auditory rehabilitation; prelingual hearing loss
92633	Auditory rehabilitation; postlingual hearing loss
ICD-10 Codes	**Description**
H93.11-H93.19	Tinnitus-right ear, left ear, bilateral and unspecified

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/1998	04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 08/06/2013MPC, 06/03/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC, 09/04/2018MPC, 09/03/2019MPC, 09/01/2020MPC, 09/07/2021MPC, 09/06/2022MPC	09/01/2020

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/01/2020	Added KPWA Medical Policy statement under Medicare section

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Clinical Review Criteria
Total Knee Arthroplasty
- Inpatient Knee Arthroplasty &
- Knee Arthroplasty Medical Necessity Criteria

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Total Knee Arthroplasty (L36577) –*Not subject to medical necessity review, refer to Inpatient versus Ambulatory/Outpatient Level of Care requests* Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule
Local Coverage Article (LCA)	None
MLN Matters Article	Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule
Inpatient versus Ambulatory/Outpatient Level of Care requests	***Inpatient* Total Knee Arthroplasty** For elective total knee replacement (27438, 27446, 27447) to be approved as inpatient, **ONE of the following** criteria must be met: 1. Bilateral knee replacement 2. Coexisting neurologic condition (such as multiple sclerosis, hemiparesis, severe Parkinson's, or other neurologic conditions that would likely seriously affect ambulation) where the expected length of stay is planned to be longer than 2 midnights. ***Ambulatory* Total Knee Arthroplasty** can be approved without medical necessity review ****Effective 01/01/2022*—The following knee revision codes- 27486, 27487, 27488 are listed in the Medicare inpatient only (IPO) list and should not be reviewed for ambulatory or outpatient status.**

For Non-Medicare

I. *Level of Care*

***Inpatient* Total Knee Arthroplasty (for ambulatory/outpatient requests, proceed to II.)**

A. For elective total knee replacement (27438, 27446, 27447) or revision/replacement of a knee arthroplasty (27486, 27487, or 27488) to be approved as inpatient, **ONE of the following** criteria must be met:
   1. Bilateral knee replacement

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2. Coexisting neurologic condition (such as multiple sclerosis, hemiparesis, severe Parkinson's, or other neurologic conditions that would likely seriously affect ambulation) where the expected length of stay is planned to be longer than 2 midnights.

If the patient qualifies for inpatient status, must also meet the following:

II. Non-Medicare only request for ALL Total Knee Arthroplasty (includes ambulatory & inpatient) must meet the Medical Necessity Criteria:

A. Total knee and unicompartmental (partial) arthroplasty may be considered medically necessary for degenerative joint disease when **ALL of the following** are met:
   1. Treatment is needed because of functional disabling pain of at least 3 months duration which interferes with the ability to carry out activities of daily living

   AND
   2. Radiographic imaging or arthroscopic evidence of moderate or severe osteoarthritis as evidenced by **ONE of the following**:
      a. Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour (Kellgren-Lawrence Grade 3)
      b. Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (Kellgren-Lawrence Grade 4)
      c. Exposed subchondral bone (full thickness cartilage loss with underlying bone reactive changes) noted on arthroscopy or MRI (Outerbridge Grade IV)

   AND
   3. Patients must have three months of non-operative, conservative treatment as demonstrated by a trial of one or more of the following medications:
      a. Non-steroidal anti-inflammatory drugs (oral or topical)
      b. Acetaminophen
      c. Intra-articular injection of corticosteroids as appropriate

   AND
   4. A trial of Physical Therapy* in the last 12 months, which should include some of the following features:
      a. Supervised Physical therapy, attendance at >75% of sessions
      b. Flexibility and muscle strengthening exercises
      c. Reasonable restriction of activities

   **If Physical Therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.*

   AND
   5. All patients who meet the above criteria to undergo standard elective surgery must also meet **ALL of the following**:
      a. BMI < 35: if BMI is > 35, optimization efforts must be documented, demonstrating active attempts towards weight loss as shown by sustained weight loss over 3-6 months OR stagnant weights despite documented active participation in a weight loss or exercise program. Formal nutritional counseling must be documented. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. However, BMI > 40 is a relative contraindication. Despite not achieving this BMI, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.
      b. No diabetes, or diabetes with HbA1c < 7.5 (with the presence of heart disease, no lower than 7.5). Members who have an A1C >7.5 must actively be involved with medical management and demonstrate a reduction in A1c over 3-6 months. If optimization attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. A1c > 8.0 is a relative contraindication. Despite not achieving this A1c, if the provider has documented adequate efforts to improve these parameters, the case will be reviewed on a case-by-case basis by a medical director.
      c. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery or have a 90% reduction in nicotine/tobacco use. If nicotine/tobacco reduction attempts are unsuccessful, the surgeon and patient may proceed if there is documentation of understanding of the risks through shared decision making. No changes in nicotine/tobacco use is a relative contraindication.

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B. Knee arthroplasty may **ALSO be considered medically necessary**, after failure of nonoperative interventions, for the following diagnoses:
   - Distal femur fracture repair in a patient with osteoporosis
   - Failure of a previous proximal tibial or distal femoral osteotomy
   - Hemophilic arthroplasty
   - Limb salvage for malignancy
   - Posttraumatic knee joint destruction
   - Avascular necrosis (osteonecrosis) of tibial or femoral condyle
   - Inflammatory Arthritis

***Kellgren-Lawrence Classification of Osteoarthritis**

Grade	Description
grade 0 (none)	definite absence of x-ray changes of osteoarthritis
grade 1 (doubtful)	doubtful joint space narrowing and possible osteophytic lipping
grade 2 (minimal)	definite osteophytes and possible joint space narrowing
grade 3 (moderate)	moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends
grade 4 (severe)	large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends

Osteoarthritis is deemed present at grade 2 although of minimal severity.
Reference: Pai, V., Knipe, H. Kellgren and Lawrence system for classification of osteoarthritis. Reference article, Radiopaedia.org. (accessed on 29 Mar 2022) https://doi.org/10.53347/rID-27111

Outerbridge
Outerbridge 0: Cartilage is normal
Outerbridge 1: Cartilage shows chondromalacia,
Outerbridge 2: Cartilage shows partial thickness fibrillation
Outerbridge 3: Cartilage shows deep fibrillation
Outerbridge 4: Full thickness cartilage loss

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist, including a history & physical
- If the orthopedist has a patient who does not meet one of the criteria above but has determined that the procedure should be performed in an inpatient setting, the orthopedist can submit a separate explanation with the request that will be reviewed by clinical staff on a case-by-case basis.
- If a patient is approved for ambulatory status under the prior authorization request but ends up staying longer than expected, the inpatient claim could be adjusted to inpatient if deemed appropriate.

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Background

Joint replacement surgery has been performed on millions of people over the past several decades and has proved to be an important medical advancement in the field of orthopedic surgery. The hip and knee are the two most commonly replaced joints. The knee is the largest joint in the body and includes the lower end of the femur, the upper end of the tibia and the patella. The knee joint has three compartments, the medial, the lateral and the patellofemoral. The surfaces of these compartments are covered with articular cartilage and are bathed in synovial fluid. The bones of the knee joint work together, allowing the knee to function smoothly.

The most common reason for total knee replacement surgery is arthritis of the knee joint. Types of arthritis include:

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• osteoarthritis,
• rheumatoid arthritis and
• traumatic arthritis (arthritis which occurs as a result of injury).

Arthritis causes a severe limitation in the activities of daily living (ADLs), including difficulty with walking, squatting, and climbing stairs. Pain is typically most severe with activity and patients often have difficulty getting mobilized when seated for a long time. Other findings include chronic knee inflammation or swelling not relieved by rest, knee stiffness, lack of pain relief after taking non-steroidal anti-inflammatory medications and failure to achieve symptom improvement with other conservative therapies such as steroid injections and physical therapy.

Osteonecrosis and malignancy are additional reasons to proceed with total knee replacement surgery. The use of TKR in patients with malignancy must be weighed against considerations of life expectancy and possible alternative procedures to relieve pain. The goal of total knee replacement surgery is to relieve pain and improve or increase patient function.

Occasionally, there may be a need to perform a reoperation on a previous total knee replacement. This is often referred to as a revision total knee.

Circumstances that lead to the need for a revision Total Knee Arthroplasty continued disabling pain, continued decline in function which can be attributed to failure of the primary joint replacement. Failure can be due to infection involving the joint, substantial bone loss in the structures supporting the prosthesis, fracture, aseptic loosening of the components and wear of the prosthetic components.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Total Knee:

CPT® or HCPC Codes	Description
27438	Arthroplasty, patella; with prosthesis
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; 1 component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
05/03/2022	05/03/2022[MPC], 05/02/2023[MPC]	05/15/2023

[MPC] Medical Policy Committee

Revision History	Description
05/03/2022	MPC approved to adopt criteria for Inpatient-Total Knee for non-Medicare members. Requires 60-day notice, effective date 10/01/2022.
06/21/2022	Added clarification around Medicare inpatient only list

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09/15/2022	Updated criteria effective date to 10/25/2022.
10/13/2022	Added preexisting inpatient criteria for total knee.
10/18/2022	Moved Medicare IPO applicable codes up under Medicare Criteria for more clarity
02/06/2023	Add clarification on when Medicare IPO list of codes was updated 1/1/2022.
03/24/2023	Clarified Level of Care requirement for Medicare and Non-Medicare members.
05/15/2023	Clarified PT episode of care timeframe

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Clinical Review Criteria
Transcatheter Aortic or Pulmonary Valve Replacement (TAVR/TPVI)

- Valve-in Valve Transcatheter Aortic Valve Implantation (VI-TAVI) in Failed Bioprosthetic Aortic Valves Transcatheter Valve-in Valve Implantation (TAVIV)
- Transcatheter Aortic Valve in Surgical Aortic Valve (TAV-in-SAV)
- Transcatheter Pulmonary Valve Implantation (TPVI)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Transcatheter Aortic Valve Replacement (TAVR) (20.32)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for transcatheter valve-in-valve replacement or transcatheter pulmonary valve implantation, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Valve-in-Valve Transcatheter Aortic Valve Implantation*** *and* ***Transcatheter Pulmonary Valve Implantation (TPVI)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

I. Transcatheter Aortic Valve Replacement (TAVR)

A. Transcatheter aortic valve replacement is medically necessary when **ALL of the following** are true:
   1. Use of an FDA approved device
   2. Documentation of severe, symptomatic aortic valve stenosis
   3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team includes the following:
      a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
         I. independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
         II. documented and made available to the other heart team members the rationale for their clinical judgment.
      b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.

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4. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
5. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
   a. On-site heart valve surgery and interventional cardiology programs,
   b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
   c. Appropriate volume requirements per the applicable qualifications below:

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

Qualifications to begin a TAVR program for hospitals without TAVR experience:

The hospital program must have the following:

a. ≥ 50 open heart surgeries in the previous year prior to TAVR program initiation, and;
b. ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
c. ≥ 2 physicians with cardiac surgery privileges, and;
d. ≥ 1 physician with interventional cardiology privileges, and;
e. ≥ 300 percutaneous coronary interventions (PCIs) per year.

Qualifications to begin a TAVR program for heart teams without TAVR experience:

The heart team must include:

a. Cardiovascular surgeon with:
   i. ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related; and,
b. Interventional cardiologist with:
   i. Professional experience of ≥ 100 career structural heart disease procedures; or, ≥ 30 left-sided structural procedures per year; and,
   ii. Device-specific training as required by the manufacturer

Qualifications for hospital programs with TAVR experience:

The hospital program must maintain the following:

a. ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; or,
b. ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and,
c. ≥ 2 physicians with cardiac surgery privileges; and,
d. ≥ 1 physician with interventional cardiology privileges, and
e. ≥300 percutaneous coronary interventions (PCIs) per year; and,

Participation in the STS/ACC TVT Registry is required.

All other indications are not covered as there is insufficient evidence to support effectiveness.

II. Valve-in-Valve Transcatheter Aortic Valve Implantation

A. Valve in Valve TAVR is medically necessary when **ALL of the following** are meet:
   1. Use of an FDA approved device
   2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals.
   3. Documentation of a failed aortic tissue prosthesis resulting in symptomatic stenosis or regurgitation.

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III. Transcatheter Pulmonary Valve Implantation (TPVI)

A. Transcatheter pulmonary valve implantation is considered medically necessary for patients with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation including the following indications:
- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation **OR**
- Individuals with native or patched RVOT with at least moderate pulmonic regurgitation **OR**
- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg) **OR**
- Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg)

All other indications are not covered as there is insufficient evidence to support effectiveness.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

Aortic stenosis (AS) is one of the most frequent degenerative valve diseases in developed countries with a prevalence of approximately 5% in individuals over the age of 75 years. The absolute numbers continue to increase with the increase in life expectancy. Aortic stenosis has a long latency period followed by a rapid progression after the appearance of symptoms. It is estimated that up to 2.9% of adults between the ages of 75 and 86 years have severe aortic stenosis, and that the two-year mortality among adults with severe symptoms is as high as 50% (Leon 2010, Rajani 2011, Amonn 2012).

Currently, surgical aortic valve replacement (SAVR) is the treatment of choice in patients with symptomatic severe aortic stenosis in the absence of severe co-morbid conditions. It is the only treatment that has been shown to reduce symptoms and improve functional status and survival in patients with severe aortic stenosis. The conventional surgical aortic valve replacement is performed via sternotomy using cardiopulmonary bypass. The procedure is associated with low operative mortality; however, at least 30% of the patients with severe symptomatic aortic valve stenosis are not suitable candidates for open SAVR due to advanced age, left ventricular dysfunction, concomitant coronary artery disease, and/or other pre-existing conditions. Historically these high surgical risk patients were treated with palliative medical therapy or aortic valve balloon valvuloplasty (BAV) (Leon 2010, Rajani 2011, Amonn 2012, Staubach 2012).

Transcatheter aortic valve replacement (TAVR) has emerged as an alternative minimally invasive treatment option for elderly patients with aortic stenosis who are at high surgical risk. The first transcatheter aortic valve implantation in humans was performed by Alain Cribier in France ten years ago and has developed rapidly and tremendously since then. Over 50,000 patients in 500 European centers have undergone the procedure after two prosthetic valves (Edwards SAPIEN and Medtronic CoreValve) was approved by the Conformité Européenne (CE) in 2007. TAVR involves the insertion of a bioprosthetic aortic valve through a catheter and implanting it within the diseased native aortic valve. Patients are treated off-pump i.e. on a beating heart, and the new prosthesis is implanted within the calcified native valve leaflets that remain in place while being squeezed aside. In most patients the prosthetic valve is inserted through the groin and advanced to the heart using X-ray guidance (retrograde approach). In patients who cannot undergo catheterization of the femoral artery due to vessel disease, the valve can be delivered from the left ventricular apex (antegrade approach) through a small chest incision between the ribs (Amonn 2012, Walther 2012).

Currently, TAVR is indicated for the management of high-risk patients with severe aortic stenosis who are not candidates for open surgical valve replacement. However, some patients are at too high risk even for TAVR, and patient selection plays a crucial role in the success of the procedure. Patients have to be evaluated thoroughly for their risk and anatomical suitability for the procedure. A heart team comprised of clinical cardiologists, cardiac

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surgeons, interventionists, anesthesiologists, geriatricians, and imaging specialists, is essential for the patient selection and performance of the procedure. The collaboration of such a multidisciplinary team is reported to be a key to the success of the procedure and achievement of optimal clinical outcomes (Piazza 2012, Vahanian 2012).

TAVR is not without complications; the increased risk of stroke is a significant safety concern of the procedure. Other major vascular complications, valve embolization, complete heart block, and moderate to severe paravalvular aortic regurgitation have also been reported. In addition, once the transcatheter aortic valve is implanted, it cannot be removed, and may lead to performing other risky procedures. Researchers are investigating different approaches to reduce the occurrence of these TAVR-related complications e.g. through better screening of the candidates for the intervention; refinement of the implantable devices and their delivery systems; improving the techniques in valve sizing and positioning; use of embolic protection devices as cerebral filters, carotid filters, or membrane covering of the carotid ostia; modification of periprocedure and postoperative antiplatelet strategies; use of antiarrhythmic treatment, and others (Vahanian 2012, Cribier 2012).

Over the years, different prostheses have become available for performing TAVR. The Edward SAPIEN (Edwards Lifesciences, Irvine, CA, USA) prosthesis consists of bovine pericardial leaflets mounted on a balloon-expandable cobalt-chromium stent. It is available in 2 sizes (23 mm and 26 mm) and can be inserted by either the retrograde or antegrade approach. The prosthesis was approved by the US Food and Drug Administration in 2011 based on data from the inoperable cohort of PARTNER study, for its use patients with severe aortic stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement, and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis (FDA website). The FDA requested two post-approval studies to assess the long-term safety and effectiveness of the TAVR, as well as adherence to the indication of SAPIEN utilization. Other devices including the COREValve ® (Medtronic, Minneapolis, MN, USA), ACURATE TATM valve, and JenaValveTM, haves received CE approval, but have not been approved by the USA FDA to date.

Medical Technology Assessment Committee (MTAC)

Transcatheter Aortic Valve Replacement (TAVR)

6/18/2012: MTAC REVIEW

Evidence Conclusion:

Conclusion: PARTNER Cohort A showed that transcatheter aortic valve replacement was non-inferior to open heart surgical aortic valve replacement for all-cause mortality at one year in patients with severe aortic stenosis at high-risk of operation. PARTNER Cohort B showed a 19% absolute mortality reduction at one year after transcatheter aortic valve replacement (number needed to treat of 5) when compared to standard medical therapy in patients with severe aortic stenosis and symptoms who are not suitable candidates for surgery. In the two cohorts TAVR was associated with a higher risk of neurological and cardiovascular events. The follow-up duration in the two cohorts of PARTNER may be insufficient to determine long-term safety and durability of the prosthesis, and whether the benefits observed with TAVR will be sustained over time.

Articles: The literature search revealed several publications on the PARTNER trial; another small trial (STACCATO trial); a meta-analysis that pooled the results of 16 heterogeneous studies; and a large number of case series, feasibility studies, and registry data. The pivotal PARTNER trial was selected for critical appraisal. The STACCATO study, a randomized controlled trial conducted on operable elderly patients with aortic stenosis, was not selected for critical appraisal due to its small size and premature termination. The meta-analysis was not reviewed further due to the heterogeneity of studies it included. The following studies were critically appraised:
Leon MB, Smith CR, Mack M, for the PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010; 363:1597-607. See Evidence Table
Smith CR, Leon MB, Mark MJ, for the PARTNER trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med .2011;364:2187-2198.
See Evidence Table

The use of TAVR does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Valve-in Valve Transcatheter Aortic Valve Implantation (VI-TAVI) in Failed Bioprosthetic Aortic Valves [Transcatheter Valve-in Valve Implantation (TAVIV), transcatheter aortic valve in surgical aortic valve (TAV-in-SAV)]

BACKGROUND

Degenerative aortic stenosis is one of the most common and most serious acquired valvular heart diseases among adults. Surgical aortic valve replacement (SAVR) has been the standard treatment for symptomatic severe aortic stenosis for over forty years. SAVR is an open-heart procedure that involves removing the

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diseased aortic valve and replacing it with either a man-made mechanical valve or a biological valve. Mechanical valves are strong and long-lasting, but patients receiving them will need to use a blood thinning medication for the rest of their lives. In the last two decades, there has been a shift toward the use of biological (bioprosthetic) valve implants rather than mechanical valves. These are tissue valves made from human aortic valves (homografts) or more commonly from animal tissue (xenografts). The latter are made from porcine valve leaflets, bovine pericardium, or less frequently from porcine pericardium. Surgical bioprosthesis are commonly stratified into stented and stentless valves. Compared with mechanical valves, bioprosthetic valves are associated with a lower risk of thromboembolic events and do not require long-term anticoagulation. However, these tissue valves have a limited durability, and the majority deteriorates within 10-20 years leading to structural dysfunction. Valve failure may present as stenosis due to calcification, pannus or thrombosis; regurgitation secondary to wear and tear or infection; or as a combination of both stenosis and regurgitation (Seiffert 2010, Bapat 2012, Webb 2013, Dvir 2014).

Treatment of patients with failed bioprosthetic valve is a clinical challenge. Re-operation is considered the standard of care, but a repeat cardiac surgery is associated with high risk of morbidity and mortality, not only of the complexity of the procedure, but also because of the comorbidities and advanced age of the patients who usually need it. The operative mortality for elective redo valve surgery is reported to range from 2-7% and may increase to more than 30% among those at high-risk. Patients who are considered inoperable have no other effective treatment option; supportive medical therapy is associated with poor prognosis, and balloon valvuplasty is not recommended for stenotic bioprosthetic valves due to the high risk of tearing of the leaflets (Seiffert 2010, Bapat 2012, Dvir 2014).

Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI) has become an alternative less invasive treatment modality for patients with severe native aortic valve stenosis who are at high surgical risk due to advanced age, significant comorbidities, frailty, prior chest radiation and other factors. The current widespread use and success of TAVI in high-risk patients together with the major complications of redo aortic valve surgery in these patients; have led to considering the valve-in-valve TAVI (VIV-TAVI) (also referred to as TAV-in-SAV) approach as an option for patients with degenerated failed bioprosthetic heart valve. TAVI is performed with a beating heart and avoids the risks associated with using cardioplegia and cardiopulmonary bypass during redo surgery. Currently, the main transcatheter valves used for valve-in-valve procedures are the Edwards SAPIEN or SAPIEN XT (Edwards Lifesciences, Irvine, California), and the CoreValve (Medtronic, Minneapolis, Minnesota) (Eggebrecht 2011, Linke 2012, Dvir 2014).

Edwards SAPIEN XT Transcatheter Heart Valve (SAPIEN XT THV) system consists of a transcatheter aortic valve and the accessories used to implant it. The valve is made of cow tissue attached to a balloon-expandable, cobalt-chromium frame for support, and comes in three sizes: 23 mm, 26 mm, and 29 mm. The valve is compressed and placed on the end of a balloon catheter, which is then inserted through either the femoral artery or a small cut between the ribs and advanced through the blood vessels until it reaches the failed valve. The SAPIEN XT valve is then expanded with the balloon until it anchors to the failed valve (valve-in-valve). Once the new valve is in place, it opens and closes properly, allowing the blood to flow in the correct direction. According to the FDA The Edwards SAPIEN XT THV is indicated for patients with symptomatic heart disease due to either severe native calcific aortic stenosis, or more recently (in 2015) due failure of a surgical bioprosthetic aortic valve who are judged by a heart team to be at high or greater risk for open surgical therapy (i.e. Society of Thoracic Surgeons operative risk score ≥8% or at a ≥15% risk of mortality at 30 days). It is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen, have a mechanical artificial aortic valve, or have active bacterial endocarditis or other active infections in the heart or elsewhere (FDA and the manufacturer's webpages).

The CoreValve system consists of a catheter-based artificial aortic heart valve and the accessories used to implant it. The valve is made of pig tissue attached to a flexible, self-expanding, nickel-titanium frame for support. The CoreValve is compressed and placed on the end of a delivery catheter, which is then inserted through the femoral artery. If the femoral arteries are not suitable, the valve can be inserted through other arteries or through the aorta. The catheter is pushed through the blood vessels until it reaches the diseased aortic valve. The valve is then released from the catheter, expands on its own and anchors to the diseased valve. The CoreValve functions the same as a normal valve, allowing the blood flow in the correct direction. The CoreValve System had been previously approved by the FDA to treat patients whose native aortic valve has become severely narrowed as a result of calcium buildup and who are considered to be at "extreme risk" or "high risk" for surgical aortic valve replacement. In March 2015 the FDA expanded the use of CoreValve system for aortic valve-in valve replacement inpatients who need replacement of a failed tissue aortic valve but are at extreme or high risk of death or serious complications from traditional open-heart surgery based on the
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judgement of a heart medical team. The CoreValve System use is contraindicated in patients with a mechanical aortic heart valve, have any infection, cannot tolerate blood thinning medicines; or have sensitivity to titanium or nickel or contrast media (FDA News Release March 30, 2015).

Reported adverse events with of VIV-TAVI include death, stroke, acute kidney injury, myocardial infarction, major bleeding, and the need for a permanent pacemaker. Other limitations associated with VIV-TAVI are the increase risk of coronary obstruction (especially in patients with stentless valves); high residual gradients which may result from under expansion of the result transcatheter heart valve in smaller surgical bioprothesis; and paravalvular leaks between the surgical and transcatheter valves. Successful outcome of the VIV procedure is thus dependent on patient selection, knowledge of prior cardiac surgery, internal diameter and material of the degenerated bioprosthetic valve as well as mode of valve failure, anticipation of complication, procedural planning, and experience of the cardiac team with TAVI (Bapat 2012, Webb 2013, Verhoye 2015, Phan 2016)

In 2015, the US Food and Drug administration (FDA) expanded the approved use of the SAPIEN XT (Edwards Lifesciences) and CoreValve System (Medtronic) to include "valve-in-valve" repair in patients who failed surgical bioprosthetic heart and are at high or extreme risk for complications associated with traditional open-heart surgery.

06/20/2016: MTAC REVIEW
Evidence Conclusion:
Conclusion:

- There is fair evidence from a number of observational studies that valve-in-valve implant in a failed aortic prosthetic valve is feasible and relatively safe.
- There is insufficient direct evidence to determine whether the outcomes of valve-in-valve implantation in a failed aortic prosthetic valve are equivalent or superior to the outcomes of a redo conventional operation to replace the valve.
- There is insufficient published evidence to determine the long-term efficacy and durability of valve-in-valve implant in a failed aortic prosthetic valve.

Articles: The literature search for studies on valve-in-valve transcatheter aortic valve replacement in high risk patients with failed bioprosthetic valves identified a number of observational studies and case series from single institutions as well as registries for patients receiving a VIV-TAVI in various countries (Canadian registry, German registry, Italian registry, Germany/Switzerland registry, and a global registry that collects data form more than 60 countries worldwide). A recent systematic review with meta-analyses (Chen 2016) pooled the results of studies reporting on clinical outcomes of transcatheter VIV in failed surgical bioprosthetic aortic and mitral valves. Two other systematic reviews (with no meta-analyses) that summarized the results of studies on VIV-TAVI published through July 2014 were also identified (Tourmousoglou, et al, 2015, and Raval et al, 2014). To date, there are no published randomized controlled trials that directly compared the VIV-TAVI to surgical reoperation in patients with failed bioprosthetic aortic valves. The search identified a recent systematic review and meta-analysis (Phan, et al, 2016) that indirectly compared VIV-TAVI versus surgical valve redo operation (i.e. TAV-in-SAV versus SAV-in-SAV), and Erlebach et al, 2015 study that compared retrospective data on postoperative outcomes for patients with failing bioprosthetic valve who received a VIV-TAVI or underwent a redo aortic surgery in a single center in the period from January 2001 through October 2014. The two United States pivotal studies that were the basis of the FDA approvals of the systems are not published to data but are available at the FDA website. The meta-analysis that pooled the results of the cohort studies on VIV-TAVI and the analysis that compared VIV-TAVI with reoperation, as well as the global VIVID registries and the two pivotal studies submitted to the FDA were selected for critical appraisal. Chen HL, Liu K. Clinical outcomes for transcatheter valve-in-valve in treating surgical bioprosthetic dysfunction: A meta-analysis. *Int J Cardiol*. 2016 Mar 18; 212:138-141. (See Evidence Table 1)
Phan K, Zhao DF, Wang N, et al. Transcatheter valve-in-valve implantation versus re-operative conventional aortic valve replacement: a systematic review. *J Thorac Dis.* 2016 Jan; 8 (1): E83-93. (See Evidence Table 2)
Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA. 2014 Jul; 312(2):162-170. (See Evidence Table 3).

The use of Valve-in Valve Transcatheter Aortic Valve Implantation does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

01/13/2020: MTAC REVIEW
Evidence Conclusion:

- Overall the results of the two pivotal RCTs (PARTNER 3 and Evolut Low Risk trial) that compared the outcomes of TAVR with those of SAVR in low-surgical risk patients with

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severe aortic stenosis (excluding those with a bicuspid valve) show that TAVR is non-inferior to surgical valve replacement with respect to the primary composite endpoint as defined in each trial. PARTNER 3 trial defined the primary endpoint as a composite of death from any cause, stroke, or rehospitalization at 1 year after the procedure, while Evolut Low Risk trial defined it as a composite of all-cause mortality or disabling stroke in TAVR vs. SAVR at 24 months.

- PARTNER 3 trial is the only published trial, to date, that suggests that TAVR is superior to SAVR in reducing the composite rate of death from any cause, stroke, or rehospitalization at 1-year in low-surgical risk patients with severe aortic stenosis. However, there was no significant difference between the two procedures when each of the components was considered individually.
- The published results of Evolut Low-Risk trial are for interim analysis; the 1-year and 2-year event rates were derived from estimates not true observed incidence.
- Meta-analyses pooling the results of the two pivotal trials with NOTION study and with or without SURTAVI/low risk showed conflicting results: Anantha-Narayana et al's analysis showed that all-cause mortality was significantly lower with TAVR at 30 days, but not with long-term follow-up, Al-Abdouh et al, also found no statistically significant difference between TAVR and SAVR in all-cause mortality at one year, while Kolte et al's analysis showed a significantly lower rate of all-cause mortality at one year with TAVR vs. SAVR.
- The overall 1-year results of trials in low-risk patients indicate that compared to surgery, TAVR is associated with significantly lower risk of stages II &III acute kidney injury, new onset atrial fibrillation and life threatening or disabling bleeding. However, it is associated with a statistically significant higher risk of the need for permanent pacemaker implantation, and moderate -severe paravalvular leak compared to SAVR.
- The trials had strict legibility criteria that may limit generalization of their results.
- There is no long-term follow-up data from large RCTs to determine the long-term efficacy and safety of TAVR, the performance and durability of the TAV, potential formation of subclinical leaflet thrombosis, and long-term difference between the surgical and transcatheter valves with respect to their durability and structural degeneration.
- To date the only published long-term follow-up data is provided by the 5-year results of NOTION trial that shows no difference between TAVR and SAVR in the composite primary endpoint of all-cause mortality, stroke or myocardial infarction in mostly low surgical risk patients. The trial was small, and the lack of statistically significant differences does not indicate that the two interventions are equivalent. In addition, the study used the first generation CoreValve as well as earlier SAVR techniques, which may limit generalization of the results.
- The rapid progress in technology and continuous improvements in the design of the devices as well as the surgical and implant techniques, would be a common limitation for the pivotal studies with planned 10-year follow-up, as well as any other interventional study with 5-10 years follow-up duration.

Articles: The literature search revealed the recently published trials: PARTNER 3 trial, Evolut Low Risk trial, and the 5-year follow-up of NOTION trial, as well as 3 meta-analyses of RCTs comparing TAVR vs SAVR in low-risk patients with symptomatic severe aortic stenosis. Three other meta-analyses identified by the search pooled the results of RCTs and observational studies on TAVR for patients with low-intermediate risk. The PARTNER 3 and Evolut Low Risk trials were selected for critical appraisal. The NOTION trial and the three meta-analyses of trials in low-risk patients were summarized. The meta-analyses including observational studies and /or trials on intermediate- risk patients were excluded. See Evidence Table.

The use of Transcatheter aortic valve replacement (TAVR) for low-surgical risk patients with aortic valve stenosis does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Transcatheter aortic valve replacement (TAVR/TAVI)

CPT®	Description

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Codes	
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

Transcatheter pulmonary valve implantation (TPVI)

CPT® Codes	Description
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
07/03/2012	07/03/2012[MDCRPC], 05/07/2013[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 09/02/2016[MPC], 04/04/2017[MPC], 06/05/2018[MPC] ,06/04/2019 [MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	06/01/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2015	Changed ejection fraction from >15% to >20%
03/01/2016	Added two indications to criteria
08/02/2016	Added MTAC review for Valve-in Valve Transcatheter Aortic Valve Implantation
09/06/2016	New policy for Valve-in-Valve Implantation was adopted
04/04/2017	Added indication for TAVR to clarify risk score and the ability for 2 cardiac surgeons to override risk scoring
12/03/2019	MPC approved to adopt the updated Medicare indication requiring one cardiologist and one interventional cardiologist for commercial members, however KPWA will retain the high-risk restriction.

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02/04/2020	MPC approved to adopt clinical indications for Transcatheter Pulmonary Valve Implantation
03/03/2020	MPC approved to endorse coverage policy for TAVR for low-surgical risk patients with aortic valve stenosis. Added January 2020 MTAC review.
05/05/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 9/1/2020.
06/01/2021	Retitled to include TPVI.

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Clinical Review Criteria

Transition of Care

- Requests by new enrollees for continuing care with Providers outside of the member's Kaiser Permanente Health Plan Network
- Continuing inpatient coverage for terminating Kaiser members while currently hospitalized

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Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

No Medicare regulation mandates ongoing coverage with former non-network provider for new members joining Kaiser Permanente Medicare Advantage plans, other than for inpatient hospital stays or hospice care (see below).

Source	Policy
Code of Federal Regulations (CFR	*42 CFR § 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.* *42 CFR § 422.320 Special rules for hospice care.*
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None

For Non-Medicare Members (HMO Only)

No Washington State RCW or WAC applies to new members joining Kaiser Permanente, in reference to transition of care.

This document applies to members who are inpatient status at the time of enrollment or at the time of disenrollment***
This document does not apply to existing KPWA members whose provider's contract has been terminated – see Continuity of Care Policy

Members joining Kaiser Permanente PPO or POS plans may continue to see former providers using their out of network benefit.

Criteria

A. Continued coverage for new HMO and Medicare Advantage HMO enrollees with a non-network provider may be covered ***at the discretion*** of the health plan when **all of the following** criteria are met:

1. Has completed a Transition of Care request form within 30 days of enrollment in a Kaiser Permanente plan (only required for new enrollees).
2. The most recent documentation of care provided by the treating practitioner/clinic must be provided and support need for ongoing care.
3. The member is undergoing an active** course of treatment for a chronic or acute medical condition with this requested provider. In this circumstance, the member may be permitted to receive coverage until the acute phase is resolved or up to 30 days whichever is shorter.

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4. Discontinuity could cause a recurrence or worsening of the condition under treatment and interfere with anticipated outcomes, based on clinical notes and KPWA Medical Director's clinical judgment.

B. ***Members currently in the hospital when *joining* KPWA

1. The hospital stay prior to joining KPWA is the financial responsibility of the prior insurance or the patient.
2. KPWA will cover medically necessary hospital stays starting day of enrollment (for non-Medicare patients only)
3. At KPWA discretion, patient may be transferred to in-network hospital

C. ***Members currently in the hospital when *terminating* KPWA Coverage
Per EOC language effective thru December 31, 2022

1. Member who is receiving Covered Services in a hospital on the date of termination shall continue to be eligible for Covered Services while an inpatient for the condition which the Member was hospitalized, until one of the following events occurs:
   - According to KFHPWA clinical criteria, it is no longer Medically Necessary for the Member to be an inpatient at the facility.
   - The remaining benefits available for the hospitalization are exhausted, regardless of whether a new calendar year begins.
   - The Member becomes covered under another agreement with a group health plan that provides benefits for the hospitalization.
   - The Member becomes enrolled under an agreement with another carrier that provides benefits for the hospitalization.
2. This provision will not apply if the Member is covered under another agreement that provides benefits for the hospitalization at the time coverage would terminate, except as set forth in this section, or if the Member is eligible for COBRA continuation coverage.

D. As an exception, pregnancy related services: If the member is at 32 weeks or beyond in their pregnancy at the time of their enrollment with Kaiser Permanente. In this case, the member will be permitted to receive continued coverage with her previously established obstetric provider for the remainder of her pregnancy through the postpartum period (six weeks after the delivery date).

E. Outpatient Prescription Drugs
Within 90 days of enrollment, members may fill up to a 30-day supply of medication, including nonformulary drugs and with waiver of Kaiser Permanente's step therapy and prior authorization requirements. This 30-day supply does not include excluded drugs and specialty products and does not override quantity limits that are in the place for quality or safety reasons.

An active course of treatment is defined as a program of planned services to correct or treat a diagnosed condition for a defined number of services or treatment period until care is completed or a transfer of care with relevant clinical information required to ensure continuity can be initiated.**

The following situations will be directed to an in-network provider:

1. Scheduled elective procedure following enrollment to a Kaiser Permanente plan
2. Physical examination
3. Elective service and procedures
4. Second opinion evaluations
5. Home care services
6. Routine monitoring of a chronic condition

The above criteria do not include routine monitoring for a chronic condition.

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Background

Transition of Care for New Enrollees: The criteria were developed to promote consistency in identifying the clinical situations where the practitioner may continue to provide care for a Kaiser Permanente enrollee for the time required to complete the course of treatment. Kaiser Permanente will assist members in planning for continued care in selected case-specific situations where the member is changing from another health plan to a Kaiser Permanente plan.

Date Created	Date Reviewed	Date Last Revised
12/19/2001	07/6/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC], 11/05/2013[MPC], 09/02/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC]	02/01/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/04/2015	MPC approved to merge policies to speak to continued coverage with a non-network provider. It is compliant with NCQA and Medicare regulations for transition of care.
01/11/2016	Added Medicare link
02/07/2017	MPC approved to adopt minor changes to criteria to specify **Outpatient** Mental Health Services & approval for no more than **3 visits** within 30 days.
04/04/2017	Added indication to clarify this policy only applies to HMO members receiving outpatient care
04/07/2020	Added additional language per WAC 284-170-360, regarding continuing primary care for Access PPO and POS members when a network provider is termed with no cause.
01/05/2021	MPC approved the changes related to Pregnancy services to include the member is at 32 weeks or beyond in their pregnancy at the time of their enrollment with Kaiser Permanente or at the time their provider changes network status. Requires 60-day notice, effective date 06/01/2021.
02/01/2022	MPC approved updates to the Transition of Care Policy that is specific for members who are new enrollees for continuing care with Providers outside of the member's Kaiser Permanente Health Plan Network and as well as guidance on continuing inpatient coverage for terminating Kaiser members while currently hospitalized.

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Clinical Review Criteria
Treatments for Obstructive Sleep Apnea

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4)
Local Coverage Determinations (LCD)	Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) Oral Appliances for Obstructive Sleep Apnea (L33611) Surgical Treatment of Obstructive Sleep Apnea (OSA) (L34526) Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38312)
Local Coverage Article	Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article (A52467) Oral Appliances for Obstructive Sleep Apnea (A52512) Surgical Treatment of Obstructive Sleep Apnea (OSA) (A56905) Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A57949)
Kaiser Permanente Medical Policy	For services that are not covered by the above NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Treatments of Obstructive Sleep Apnea for Mandibular Advancement Surgery” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Treatment	Criteria Used
Positive Airway Pressure Devices	Has one of the following indications: 1) AHI of 15 events or greater per hour 2) AHI between 5 and 15 events per hour with documented excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke. 3) A Sleep Apnea Clinical Score (SACS) greater than 15 and meets all of the following: a) Completed a baseline Stanford Sleepiness Score b) Completed a 3-night auto titration PAP c) Reported one of the following: i) A positive response to initial auto titration* ii) A negative response to initial auto titration but has completed a polysomnography test and met either of the two initial criteria above. **If there is a positive response to initial auto titration, subsequent polysomnography*

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Treatment	Criteria Used
	is only covered if documentation in the medical records indicates the study is medically necessary. The AHI (Apnea-Hypopnea Index) is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (not projected or extrapolated). Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. Respiratory disturbance index is a term previously used for the measure to determine eligibility for PAP. It used the same parameters as the AHI. The more current term is AHI. Because some coverage requests are received with an RDI, the definition is included to help reviewers.
Hypoglossal Nerve Stimulation, Implantable	Kaiser Permanente has elected to use the Hypoglossal Nerve Stimulation, Implantable (A-0973) MCG* for medical necessity determinations. This service is not covered per MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea **Pillar Implants for Obstructive Sleep Apnea and Snoring** **Oral pressure therapy (OPT) for the treatment of obstructive sleep apnea**	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Laser Treatments for Snoring and OSA	**Please see clinical criteria:** Laser Treatments for Snoring
Maxillo-mandibular Advancement Surgery for Sleep Apnea **Geniohyoid Advancement Myotomy Combined with Hyoid Re-Suspension**	Kaiser Permanente has elected to use the Maxillomandibular Osteotomy and Advancement Surgery (A-0248) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • For sleep related issues, please send initial sleep study and all follow up notes. • For congenital malformation, submit all cranial facial clinic notes (oral surgeon, ENT, Orthodontist)
Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea	Medical Necessity review is not required for this service.

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The MCG Manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

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Background

Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive sleep apnea syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also has mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone.

Patients with primary snoring have an apnea-hypopnea index of fewer than five events per hour and no complaints of daytime sleepiness. Snoring is believed to be caused by loss of tissue integrity of the soft palate. Because tissues lack support, they stretch and collapse as muscles relax during sleep. This results in a narrowed airway and causes the soft palate to vibrate, causing snoring sounds. Primary snoring can be socially disruptive but is not harmful to the health of the patient.

There has been increasing recognition of a continuum of sleep disordered breathing disorders, ranging from simple snoring to obstructive sleep apnea (OSA). OSA refers to recurrent episodes of breathing cessation during sleep due to mechanical blockage of the airway. The diagnosis of OSA requires a minimum of 30 episodes of apnea, each lasting at least 10 seconds, during 6-7 hours of sleep. OSA patients are generally obese and the cardinal symptom is excessive daytime sleepiness. Upper airway resistance syndrome (UARS), a term first used in 1993, is a form of sleep-disordered breathing that is also associated with daytime sleepiness. Patients do not meet diagnostic criteria for OSA and are generally non-obese. Recent investigations suggest that UARS may have different pathophysiology than OSA, for example UARS patients may have increased airway collapsibility and craniofacial abnormalities. Common polysomnographic findings for UARS include apnea-hypopnea index (AHI) <5, minimum oxygen saturation >92%, increase in alpha rhythm and a relative increase in delta sleep (Bao & Guilleminault).

Continuous Positive Airway Pressure (CPAP) is widely used as first-line therapy for UARS, although there is a lack of high-grade evidence supporting its effectiveness. CPAP is also often used as a tool to diagnose UARS by seeing whether patients respond to a trial of CPAP treatment. Other treatment alternatives include oral appliances, septoplasty and radiofrequency reduction of enlarged nasal inferior turbinates. Classic surgical procedures used for OSA are considered by many clinicians to be too aggressive for treatment of UARS (Bao & Guilleminault).

Other methods of treating snoring and OSA include weight loss, nasal continuous positive airway pressure (CPAP), laser-assisted uvula palatoplasty (LAUP), uvulopalatopharyngoplasty (UPPP) and radiofrequency tissue ablation. Disadvantages of the surgical procedures are that they can be painful and are often associated with side effects. Radiofrequency ablation generally requires multiple treatment sessions.

A **CPAP** is defined as a device that provides constant air pressure to keep the airway open and allows patients to breathe unassisted. It is prescribed for patients with obstructive sleep apnea. The immediate clinical effectiveness of CPAP for patients with obstructive sleep apnea is well documented.

There are currently more than 35 different oral appliances on the market for OSA and/or snoring. The most widely used type of oral device is **mandibular advancement devices (MAD)** which act to keep the pharyngeal airspaces open by moving the mandible forward by advancing or downwardly rotating the mandible (Schoem, 2000).

Hypoglossal nerve stimulation is a new treatment for obstructive sleep apnea (OSA). It addresses the issue of tongue prolapse into the pharynx which causes airway blockage. Tongue prolapse may be due to decreased neuromuscular activity in the genioglossus muscle, the principal tongue protrusion muscle. Electrical stimulation

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of the hyoglossus muscle my result in activation of the genioglossus muscle, increasing tongue protrusion and opening the pharynx (Eisele, 1997).

A review article published in 1999 (Loube) mentioned that there is a multicenter clinical trial underway on the feasibility of a hypoglossal nerve stimulator (Inspire system; Medtronic), but that the trial has been slowed due to technical issues. The most recent entry on hypoglossal nerve stimulation on the Medtronic Web site was in 1997.

A **new nasal expiratory positive airway pressure device** (Provent® Sleep Apnea Therapy, Ventus Medical Inc.) has recently been approved by the FDA for the treatment of OSA. The Provent® Sleep Apnea Therapy device is a disposable, nightly-use device that consists of a one-way valve surrounded by a ring of soft foam. The device is placed just inside the nostrils and is held in place with adhesive. It works by limiting the airflow out of the nose during expiration, which increases pressure in the upper airway to keep it open for subsequent inspiration. During inspiration, the patient breaths freely through the nose and/or mouth (Kaiser 2010).

The **Pillar Palatal Implant System** (Restore Medical; St Paul, MN) is a treatment option for snoring and obstructive sleep apnea (OSA). Three implants made of braided polyester filaments are placed in the soft palate to help stiffen the soft palate and increase structural integrity. The implant system also includes a disposable delivery tool that is used for positioning and placement of the implant. Pillar implants are inserted during a single office visit under local anesthesia.

Evidence and Source Documents

CPAP
Hypoglossal Nerve Stimulation
Nasal Expiratory Positive Airway Pressure Device
Pillar implants for obstructive sleep apnea and snoring
Oral pressure therapy (OPT) for the treatment of obstructive sleep apnea
Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea
Maxillomandibular Advancement Surgery for Sleep Apnea
Laser Treatments for Snoring and Sleep Apnea

Medical Technology Assessment Committee (MTAC)

Positive Airway Pressure Device (CPAP)

BACKGROUND
The criteria set previously used by Kaiser Permanente (from 1/1/92 through 3/96) were a direct adoption of the Medicare criteria. Changes in testing equipment have made it possible to test with greater specificity in a shorter testing period. In addition, many tests are now done using a split study, which uses half the test time for actual testing, and the other to titrate the most beneficial CPAP fit to affect the apnea previously documented. Since most of the Kaiser Permanente coverage contracts include a benefit for coverage of CPAP devices at 50-80% level, the existing criteria were reviewed and modified to allow for shorter testing periods and use of the in-home testing. Throughout 1996 and 1997 with experience in managing sleep anomaly cases, a new patient population has been identified that would benefit from the use of CPAP: The Upper Airway Resistance Syndrome (UARS). Dr. Jim DeMaine requested in April 1998 that the criteria be expanded to allow use of CPAP in such cases. Although there is no clinical evidence of benefit for such treatment, there is significant expert opinion and practice that would support such a change in the criteria. In addition, Kaiser Permanente Northwest has decided to cover CPAP for UARS as long as the patient has durable medical equipment coverage (DME). While the Kaiser Permanente plan criteria were modified in May 1998 to allow inclusion of UARS patients, this is not true for the private Medicare patients seen by Kaiser Permanente providers. It is still important to check coverage before ordering this treatment option so that the patient understands the financial obligation represented by the treatment option selected. A CPAP is defined as a device that provides constant air pressure to keep the airway open and allows patients to breathe unassisted. It is prescribed for patients with obstructive sleep apnea. The immediate clinical effectiveness of CPAP for patients with obstructive sleep apnea is well documented. REFRENCES Fairbanks, David N.F., Fairbanks, David W.: Obstructive Sleep Apnea: Therapeutic Alternatives. American Journal of Otolaryngology. 13: 265-270, 1992. Effective treatment of Obstructive Sleep Apnea is contingent on the establishment of a correct diagnosis and the identification of pathophysiologic conditions affecting the upper airway. CPAP is a forceful stream of air delivered to the collapsible oropharyngeal airway acting as a splint to keep the airway open. Almost all OSA patients can benefit from this treatment except those with obstructed nasal airways. Short-term compliance is 90%. Long-term compliance (2-4 yr.) is 50 - 80%. Over 300 devices are patented as “anti-snore” remedies: chin strap, whip-lash type collar, psychological conditioning devices, custom

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made orthodontic devices, and the tongue retaining device are examples of a few. Most of these have not been proven efficacious for sleep apnea. Surgical treatments include nasal surgery (often disappointing as a solitary treatment for severe OSA), uvulopalatopharyngoplasty, UPPP (Highly effective, 80-90%, for simple snoring in young patients, but if bulky tongue, receding chin, nasal airway obstruction, or pronounced obesity exists it is less effective a single therapy), mandibular-maxillary advancement phase 1 and 2 (97% when combined with UPPP and nasal surgery), tongue surgery (limited studies but results are promising), and tracheostomies (most successful treatment but has been almost entirely replaced by CPAP). Watson, Robert K., Thompson, A. Siobhan: Treatment Outcome of Sleep Apnea. CONN Med. 56: 125-129, 1992.101 patients. Interviewed over 12-24-month period. CPAP most often treatment used with results of improved daytime alertness (84%). Patients with moderate OSA often had surgery which led to 85% improved daytime sleepiness, and patients with mild OSA were treated with sleep position change and weight loss with 64 - 66% improved daytime alertness. Kryger, Meir: Management of Obstructive Sleep Apnea. Clinics in Chest Medicine 13: 481-492, September 1992 Diagnosis with increased risk of death (chronic respiratory failure or obtundation) the patient should be hospitalized and monitored in ICU. Do Dx Sleep Study ASAP. O2 treatment may result in severe CO2 retention. If severe OSA Dx -- treat with urgent CPAP therapy. Mechanical ventilation recommended for patients with hypercapnia that are difficult to arouse or obtunded. BiPAP is used when all night treatment with CPAP is found to be ineffective. ATS Board of Directors: Indications and Standards for Use of Nasal Continuous Positive Airway Pressure (CPAP) in Sleep Apnea Syndromes. American Journal of Respiratory Critical Care Medicine 150: 1738-1745, 1994 Indications for CPAP: Effective in the treatment of patients with clinically important obstructive sleep apnea/hypopnea syndrome. Treatment is indicated when there is documented sleep-related apnea/hypopnea and evidence of clinical impairment. CPAP may be effective in the treatment of patients with clinically significant Cheyne Stokes respiration or central apnea with clinical impairment. Limited data to substantiate the later. CPAP is not routinely indicated in individuals with simple snoring that is not associated with pauses in respiration or with clinical impairment. CPAP is a safe, effective for therapy with rare contraindications. Relative contraindications include patients with bullous lung disease and recurrent sinus or ear infections. There are no absolute contraindications. Greater than 5-10 episodes of apnea or hypopnea per hour is considered beyond the board limits of normal. Strollo, Patrick J. and Rogers, Robert M.: Obstructive Sleep Apnea. The New England Journal of Medicine 334: 99-104, 1996 Affects 2-4% of middle age adults.
Positive airway pressure, delivered through mask, is the initial treatment of choice in clinically important sleep apnea. The following are conditions associated with the varieties of Sleep Apnea:
Obstructive Sleep Apnea: Cessation of airflow for greater than or equal to 10 seconds despite continued ventilatory effort. 5 or more episodes per hour Usually associated with a decrease of greater than or equal to 4% in oxyhemoglobin saturation. Obstructive sleep hypopnea: Decrease of 30-50% in airflow for greater than or equal to 10 seconds 15 or more episodes per hour of sleep May be associated with a decrease of greater than or equal to 4% in oxyhemoglobin saturation. Upper-airway resistance: No significant decrease in airflow (snoring is usual) 15 or more episodes of arousal per hour of sleep No significant decrease in oxyhemoglobin saturation Features Common to all three: Arousal associated with increasing ventilatory effort (as measured by esophageal balloon) Excessive daytime sleepiness Sleep 1996 Nov; 19(9 Suppl):S101-S110, Management of simple snoring, upper airway resistance syndrome, and moderate sleep apnea syndrome. Levy P, Pepin JL, Mayer P, Wuyam B, Veale D; Sleep and Respiration Unit, Grenoble University hospital, France. The spectrum of respiratory sleep disorders has been extended in the last years to include conditions that are less well defined than severe obstructive sleep apnea (OSA). Moderate OSA< snoring, and upper airway resistance syndrome (UARS) represent three clinical questions. Therefore, the therapeutic approach remains unclear. We have tried to define these entities and to review the respective indications and efficacy of pharmacological treatment, weight loss, sleep posture, oral appliances, upper airway surgery, and finally, continuous positive airway pressure (CPAP). From these data, we also aim to define strategies of treatment for moderate OSA, snoring, and UARS. However, these conditions are likely to be particularly appropriate for randomized trials comparing different modalities of treatment that may be the only way to validate these treatment strategies. Sleep1993 Aug; 16(5):403-408, Significance and treatment of non-apneic snoring. Strollo PJ Jr, Sanders MH, Wilford Hall Medical Center, Lackland Air Force Base, Texas. Snoring has been associated with an increased risk of vascular morbidity and mortality and with the complaint of excessive daytime sleepiness. Much of this risk may be attributable to concomitant sleep apnea or hypopnea. Recent work suggests that in certain individuals, snoring without apnea or hypopnea can lead to sleep disruption. This appears to be due to augmented ventilatory effort in response to an increased “internal” resistive load that results in repetitive arousals from sleep. This condition has been termed the upper airway resistance syndrome (UARS). Identification of load-related arousals in patients with the UARS may require the addition of esophageal pressure monitoring to the diagnostic polysomnogram. Nasal continuous positive airway pressure (CPAP) effectively eliminates snoring, hypopnea and apnea and, therefore, may be useful in treating this form of sleep-disordered breathing. The diagnostic criteria and indications, if any, for chronic treatment of these non-apneic snorers with nasal CPAP as well as long-term compliance remain to be determined.

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Sleep Apnea: Hypoglossal Nerve Stimulation

BACKGROUND

Hypoglossal nerve stimulation is a new treatment for obstructive sleep apnea (OSA). It addresses the issue of tongue prolapse into the pharynx which causes airway blockage. Tongue prolapse may be due to decreased neuromuscular activity in the genioglossus muscle, the principal tongue protrusion muscle. Electrical stimulation of the hyoglossus muscle my result in activation of the genioglossus muscle, increasing tongue protrusion and opening the pharynx (Eisele, 1997). A review article published in 1999 (Loube) mentioned that there is a multicenter clinical trial underway on the feasibility of a hypoglossal nerve stimulator (Inspire system; Medtronic), but that the trial has been slowed due to technical issues. The most recent entry on hypoglossal nerve stimulation on the Medtronic web site was in 1997.

08/08/2001: MTAC REVIEW
Sleep Apnea: Hypoglossal Nerve Stimulation
Evidence Conclusion: There is insufficient evidence on which to base conclusions about the effect of hypoglossal nerve stimulation on health outcomes associated with obstructive sleep apnea.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There was one empirical article on hypoglossal nerve stimulation. This was a small case series which included only 5 patients with sleep apnea (also included were 15 patients that were undergoing a surgical procedure involving the neck). Because of the small number of sleep apnea patients and a dearth of clinical outcomes, this study was not reviewed.

The use of hypoglossal nerve stimulation in the treatment of sleep apnea does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

07/08/2019: MTAC REVIEW
Hypoglossal Nerve Stimulation
Evidence Conclusion:

- Although hypoglossal nerve stimulation surgery with the implantable device Inspire improves AHI, ODI, FOSQ, ESS in patients with moderate-to-severe obstructive sleep apnea (OSA) who failed or intolerant to CPAP, the evidence is insufficient to draw conclusions on its effectiveness and safety.
- Comparative studies with higher quality are warranted.

Articles: PubMed was searched from inception through April 23, 2019 with the following search terms (Hypoglossal OR (upper AND airway)) AND (neurostimulation OR neurostimulator OR stimulation OR stimulator OR inspire)) AND ((obstructive sleep apnea OR sleep apnea) OR (sleep AND apnea)). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. PubMed search was performed for the comparison between hypoglossal nerve stimulation and uvulopalatopharyngoplasty or mandibular advancement devices or maxillomandibular advancement surgery or preimplantation measures. See Evidence Table.

The use of the Hypoglossal Nerve Stimulation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea

BACKGROUND

Obstructive sleep apnea (OSA) is a relatively common disorder that is characterized by recurrent episodes of complete (apnea) or partial (hypopnea) upper airway obstruction during sleep, with recurrent arousals and sleep fragmentation. Patients with OSA often experience daytime sleepiness, fatigue, or poor concentration, and have signs of sleep disturbance such as snoring and restlessness. If untreated OSA is associated with an increased risk of hypertension, cardiovascular complications, diabetes, and motor vehicle accidents (Balk 2012). A new nasal expiratory positive airway pressure device (Provent® Sleep Apnea Therapy, Ventus Medical Inc.) has recently been approved by the FDA for the treatment of OSA. The Provent® Sleep Apnea Therapy device is a disposable, nightly-use device that consists of a one-way valve surrounded by a ring of soft foam. The device is placed just inside the nostrils and is held in place with adhesive. It works by limiting the airflow out of the nose during expiration, which increases pressure in the upper airway to keep it open for subsequent inspiration. During inspiration, the patient breaths freely through the nose and/or mouth (Kaiser 2010).

10/16/2012: MTAC REVIEW
Nasal Expiratory Positive Airway Pressure for Obstructive Sleep Apnea

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Evidence Conclusion: In 2010, Kaiser reviewed the safety and efficacy of a nasal EPAP device. Based on data from two case-series, Kaiser concluded that there was insufficient evidence to determine whether the device is a medically appropriate treatment for obstructive sleep apnea (Kaiser 2010).
A recent randomized controlled trial (RCT) evaluated the safety and efficacy of a nasal EPAP device compared to a sham device in 250 subjects with newly diagnosed or previously untreated obstructive sleep apnea. Polysomnography was performed on 2 non-consecutive nights (random order: device-on, device-off) at week1 and after 3 months of treatment. Results from this study suggest that after 3 months patients using the EPAP device had significantly greater improvements in Apnea Hypoxia Index (AHI) compared to the sham group. Adherence to treatment was determined by self-report and was approximately 88% in the EPAP group and 92% in the sham group. The most common device related adverse events were nasal congestion, nasal discomfort, dry mouth, exhalation difficultly, and discomfort with the device. There was no serious device related adverse events. This study had several limitations: power was not assessed, the intent to treat analysis did not include all randomized patients, results are not generalizable to previously treated patients, and the study was funded by the manufacturer (Berry 2011).

AHI results at week 1 and month 3 (Berry 011)

	EPAP		Sham		
	Device-off	Device-on	Device-off	Device-on	P-value*
	Median (25th to 75th quartiles)				
Week 1	13.8 (5.3 to 22.6)	5.0† (1.7 to 11.6)	11.1 (4.8 to 21.8)	11.6 (4.0 to 21.0)	<0.001
Month 3	14.4 (5.5 to 21.4)	5.6† (2.1 to 12.5)	10.2 (3.4 to 19.3)	8.3 (4.2 to 20.6)	<0.001

*P-value (EPAP vs. Sham).
†P<0.001 EPAP device-on vs. EPAP device off.

Conclusion: Results from an RCT that compared the safety and efficacy of a nasal EPAP device compared to a sham device found that after 3 months of use patients using the EPAP device had significantly greater improvements in Apnea Hypoxia Index (AHI) compared to the sham group. This trial had several limitations. Additionally, the safety and efficacy of this device compared to CPAP is unknown.
Articles: The literature search revealed 6 studies (1 randomized controlled trial and 5 observational studies) that evaluated the safety and effectiveness of the EPAP device. Studies were excluded if they had severe methodological limitations, less than 25 subjects, or less than 30 days of follow-up. The following studies were selected for review: Berry RB, Kryger MH, Massie CA. A novel nasal expiratory airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *Sleep.* 2011; 34:497-485. See Evidence Table . Kaiser Permanente. Provent Nasal Resistance Device for obstructive sleep apnea. September 2010. http://pkc.kp.org/national/cpg/intc/topics/03_07_112.html.

The use of nasal expiratory positive airway pressure for obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Pillar Implants for Obstructive Sleep Apnea and Snoring

BACKGROUND
Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive sleep apnea syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also has mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone. Patients with primary snoring have an apnea-hypopnea index of fewer than five events per hour and no complaints of daytime sleepiness. Snoring is believed to be caused by loss of tissue integrity of the soft palate. Because tissues lack support, they stretch and collapse as muscles relax during sleep. This results in a narrowed airway and causes the soft palate to vibrate, causing snoring sounds. Primary snoring can be socially disruptive but is not harmful to the health of the patient. The Pillar Palatal Implant System (Restore Medical; St Paul, MN) is a treatment option for snoring and obstructive sleep apnea (OSA). Three implants made of braided polyester filaments are placed in the soft palate to help stiffen the soft palate and increase structural integrity. The implant system also includes a disposable delivery tool that is used for positioning and placement of the implant. Pillar implants are inserted during a single office visit under local anesthesia. Other methods of treating snoring and OSA include weight loss, nasal continuous positive airway pressure (CPAP), laser-assisted uvula palatoplasty (LAUP), uvulopalatopharyngoplasty (UPPP) and radiofrequency tissue ablation. Disadvantages

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

of the surgical procedures are that they can be painful and are often associated with side effects. Radiofrequency ablation generally requires multiple treatment sessions. The Restore Medical Web site claims that pillar implants are cleared by the FDA for treatment of snoring and OSA. The review request noted that approval could not be confirmed on the FDA Web site.

12/05/2005: MTAC REVIEW
Pillar Implants for Obstructive Sleep Apnea and Snoring
Evidence Conclusion: *Obstructive sleep apnea*: There is no published evidence on the effect of pillar implants on health outcomes for patients with obstructive sleep apnea. *Snoring:* The only published studies on the effectiveness of pillar implants for treating primary snoring were case series. The two studies with the largest sample sizes and longest follow-up periods were reviewed. The authors of the larger study (Kuhnel et al., 2005, n=106) did not clearly list their outcome variables and may have selectively reported positive outcomes. They reported a significant decrease in daytime sleepiness and a reduction in the snoring index after treatment. The smaller study (Maurer et al., 2005, n=40) reported a significant reduction in bed-partner-reported snoring and self-reported daytime sleepiness a year after treatment. There was no significant change when recordings of snoring were evaluated recordings were available for only half of the patients. No serious adverse effects were reported in either study. The efficacy of the intervention compared to an alternative treatment or no treatment can be evaluated.
Articles: *Obstructive sleep apnea:* No empirical studies were identified. The Kaiser review stated, "there were no studies published in the Medline literature reporting use of palatal implant in patients with obstructive sleep apnea." *Snoring:* No randomized controlled trials or non-randomized comparative studies were identified. There were several case series. The two largest case series, which also had the longest follow-up, were critically appraised. The articles were by a similar team of German researchers, but there does not appear to be overlap in the patients included in the two studies. The two articles critically appraised are: Kuhnel TS, Heln G, Hohenhorst W, Maurer JT. Soft palate implants: a new option for treating habitual snoring. Eur Arch Otorhinolaryngol 2005; 262: 277-280. See Evidence Table. Maurer JT, Hein G, Verse T. Long-term results of palatal implants for primary snoring. Otolaryngology-Head and Neck Surgery 2005; 133: 573-578. See Evidence Table.

The use of Pillar implants in the treatment of obstructive sleep apnea and snoring does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Oral pressure therapy (OPT) for the Treatment of Obstructive Sleep Apnea
BACKGROUND
Obstructive sleep apnea (OSA) is a common medical condition that affects approximately 2-4% of middle-age men and women in the United States. It is characterized by recurrent episodes of partial or complete collapse or obstruction of the upper airways during sleep. This leads to repeated momentary cessation of breathing (apnea) or significant reductions in breathing amplitude (hypopnea) resulting in significant hypoxemia and hypercapnia. The apnea /hypopnea index (AHI) describes the total number of apnea/hypopnea episodes per hour of sleep which is usually <5 in normal individuals. AHI scores of 5-15, 15-30, and >30 categorize patients with sleep apnea as mild, moderate, and severe, respectively. OSA is often associated with loud snoring, increasing respiratory effort, intermittent arterial oxygen desaturation, observed apnea, and disrupted sleep. Other symptoms include excessive daytime sleepiness, sleep attacks, and non-restorative sleep. OSA is a serious disorder that may significantly increase morbidity and mortality. Its potential health consequences include hypertension, arrhythmia, cerebrovascular disease, neuropsychiatric problems. It may also be associated with motor vehicle accidents, as well as social and work-related problems (Farid-Moayer 2013, van Zeller 2013, Badran 2014, Jordan 2014, Ward 2014). Conservative treatments for OSA include weight loss, modification of the patient's sleep position, medications to relieve nasal obstruction, as well as avoidance of evening alcohol, sleep medications, and sedatives. For those who fail these measures, night-time continuous positive airway pressure (CPAP) via nasal or face mask is the recommended standard and effective treatment for OSA. This positive airway ventilation stabilizes the whole upper airway reduces the AHI, normalizes the oxyhemoglobin saturation, and reduces the cortical arousals associated with the apnea /hypopnea events. However, CPAP is not well tolerated by patients, is contraindicated in claustrophobic patients, and may be associated by a number of side effects. It was reported that up to 30% of OSA patients refuse CPAP treatment, and only 50% of those who accept it can tolerate its long-term use. When adherence is defined as more than 4 hours nightly use, 46-83% of patients have reported to be non-adherent (Sawyer 2011, Zeller 2013, Jordan 2014). Alternative therapies for cases who cannot tolerate or do not respond to CPAP therapy, include the use of oral and nasal appliances, surgical procedures, laser treatment, or tracheotomy when all other treatments fail. Despite the range therapeutic options available for managing OSA, there is no treatment that is both completely effective and fully tolerated by all patient (Farid-Moayer 2013, Colrain 2013). Oral pressure therapy (OPT) is a new concept for relieving airway obstruction to treat OSA. It is a novel noninvasive treatment modality that applies vacuum in the mouth to stabile upper airway tissue in patients with
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OSA. The commercially available OPT system is composed of three components: an oral interface, a bedside console containing a pump, and tubing set. The oral interface is a mouthpiece that incorporates a lip seal and a connector. The pump applies continuous negative pressure to the oral interface and consists of a vacuum pump, a controller, and pressure measurement component. The tubing set connects the pump to the oral interface. The negative pressure in the oral cavity is intended to create a pressure gradient to draw the soft palate anteriorly into contact with the tongue to improve the airway flow during sleep. The patient breathes normally through the nose while sleeping, thus nasal patency to allow closed-mouth breathing is required for the use of that device (Colrain 2013, Farid-Moayer 2013). The Attune Sleep Apnea System and the Winx Sleep Therapy System (that has an additional data management software application) were approved by US Food and Drug Administration in 2012 for home use in the treatment of obstructive sleep apnea (OSA) in adults.

06/16/2014: MTAC REVIEW
Oral pressure therapy (OPT) for the Treatment of Obstructive Sleep Apnea
Evidence Conclusion: The published studies on the oral pressure therapy for obstructive sleep apnea were conducted by the same group of investigators who had financial ties to ApniCure the manufacturer of the device, which also funded the studies. These were only observational studies where the patients acted as their own controls. The first (Farid-Moayer et al, 2013) was a feasibility study conducted among 71 patients from a single center, and the second (ATLAST study, Colrain et al, 2013) was a larger multicenter study initially, but included only a limited number of patients in the final analysis. The authors of ATLAST described the study as a prospective, randomized, crossover study. However, as they indicated, randomization was for the “first-night order of control versus treatment”. The study did not have a control group, and OPT therapy was not compared to CPAP therapy, sham therapy, or any other treatment for OSA. The control subjects were those who underwent their baseline PSG before OPT while the treatment group had their PSG in the first treatment night. After the first night PSG, all participants received OPT for 28 days. The study included highly selected and motivated individuals with OSA, and only 14% of those who signed the consent were included in the analysis cohort. PSG was only performed at 2 nights at baseline and after 28 days of therapy. This does not allow for excluding the effect of the night to night variations in PSG or evaluating the long-term efficacy safety, or tolerability of the OPT. Conclusion: There is insufficient published evidence to date to determine the safety, efficacy, long term effect, tolerability and compliance with the oral pressure therapy for the treatment of obstructive sleep apnea.
Articles: The literature search for studies on oral pressure therapy for the treatment of obstructive sleep study revealed two publications for a feasibility study, and a larger observational study. All were conducted by the same group of authors. The two published feasibility studies were conducted by the same group of investigators in the same center, with similar inclusion/exclusion criteria and patient characteristics, which makes it hard to determine if there is patient overlap between the studies. The authors indicate that in one study the mouthpiece was individually customized to the subjects, while it was only selected from 10 available fits in the other. The first feasibility study and the multicenter study were critically appraised. Colrain IM, Black J, Siegel LC, Bogan RK, A multicenter evaluation of oral pressure therapy for the treatment of obstructive sleep apnea. Sleep Med. 2013; 14:830-837. See Evidence Table. Farid-Moayer M, Siegel LC, Black J. A feasibility evaluation of oral pressure therapy for the treatment of obstructive sleep apnea. Ther Adv Respir Dis. 2013; 7:3-12. See Evidence Table.

The use of Oral pressure therapy (OPT) for the treatment of obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea
BACKGROUND
There has been increasing recognition of a continuum of sleep disordered breathing disorders, ranging from simple snoring to obstructive sleep apnea (OSA). OSA refers to recurrent episodes of breathing cessation during sleep due to mechanical blockage of the airway. The diagnosis of OSA requires a minimum of 30 episodes of apnea, each lasting at least 10 seconds, during 6-7 hours of sleep. OSA patients are generally obese and the cardinal symptom is excessive daytime sleepiness. Upper airway resistance syndrome (UARS), a term first used in 1993, is a form of sleep-disordered breathing that is also associated with daytime sleepiness. Patients do not meet diagnostic criteria for OSA and are generally non-obese. Recent investigations suggest that UARS may have different pathophysiology than OSA, for example UARS patients may have increased airway collapsibility and craniofacial abnormalities. Common polysomnographic findings for UARS include Apnea-hypopnea index (AHI) <5, minimum oxygen saturation >92%, increase in alpha rhythm and a relative increase in delta sleep (Bao & Guilleminault). Continuous Positive Airway Pressure (CPAP) is widely used as first-line therapy for UARS although there is a lack of high-grade evidence supporting its effectiveness. CPAP is also often used as a tool to diagnose UARS by seeing whether patients respond to a trial of CPAP treatment. Other treatment alternatives include oral appliances, septoplasty and radiofrequency reduction of enlarged nasal inferior turbinates. Classic surgical procedures used for OSA are considered by many clinicians to be too aggressive for treatment of UARS
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(Bao & Guilleminault). There are currently more than 35 different oral appliances on the market for OSA and/or snoring. The most widely used type of oral device is mandibular advancement devices (MAD) which act to keep the pharyngeal airspaces open by moving the mandible forward by advancing or downwardly rotating the mandible (Schoem, 2000).

12/13/2000: MTAC REVIEW
Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea
Evidence Conclusion: There is insufficient evidence to permit conclusions about the effect of oral appliances on health outcomes. Since there are over 35 OAs, each needs to be considered separately. Only one commercially available oral appliance (Herbst device, Bloch RCT) was evaluated in the recent studies. The Bloch RCT was subject to threats to validity including small sample size, absence of a placebo controlled-group, no washout period between treatments, short intervention period (one week per treatment) and inappropriate p-value cut-off (i.e. did not adjust for multiple comparisons). The other new RCT, Wilhelmsson, used a custom-made oral appliance rather than a commercially available device. There were no long-term data on the effectiveness of any oral device. There were also no long-term data from RCTs on potential adverse effects associated with long-term use of oral devices. A cross-sectional study (Clark) suggests that there may be a high prevalence of adverse effects; this study was not able to measure the severity of complications.
Articles: Since the articles reviewed for the previous MTAC evaluation, there were two new RCTs (one was a cross-over trial), one cross-sectional study examining long-term use of an oral appliance and one case series. The randomized cross-over study compared two types of oral appliances and a no-treatment control group. The other RCT compared an oral appliance with uvulopalatopharyngoplasty (UPPP). *Evidence tables were created for two RCTs and the cross-sectional study:* Bloch KE, Jinnong AI, Zhang N, Kaplan V, Stohckli PW, Russi EW. A randomized, controlled crossover trial of two oral appliances for sleep apnea treatment. Am J Respir Crit Care Med 2000; 162: 246-51. See Evidence Table. Clark GT, Sohn JW, Hong, CN. Treating obstructive sleep apnea and snoring: Assessment of an anterior mandibular positioning device. JADA 2000:131: 765-771. See Evidence Table. Wilhelmsson B, Tegelberg A, Walker-Engstrom ML, Ringqvist M, Andersson L, Krekmanov L, Ringqvist I. A prospective randomized study of a dental appliance compared with uvulopalatopharyngoplasty in the treatment of obstructive sleep apnea. See Evidence Table.

The use of the Herbst, and Monbloc mandibular advancement devices for the treatment of obstructive sleep apnea meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/06/2005: MTAC REVIEW
Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea
Evidence Conclusion: There was only one empirical study evaluating the safety and efficacy of MAD for UARS, a case series with 32 patients (Yoshida, 2002). The investigators created an oral device for patients diagnosed with UARS. They assessed clinical variables using polysomnography at baseline, and 14-60 days after first use of the device. The investigators found statistically significant improvement in most of the polysomnography outcomes at follow-up, including a significant reduction in daytimes sleepiness according to the Epworth sleepiness scale. The study is limited by the small size and case series design—patients were not blinded and there was no comparison or control group. Improvement could have been due to the natural history of the condition or to a placebo effect. In addition, the performance of the devices may differ from other custom-made or commercially available mandibular advancement devices.
Articles: Only one empirical study was identified. This was a case series with 32 patients and was critically appraised: Yoshida K. Oral device therapy for the upper airway resistance syndrome patient. *J Prosthet Dent* 2002; 87: 427-30. See Evidence Table.

The use of the Herbst, and Monbloc mandibular advancement devices for the treatment of upper airway resistance syndrome does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Maxillomandibular Advancement Surgery for Sleep Apnea
BACKGROUND
Sleep apnea is characterized by repeated apnea or hypopnea during sleep. Apnea, which is the cessation of airflow for ten or more seconds, could be central or obstructive. If respiratory efforts persist despite cessation of airflow, the apnea is obstructive. Obstructive sleep apnea syndrome (OSAS) is defined by the presence of at least a minimum number of apneas or hypopneas per hour, and the presence of mental or physical effects or both. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries, and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone. Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, and tracheostomy when all other
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treatments fail. Surgical treatment approach varies, and the results are affected by age, cause of obstruction, and severity of disease. The best method to of treatment remains controversial. Maxillomandibular advancement (MMA) pulls forward the anterior pharyngeal tissues attached to the maxilla, mandible, and hyoid to increase the posterior airway space. It is a currently accepted treatment for OSAS; however, its indication is unsettled and is often limited to the severe cases where other surgeries have failed.

08/09/2001: MTAC REVIEW
Maxillomandibular Advancement Surgery
Evidence Conclusion: Maxillomandibular advancement (MMA) may be successful, and safe for treating selected patients with OSA. However, these series do not provide sufficient evidence to determine the efficacy of MMA in the treatment of obstructive sleep apnea. Case series offer the lowest grade of evidence and have several internal threats to their validity.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. Three articles were found on maxillomandibular advancement (MMA). All three were case series, two small (n=19 and n=21), and a bigger series (n=50). *Critical appraisal was made for the following articles:* Hochban W, Brandenburg. et al. Surgical Treatment of Obstructive Sleep Apnea by Maxillomandibular Advancement. Sleep 1994; 17 (7): 624-629 See Evidence Table. Nimkarn Y, Miles PG, Waite PD. Maxillomandibular Advancement Surgery in Obstructive Sleep Apnea Syndrome Patients: Long – Term Surgical Stability. *J Oral Maxillofac Surg* 1995; 53:1414-1418 See Evidence Table. Prinsell JR. Maxillomandibular Advancement Surgery in a Site-Specific Treatment Approach for Obstructive Sleep Apnea in 50 Consecutive Patients. *Chest* 1999; 116: 1519-1529 See Evidence Table.

The use of the Maxillomandibular Advancement Surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Laser Treatments for Snoring and Sleep Apnea
BACKGROUND
Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive Sleep Apnea Syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also have mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone.

Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, or tracheostomy when all other treatments fail. Surgical treatment approach varies, and the results are affected by age, cause of obstruction, and severity of the disease. The best method of treatment remains controversial.

08/08/2001: MTAC REVIEW
Cautery-Assisted Palatal Stiffening Operation (CAPSO)
Evidence Conclusion: Only a single small case series is available to evaluate CAPSO for treating obstructive sleep apnea. This represents insufficient evidence to draw conclusions about the effect of CAPSO on health outcomes related to sleep apnea.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There were two empirical articles on CAPSO, both were case series. One of the case series (n=25) included patients with obstructive sleep apnea, while the other, report (n=206) included patients who complained of excessive habitual snoring, no attempt was made to diagnose sleep apnea. An evidence table was created for the case series with sleep apnea patients. Wassmuth Z, Mair E, Loube D, Leonard D. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2000; 123: 55-60. See Evidence Table.

The use of cautery-assisted palatal stiffening operation (CAPSO) in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/08/2001: MTAC REVIEW
Repose Procedure

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Evidence Conclusion: The existing scientific evidence does not permit conclusions about the efficacy of the Repose procedure on health outcomes. The best evidence is a case series of 16 individuals with data available on 14 of these. This report is subject to the limitations of case series (selection and observation bias likely).
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There were three articles on the Repose procedure, one review/discussion piece and two small case series (n=9 and n=15). Because it was the best available evidence, an evidence table was created for the larger case series. DeRowe A, Gunther E, Fibbi A, Lehtimake K, Valatalo K., Maurer J, Ophir D. Tongue-based suspension with a soft tissue-to-bone anchor for obstructive sleep apnea: Preliminary clinical results of a new minimally invasive technique. Otolaryngol Head Neck Surg 2000; 122: 100-3. See Evidence Table.

The use of repose procedure in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/14/1999: MTAC REVIEW
Somnus Somnoplasty System
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1990 to February 1999 using the terms: somnoplasty, sleep apnea and radiofrequency. The Somnus Company was aware of only one published article related to the use of the Somnoplasty system for obstructive sleep apnea. This article (summarized below) reports data from a single case series of 22 patients treated for snoring, daytime sleepiness and mild obstructive sleep apnea. Results from this study show no changes in Respiratory Distress Index (RDI*) following somnoplasty, statistically significant improvements in partner report of snoring and an improvement of 3.3 points (24-point scale) in self-report of sleepiness.
Articles: Powell, NB, et al *Chest,* 1998:113:1163-74. See Evidence Table

The use of the Somnus Somnoplasty System for the treatment of obstructive sleep apnea has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria.*

08/08/2001: MTAC REVIEW
Base of Tongue Somnoplasty in the Treatment of Sleep Apnea
Evidence Conclusion: The evaluated study does not provide sufficient evidence to determine the efficacy of base of tongue somnoplasty, in the treatment of sleep apnea, due to its small sample size, together with the other limitations of case series.
Articles: The search yielded 113 articles. Most of the articles were on uvulopalatopharyngoplasty or glossectomy. There was a pilot study done for base of tongue somnoplasty on humans, and another study made on animals. *The best available article for critical appraisal was the pilot study:* Powell N B, Riley R W, et al. Radiofrequency Tongue Base Reduction in Sleep- Disordered Breathing: A Pilot Study. *Otolaryngol Head Neck Surg* 1999: 120: 656-64. See Evidence Table.

The use of base of tongue somnoplasty in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/05/2005: MTAC REVIEW
Radiofrequency Tissue Ablation (Somnoplasty)
Evidence Conclusion: There is insufficient evidence on single level base of tongue somnoplasty to draw conclusions about the efficacy of the procedure compared to placebo or the standard treatment, CPAP. There were no RCTs on single level somnoplasty. One non-randomized comparative study did not find significant between-group differences on subjective outcomes. There is evidence from one RCT that multilevel (base of tongue and soft palate) does not improve outcomes compared to sham treatment or placebo. The RCT did not identify significant between-group differences in two of three primary outcomes including the objective outcome, slowest reaction time. Findings from case series suggest that there is a relatively low complication rate, at least in institutions with extensive experience with the technology.
Articles: See Evidence Table. Stewart DL, Weaver EM, Woodson BT. Multilevel temperature-controlled radiofrequency for obstructive sleep apnea: Extended follow-up. Otolaryngol Head Neck Surg 2005; 132; 630-635. Woodson BT, Nelson L, Mickelson S et al. A multi-institutional study of radiofrequency volumetric tissue reduction for OSAS. Otolaryngol Head Neck Surg 2001; 125: 303-311. See Evidence Table. Kezirian EJ, Powell NB, Riley RW, Hester JE. Incidence of complications in radiofrequency treatment of the upper airway. Laryngoscope 2005; 115: 1298-1304. See Evidence Table. Stuck BA, Starzak K, Verse T et al. Complications of temperature-controlled radiofrequency volumetric tissue reduction for sleep-disordered breathing. Acta Otolaryngol 2003; 123: 532-535. See Evidence Table.

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These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

The use of Radiofrequency tissue ablation (somnoplasty) in the treatment of sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

PAP Devices –
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0601	Continuous positive airway pressure (CPAP) device
D9947	Custom sleep apnea appliance fabrication and placement
D9948	Adjustment of custom sleep apnea appliance
D9949	Repair of custom sleep apnea appliance

Geniohyoid Advancement Myotomy –
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
Does not require medical review	
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)

Maxillo-mandibular Advancement Surgery for Sleep Apnea-
Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
21198	Osteotomy, mandible, segmental;
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)

Hypoglossal Nerve Stimulation-
Medicare – Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare- Considered not medically necessary

CPT® or HCPC Codes	Description
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

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64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic

Nasal Expiratory Positive Airway Pressure- Considered not medically necessary

CPT® or HCPC Codes	Description
No specific codes	

Pillar Implants- Considered not medically necessary

CPT® or HCPC Codes	Description
C9727	Insertion of implants into the soft palate; minimum of three implants

Oral Pressure Therapy- Considered not medically necessary

CPT® or HCPC Codes	Description
No specific codes	

Mandibular Advancement Devices for Treatment of Obstructive Sleep Apnea-
Medicare – Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Medical review no longer required

CPT® or HCPC Codes	Description
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Dates Reviewed	Date Last Revised
04/01/1998	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 02/07/2012[MDCRPC], 10/02/2012[MDCRPC], 12/04/2012[MDCRPC],10/01/2013[MPC], 07/01/2014[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 11/06/2018[MPC], 12/04/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	10/26/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services
12/05/2017	Adopted Kaiser Permanente Policy for Mandibular Advancement Surgery for Sleep Apnea for Medicare
08/06/2019	Added MTAC review for Hypoglossal Nerve Stimulation
10/30/2019	Merged Laser Treatments for Snoring and Sleep Apnea criteria

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01/07/2020	MPC approved to retain policy of non-coverage for Hypoglossal Nerve Stimulation in accordance with MTAC recommendation
09/09/2020	Added Medicare LCD L38312 and LCA A57949
10/06/2020	MPC approved to adopt MCG A-0973, Hypoglossal Nerve Stimulation.
09/08/2022	Removed deleted codes 0466T, 0467T and 0468T; Added new codes 64582, 64583, 64584 and 42975 under Hypoglossal Nerve Stimulation section.
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
11/11/2022	Updated Medicare Links

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Clinical Review Criteria

Treatments for Stress Urinary Incontinence

- Biofeedback for the Treatment of Urinary Incontinence
- Collagen Injections for Stress Urinary Incontinence
- Extracorporeal Magnetic Innervation for Urinary Incontinence
- Implanted Electrical Stimulator, Sacral Nerve for Fecal and Urinary Incontinence
- Intravaginal Electrical Stimulation
- Radiofrequency Bladder Neck Suspension for the Treatment of Genuine
- SPARC® Sling for Treatment of Urinary Incontinence
- Stress Urinary Incontinence; Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETRTSUI)
- Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Non-Implantable Pelvic Floor Electrical Stimulator (230.8) Incontinence Control Devices (230.10) Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1) Sacral Nerve Stimulation for Treatment of Urinary Incontinence (230.18) Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) Bladder Stimulators (Pacemakers) (230.16)
Local Coverage Determinations (LCD)	3/14/2007 Noridian retired ***LCD Biofeedback Therapy Policy (L14443).*** These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L14443 for determining medical necessity.
Local Coverage Article	Posterior Tibial Nerve Stimulation Coverage (A52965)

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For Non-Medicare Members

Treatments for Urinary Incontinence	Criteria Used
Percutaneous Tibial Nerve Stimulation (PTNS) - Urgent® PC Neuromodulation System for Overactive Bladder	Percutaneous tibial nerve stimulation (PTNS) which consists of a regimen of 30-minute weekly sessions for 12 weeks is medically necessary when **ALL** of the following are present: a. Overactive bladder syndrome b. Symptoms not due to spinal cord injury c. They must meet **ONE** of the following o They must EITHER fail at least two medications with adequate trial (for example, two anticholinergics or an anticholinergic and a beta-agonist) OR o Have a contraindication to pharmacotherapy. d. Behavioral therapy (eg, bladder training, pelvic floor muscle training) that is of a sufficient duration to fully assess its efficacy. PTNS for any other urinary indication because it is considered experimental, investigational or unproven. More than 12 PTNS treatments are not medically necessary when there is no improvement of OAB symptoms.
Implanted Electrical Stimulator, Sacral Nerve for Fecal and Urinary Incontinence	Kaiser Permanente has elected to use the MCG* Implanted Electrical Stimulator, Sacral Nerve (A-0645) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting these services, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist.
Biofeedback Extracorporeal Magnetic Innervation Radiofrequency Bladder Neck Suspension Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETRTSUI) Intravaginal Electrical Stimulation	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Collagen Injections for Stress Urinary Incontinence SPARC® Sling for Treatment of Urinary Incontinence	Medical necessity review is not required for this service.

***The MCG* are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

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Stress urinary incontinence (SUI) is defined as leakage of urine during activities that cause increased abdominal pressure such as exercise or coughing in the absence of a detrusor contraction. It is the most common form of urinary incontinence in women and is estimated to affect about 6.5 million women in the United States. Current understanding is that urinary continence during stress events requires both intact supportive structures (i.e. endopelvic fascia) and functioning neurological control of the muscles of the pelvic floor and urethra (Agarwala & Liu, 2002).

Treatments for stress urinary incontinence include conservative therapies such as strengthening the pelvic floor muscles with Kegel exercises and devices such as electrical stimulation devices and pessaries. There are also medications such as estrogen and various surgical treatments.

Evidence and Source Documents

Biofeedback for the Treatment of Urinary Incontinence
Collagen Injections for Stress Urinary Incontinence
Extracorporeal Magnetic Innervation for Urinary Incontinence
Intravaginal Electrical Stimulation for Urinary Incontinence
Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETRTSUI)
SPARC® Sling for Treatment of Urinary Incontinence
Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)
Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Sacral Nerve Stimulator for Fecal Incontinence

Medical Technology Assessment Committee (MTAC)

Biofeedback for the Treatment of Urinary Incontinence

BACKGROUND

Urinary incontinence (UI), defined as the involuntary loss of urine, is a common problem affecting many women of all ages, but is more prevalent in the elderly. It is estimated that UI affects 30-60% of middle aged and older women in the community, and up to 80% of nursing home residents (Herderschee 2011, Markland 2011, Goode 2010). The main types of UI are stress incontinence (SUI), urge (or urgency) incontinence (UUI), and mixed stress and urgency incontinence (MUI). Stress urinary incontinence is the most common type and occurs in about half of incontinent women. The next most common is the mixed urinary incontinence (around 30%) followed by the urge or urgency urinary incontinence. Mixed and urge incontinence predominate in older women, while stress incontinence mainly occurs in young and middle-age women (Lipp 2011). SUI is the involuntary leakage of urine with activities that increase intra-abdominal pressure such as coughing, sneezing, lifting, or sport activities. SUI occurs as a result of a combination of intrinsic urethral sphincter muscle weakness and an anatomic defect in the urethral support, leading to insufficient closure pressure in the urethra during physical effort. The etiology of SUI is multifactorial and includes pregnancy, vaginal delivery, pelvic surgery, neurologic causes, active lifestyle, and various comorbidities. UUI is the involuntary leakage of urine accompanied by or immediately preceded by a sensation of urgency, or the sudden compelling desire to pass urine which is difficult to defer. This can be caused by an involuntary bladder contraction that overcomes the sphincter mechanism; or poor bladder compliance due to loss of the viscoelastic features of the bladder. UUI is part of the spectrum of overactive bladder. MUI is the symptom complex of involuntary leakage associate with both urgency and effort and exertion (Lipp 2011, Deng 2011, Markland 2011). Urinary incontinence is not a life-threatening condition but has a profound negative impact on the quality of life. Symptoms of UI interfere with the performance of everyday household and social activities, and may lead to anxiety, frustration, social isolation, and depression. It is reported that UI is associated with a 30% increase in functional decline, a 2-fold increase in the risk of falls, and nursing home placement (Goode 2010, Markland 2011, Mladenovic 2011). Treatment options for urinary incontinence can be divided into conservative measures, pharmacotherapy, and surgical interventions. Conservative treatment is usually the first-line therapy for many patients and is useful for both stress and urge incontinence. Behavioral treatments have been well studied and proved to be effective in reducing leakage by 50-80%, with 10-30% of the patients achieving continence. These interventions improve incontinence by teaching skills and helping patients change their behavior. Behavioral programs comprise multiple individualized components which may include bladder control strategies, self-monitoring (bladder diary), scheduled or prompted voiding, delayed voiding, urge suppression strategies, moderate weight loss, fluid management, caffeine reduction, pelvic floor muscle training, and /or other lifestyle changes. Behavioral treatment is most useful when the person is motivated, wants to be actively involved in therapy, can follow directions, and when there is a readily identifiable and measurable response (Markland 2011, Lipp 2011). Pelvic floor muscle training (PFMT) and exercise, also known as Kegel exercise, is considered a cornerstone in behavioral treatment. PFMT is a program of repeated voluntary pelvic

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floor muscle contractions taught and supervised by a health care professional. These work by increasing the strength and tone of the pelvic floor muscles, which in turn increases the urethral closure force and prevents stress incontinence during an abrupt increase in intra-abdominal pressure. It is also useful for urge incontinence as the detrusor contractions can be reflexively or voluntarily inhibited by tightening the pelvic floor. The success of PFMT depends on the patient's ability to perform the exercise correctly and the motivation to actually practice it regularly. In clinical practice, PEMT is often combined by some type of feedback or biofeedback to help the woman learn how to contract the muscle, to improve the effectiveness of the contraction through modulating the performance of the learned contraction, and to encourage further exercising (Herderschee 2011, Goode 2010, Deng 2011). Feedback is defined as the return of part of the output of a system to the input in a way that affects its performance. It thus provides information on what was done, rather than what to do, i.e. the bodily sensation felt by the woman performing the contraction gives inherent feedback about the movement. Augmented feedback is a feedback with supplementary information provided e.g. verbal feedback from a clinician palpating or observing the contraction. Biofeedback (BF) is a form of augmented feedback that uses monitoring devices to display information about the operation of a bodily function that is not normally consciously controlled, to help the patient learn to control the function consciously. When performed in conjunction with Kegel exercises for the treatment of UI, specialized pressure transducers or sensors are inserted in the vagina or rectum, or placed on the perineum, and biofeedback instruments are used to reinforce correct techniques through visual and auditory cues. BF typically gives the user an auditory or visual record of the contraction or both. This can potentially be helpful and motivating women who find it difficult to identify and isolate their pelvic floor muscles. BF devices vary considerably; many of the devices used in the studies consist of air or water filled balloons that are inserted into the rectum or vagina to measure pressure. Other devices measure electrical activity (electromyography) via surface metal electrodes on vaginal or anal probes. Some devices can only be used in clinical setting because they require a health professional to set up and use the equipment, and others are very simple and portable and are designed for home use (Herderschee 2011). A typical program of biofeedback consists of 10 to 20 training sessions; 30 minutes each. Training sessions are typically performed in a quiet environment, and under the supervision of a physiotherapist or specialized nurse. Patients are instructed to use mental techniques to contract the pelvic muscles and feedback is provided for a successful contraction. This feedback may be signals such as lights, verbal praise, or other auditory or visual stimuli. The Food and Drug Administration have cleared a variety of biofeedback devices for marketing. It defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters) so that the patient can control voluntarily these physiological parameters."

04/14/1999: MTAC REVIEW
Biofeedback for the Treatment of Urinary Incontinence
Evidence Conclusion: The published scientific evidence on biofeedback consists of small-randomized trials with typically one-month follow-up. These studies reported that adding biofeedback to a trial of pelvic floor muscle exercises did not produce any incremental benefit. It was noted that there were 3 randomized controlled trials that provided good evidence that biofeedback produces no incremental improvement in urinary incontinence compared to pelvic muscle exercise alone. It was also noted that biofeedback was currently a covered service at Kaiser Permanente Northwest and that this policy may undergo re-evaluation as a result of evaluating the evidence.
Articles: Berghmans, LCM et al, Neurology and Urodynamics, 1996:15:37-52. See Evidence Table. Burns, PA et al, J. Gerontology, 1993;48 M167-M174 See Evidence Table. Burton, JR, et al, J Am Geriatr Soc. 1988; 36:693-698 See Evidence Table. Burgio, KL, et al. Am J Obstet Gynecol, 1986;154:58-64 See Evidence Table.

Biofeedback for the treatment of stress or urge urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/09/2002: MTAC REVIEW
Biofeedback for the Treatment of Urinary Incontinence
Evidence Conclusion*:* The new evidence on the benefit of biofeedback compared to pelvic floor muscle exercise alone consists of one RCT and one meta-analysis, both with threatened validity. Even with their methodological limitations, neither found a significant benefit of adding biofeedback to PFM exercises. There was also an additional RCT that compared PFM exercise with biofeedback to drug treatment (Burgio) and found a greater reduction in incontinent episodes with PFM exercise. Although the Burgio study had reasonably valid methods, it did not include a group receiving PFM exercises without biofeedback, so the additive benefit of using a biofeedback device with an exercise program cannot be determined. The new evidence on biofeedback for the treatment of urinary incontinence is consistent with earlier evidence that biofeedback does not substantially add to the effectiveness of pelvic floor muscle exercise.

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Articles: The search yielded 73 articles, many of which were review articles or opinion pieces. There was one meta-analysis of RCTs and two RCTs. One of the RCTs was published prior to 1999 but was not included in the previous review. The two RCTs and the meta-analysis were critically appraised: Weatherall M. Biofeedback or pelvic floor muscle exercises for female genuine stress incontinence: A meta-analysis of trials identified in a systematic review. BJU Internat 1999; 83: 1015-1016. (Some methodological information taken from: Berghmans LCM, Hendriks HJM, Bo K. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized controlled trials. Br J Urol 1998; 82: 181-191. See Evidence Table. Lacock J, Brown J, Cusack C et al. Pelvic floor reeducation for stress incontinence: comparing three methods. Br. J Commun Nurs 2001; 6: 230-237. See Evidence Table. Burgio KL, Locher JL, Goode PS. Behavioral vs. drug treatment for urge urinary incontinence in older women. JAMA 1998; 280: 1995-2000. See Evidence Table.

The use of biofeedback in the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/17/2011: MTAC REVIEW
Biofeedback for the Treatment of Urinary Incontinence
Evidence Conclusion*:* Herderschee and colleagues' (2011) meta-analysis included 24 randomized or quasi randomized trials that compared the use of PFMT program with a form of feedback or biofeedback in women with urinary incontinence. The results of the meta-analysis indicate that women who received biofeedback were significantly more likely to report that their urinary incontinence was improved or cured compared to those who received PFMT alone. The meta-analysis had valid methodology; however, the trials included were small, some were quasi randomized, and all, but one small study, had moderate or high risk of bias. In addition, there were many variations in the regimens of biofeedback added to PFMT and women in the biofeedback or feedback group had more contact with the health providers. The overall results of the meta-analysis show that women in the biofeedback groups had statistically significant higher satisfaction and perception of improvement in symptoms compared to those in the PFMT only groups. However, the number of leak episodes indicates that the addition of biofeedback to PFMT leads to approximately one less leak every eight days. The limitations in the trials included in the analysis make it hard to determine whether the improvement was due to the intervention, bias, more contact with health providers, or other confounding factors.
Articles: The search revealed one recent Cochrane review of trials on feedback and biofeedback for augmenting pelvic floor muscle training in women with urinary incontinence. A number of RCTs that were included in the meta-analysis were also identified. Only the Cochrane's meta-analysis was selected for critical appraisal. Herderschee R, Hay-Smith EJ, Herbison GP, et al. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev*. 2011;(7):CD009252. See Evidence Table.

The use of biofeedback in the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Collagen Injections for Stress Urinary Incontinence
BACKGROUND
Stress incontinence is one of the two common types of urinary incontinence. The primary symptom is an involuntary loss of urine during physical exertion associated with increased intra-abdominal pressure, such as with coughing, laughing or sneezing. Treatments for stress incontinence include exercises to strengthen the external urethral sphincter, mechanical devices (pessaries) to support the urinary sphincter muscles, medications such as estrogen and phenylpropanolamine (PPA) and surgery. Injection of periurethral bulking agents for stress incontinence was first described by Murless in 1938 who used a sclerosing agent, sodium morrhuate. Injectable materials are usually used for patients with incontinence due to intrinsic sphincter deficiency (ISD). Currently, the most commonly used bulking agent is collagen. Collagen, however, is biodegradable, and therefore any benefit it may provide is short-lived. According to researchers, the ideal injectable substance has not yet been developed but it would be durable yet nonimmunogenic, noncarcinogenic, nonmigratory and produce minimal inflammatory responses (Lightner; Pannek). Collagen used for treating urinary incontinence is a bovine-derived collagen gel manufactured by the Bard Company and injected sub or periurethrally via percutaneous injection. Its mechanism of action is to increase tissue bulk in the area of the urethra until the urethra becomes closed. Multiple injections of up to 30 ml. may be injected in a single patient and up to 5 subsequent collagen treatments may be required to produce clinical improvement. A collagen implant, which is injected into the submucosal tissue of the urethra and/or the bladder neck and into the adjacent tissues of the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers. Duraphere is an injectable bulking agent that is composed of pyrolytic

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carbon-coated beads suspended in a water-based carrier gel. In September 1999 the FDA approved Durasphere. A transurethral or periurethral method of injection can be used. A potential advantage of Durasphere over collagen is that the particle size is relatively large (251 to 300*u*) and particle migration is not believed to occur. Durasphere is also believed to not cause allergic reactions. However, recent studies have refuted that assumption.

1999: MTAC REVIEW
Collagen Injections for Stress Urinary Incontinence
Evidence Review: The published scientific evidence on collagen injection consists mostly of small case series with 1-2 year follow up. Several case series with good follow up in a population of women with stress incontinence reported short term benefit in 25-80% of patients which declines to 25-30% over the course of 3 years. Reported complication rates ranged from 10 to 20%. One study report that 9% of women and 25% of men eventually required surgical intervention for their incontinence. The wide range of reported outcomes makes interpretation of the effect of collagen injection difficult. Evidence tables of the relevant published studies are presented below.
Articles: Swami, S et al. Collagen for female genuine stress incontinence after a minimum two-year follow-up. 1997, *British Journal of Urology*, 80, 757-761 See Evidence Table. Stothers, L et al. Complications of periurethral collagen for stress urinary incontinence. 1998, *J. Urol.* 159, 806-807 See Evidence Table.

Collagen Injection for urinary incontinence did not pass the *Kaiser Permanente Medical Technology Assessment Criteria*.

2002: MTAC REVIEW
Collagen Injections for Stress Urinary Incontinence
Evidence Review: The best evidence was an RCT that compared injections with Durasphere to collagen injections among women with stress urinary incontinence due to intrinsic sphincter deficiency (Lightner). The authors did not find a significant difference in effectiveness between the two treatments. In both groups, about 66% of women in the analysis had an improvement of >1 continence grade on the Stamey scale after 12 months of follow-up. There was no placebo comparison and it may be that neither collagen nor Duraphere performs better than placebo. MTAC evaluated collagen injections in 1999 and found that there was insufficient evidence of effectiveness. The validity of the Lightner study was also threatened by the high dropout rate. Only 65% of patients completed the 12-month follow-up and there was no intention to treat analysis. The other article reviewed (Pannek) was a small case series that identified two cases of particle migration three months after Durasphere injections. Additional research is needed to verify the extent of particle migration and determine any possible harms associated with this migration.
Articles: The search yielded 9 articles. There were two empirical articles, one RCT and one case series (n=20). Both articles were reviewed. A case series of this size (n=20) would not normally be reviewed, but this article was included because it dealt with the safety of the technology. *The following articles were critically appraised.* Lightner D, Calvosa C, Andersen R, Klimberg I, Brito CG, Snyder J. et al. A new injectable bulking agent for treatment of stress urinary incontinence: Results of a multicenter, randomized, controlled double-blind study of Durasphere. Urology 2001; 58:12-15. See Evidence Table. Pannek J, Brands FH, Senge T. Particle migration after transurethral injection of carbon coated beads for stress urinary incontinence. J Urol 2001; 166:1350-1353. See Evidence Table.

Durasphere Injection for urinary incontinence did not pass the *Kaiser Permanente Medical Technology Assessment Criteria.*

Extracorporeal Magnetic Innervation for Urinary Incontinence
BACKGROUND
Extra-corporeal magnetic innervation therapy (approved by the FDA in June 1998) is a technology designed to treat stress urinary incontinence. Extra-corporeal magnetic innervation therapy is a technology that has been developed to provide conservative therapy for stress urinary incontinence by creating a magnetic field and the induction of electrical activity to de-polarize the nerves and exercise the muscles of the pelvic floor. The technology provides a potential alternative to surgical treatment for incontinence. It provides an additional option to conservative therapies such as fluid restriction, medical management, timed voiding, Kegel exercises, biofeedback and electrical stimulation. Its promoters state that this technology will prove more attractive to patients than electrical stimulation because patches or probes, skin contact or gel, and undressing for treatment are not necessary. Patients are positioned in a special chair provided with a cushion containing a magnetic field generator which is powered and controlled by an external power unit. The output of the power unit consists of pulses of current at 275 microseconds in duration and which can be adjusted in amplitude by the clinician. Treatment involves approximately ten minutes of intermittent low frequency stimulation (5 Hz) followed by a rest
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interval of 1-5 minutes and then ten minutes of intermittent high frequency stimulation (50 Hz). Treatments are given twice a week for six weeks. The FDA has approved this as Class II device requiring a physician's prescription and administration.

02/06/2000: MTAC REVIEW
Extracorporeal Magnetic Innervation for Urinary Incontinence
Evidence Conclusion: Although extracorporeal magnetic innervation therapy has FDA approval, there is insufficient scientific evidence to permit conclusions regarding the effects of this technology on health outcomes. This study is a cohort study without a control group and therefore lacks the validity of a randomized control trial. Validity of the before and after results are threatened by the drop-out or lack of follow-up of 14 patients in the original group. Validity is also threatened by the likelihood of co-interventions such as advice regarding voiding and fluid management. The possibility of a placebo effect is real.
Observation bias is likely in this study (e.g., the investigators received payment from the manufacturer).
Articles: Four articles were located using Medline (OVID). Articles were sorted on the basis of study type. One case series of seven male patients was rejected because the population was limited to males with spinal cord injury. A second study was eliminated because the 12 patients underwent saline infusion into the bladder followed by magnetic stimulation of S3. A third study was excluded because it reviewed literature dealing with urethral pressure in anesthetized dogs. Gallaway NT, El-Galley RE, Sand PK et al. Extracorporeal magnetic innervation therapy for stress urinary incontinence. *Urology*. 53 (6): 1108-11, 1999 June. See Evidence Table.

The use of extracorporeal magnetic innervation for the treatment of stress urinary incontinence has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria*.

Intravaginal Electrical Stimulation for Urinary Incontinence
BACKGROUND
Urinary incontinence (UI), the accidental release of urine, affects up to 30 million women in the United States. Most symptoms of UI will fall into two different categories. The first, stress incontinence, is characterized by the involuntary loss of urine occurring after exerting some force on the bladder through physical activities such as coughing, sneezing, laughing, exercising or lifting. Urge incontinence, on the other hand, causes urine leakage due to bladder spasms or untimely contractions. Symptoms of both stress and urge incontinence may be experienced at the same time and is most often referred to as mixed incontinence. While some causes of UI can be attributed to medications or urinary tract infection and may improve after treating the cause, in most cases of urinary incontinence, the cause is difficult to target. In any case, urinary incontinence is embarrassing and uncomfortable and can severely disrupt the quality of life. Pelvic floor muscle training (PFMT) is considered first line treatment for UI and is aimed to target the pelvic musculature. It is a noninvasive education and exercise program that involves repeated voluntary contraction of the pelvic floor musculature building strength, endurance and coordination. Biofeedback is often included in PFMT in an effort to promote adherence and efficiency through the contraction and timing of the correct muscles. Biofeedback is also used to assess improvement over time (Berghmans, Hendriks et al. 1998; Domoulin and Hay-Smith 2010). In the same way, intravaginal electrical stimulation (IVES) also targets the pelvic musculature by sending a mild electric current intended to trigger muscle contraction and, consequently, a strengthening effect similar to that of PFMT. It has also been hypothesized that the electrical stimulation encourages growth of nerve cells that cause the muscles to contract (Schreiner, Santos et al. 2013). In any case, the technology is designed to be used at-home for acute and on-going treatment. With a variety of devices on the market, the technology, in its simplest form, consists of a unit with built in surface electrodes that can be temporarily inserted into the vagina. Most of the devices also come with a hand-held controller allowing the regulation of current and duration. Several IVES devices have been approved by the U.S. Food and Drug Administration (FDA) as class II devices under the non-implanted electrical continence device classification.

04/21/2014: MTAC REVIEW
Intravaginal Electrical Stimulation for Urinary Incontinence
Evidence Conclusion: In 1996, Smith randomized 18 women with genuine stress urinary incontinence to either PFMT or IVES. After at least 16 weeks of treatment, 44% of the patients in the PFMT group showed objective improvement with one patient reported as cured, three with improvement and the remaining five with no significant improvement. In the IVES group, however, there was 66% improvement with two cured patients, four with improvement and three failures. Smith concludes that the device is safe, however, there was no discussion or reports of either how safety was measured or if data on adverse events were routinely collected. In addition, Smith concludes that IVES is at least as effective as PFMT, however, the total number of patients in the group was small and not statistically significant (Smith 1996). [Evidence Table 1] In an attempt to assess the effectiveness of physiotherapeutic treatment modalities in women with proven urge urinary incontinence
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Berghmans and colleagues randomized 68 patients to one of four treatment arms. With one control group of patients receiving no treatment, the remainder of the groups received IVES, PFMT or both. The primary outcome measure, the DAI, is a combined parameter that quantifies bladder over activity using a score between 0 and 1 where '0' represents no activity and '1' represents severe over activity. Ultimately, the investigators concluded that IVES was the only effective treatment for urge urinary incontinence, with a 0.28 difference in DAI score between pre- and post-treatment, but this conclusion is prone to bias as the intended sample size was 80 and only 68 patients were included in the ITT analysis (Berghmans, van Waalwijk van Doorn et al. 2002). [Evidence Table 2]. IVES treatment was compared to PFMT in a trial including 35 women aged 65 or older. The control group was given verbal instruction on how to perform Kegel exercises while the IVES group received maximal IVES for 30 minutes three times a week. With several objective and subjective outcomes being measured the authors make several conclusions regarding treatment with IVES of one of which claims high physical and emotional cost for the treated individuals. It is unclear how they came to this conclusion as there is no mention of any kind of QoL questionnaires nor was there systematic collection of adverse effects. In terms of the effectiveness of the IVES device, the authors report no significant improvement in objective outcomes and deem it unreasonable to advise elderly women to undertake this treatment (Spruijt, Vierhout et al. 2003). [Evidence Table 3]. Limitations of the reviewed evidence include small study populations which limit the ability to rule out the role of chance as an explanation of findings and short follow-up times, which limit conclusions regarding the durability of any treatment effects. Data on adverse events and outcomes were not systematically collected in any of the selected studies. Any benefit observed in the urge and stress urinary incontinence studies do not appear to be superior to less invasive treatments such as PMFT. In general, the studies are significantly heterogeneous in their methodology and follow up and suffer from variation in stimulation parameters. Ultimately, there is no clear demonstration that IVES results in improved health outcomes in patients in the long run.
Conclusion: There is insufficient evidence to support the treatment of mixed urinary incontinence with IVES. There is insufficient evidence to support the treatment of stress urinary incontinence with IVES. There is insufficient evidence to support the treatment of urge urinary incontinence with IVES. There is insufficient evidence to support the safety of IVES in females with urinary incontinence.
Articles: The search initially revealed over 700 publications related to urinary incontinence. Articles were screened for comparison studies investigating intravaginal electrical stimulation (IVES) treatment for incontinent females after which the literature was narrowed down to 21 randomized controlled trials (RCTs) summarized in tables 1, 2 and 3. The studies varied in the treatment of urinary incontinence ranging from stress urinary incontinence, to urge and mixed urinary incontinence and none were powered to determine equivalence. In addition, IVES treatment was compared to several different treatment options including various nonpharmacologic, pharmacologic and surgical. Studies that compared IVES to PFMT were selected for critical appraisal. The following studies were selected for review: Smith, JJ. Intravaginal stimulation randomized trial. The Journal of Urology. 1996;155:127-130 Evidence Table 1. Berghmans B, van Waalwijk van Doorn E, Nieman F, et al. Efficacy of physical therapeutic modalities in women with proven bladder overactivity. European Urology. 2002;41:581-587 Evidence Table 2. Spruijt J, Vierhout M, Verstraeten R, et al. Vaginal electrical stimulation of the pelvic floor: a randomized feasibility study in urinary incontinent elderly women. Acta Obstet Gynecol Scand. 2003;82:1043-1048 Evidence Table 3.

The use of IVES does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETRTSUI)

BACKGROUND

Urinary incontinence is a common symptom that affects women of all ages. Stress urinary incontinence is one of the most common types of urinary incontinence and is defined as the involuntary leakage of urine on exertion, sneezing, or coughing. Risk factors for stress urinary incontinence include obesity, pregnancy, and childbirth (Deng 2011, Rogers 2008). Treatment options for stress urinary incontinence include conservative measures, pharmacotherapy, and surgical interventions. Conservation treatments such as weight loss, pelvic floor muscles exercise (also known as Kegel exercises), as well as other behavioral and lifestyle modifications are the first-lines of treatment for stress urinary incontinence. Duloxetine, a combined serotonin and norepinephrine reuptake inhibitor, has shown some efficacy for the treatment of stress urinary incontinence; however, it failed to obtain FDA approval due to concerns for liver toxicity and suicidal events. Currently, there are no FDA approved drug therapies for stress urinary incontinence. Surgical therapy is indicated for patients who have not responded to conservative treatment options. Surgical interventions include retropubic colposuspension (Burch suspension), midurethral or bladder neck slings, injection of urethral bulking agents, and tension-free vaginal tape (Deng 2011, Rogers 2008). Transurethral radiofrequency micro-remodeling has been proposed as a minimally invasive treatment for stress incontinence among women who fail conservative therapies. In this procedure, controlled,

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low-level radiofrequency energy results in localized collagen denaturation. This leads to reduced regional dynamic tissue compliance without creating stricture or reducing luminal caliber (Appell 2008, Elser 2009).
Another radiofrequency treatment for stress urinary incontinence is transvaginal radiofrequency bladder neck suspension. This approach differs from the transurethral procedure in two ways. First, the transvaginal procedure is a surgical procedure whereas the transurethral procedure is a non-surgical procedure that does not require an incision. Second, higher levels of radiofrequency energy are used in the transvaginal procedure. These higher levels of energy result in higher temperatures which causes tissue necrosis instead of collagen denaturation to reduce involuntary urinary leakage (Appell 2008).

08/13/2003: MTAC REVIEW
Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETRTSUI)
Evidence Conclusion: The best available evidence on TRETRTSUI is in case series reports, the weakest study design due to the potential for selection and observation bias and lack of a control or comparison group. The case series articles on the SURx laparoscopic and transvaginal systems suggest a substantial decrease in incontinence episodes 12 months after the procedure compared to baseline. In addition to type of study design, these studies are limited by the strong financial links between the authors and the SURx company, which could bias the design, analysis and/or reporting of results.
Articles: The Medline search yielded 4 articles. There were no randomized or non-randomized controlled trials. There was one case series on the SURx Transvaginal system that was critically appraised. In addition, there were two publications using the SURx Laparoscopic system that reported on the same series of patients. These two articles were critically appraised in the same evidence table. No published studies on the Novasys product were identified. SURx Transvaginal study: Dmochowski RR, Avon M, Ross J et al. Transvaginal radiofrequency treatment of the endopelvic fascia: A prospective evaluation for the treatment of genuine stress urinary incontinence. *J Urol* 2003; 169: 1028-1032. See Evidence Table. SURx Laparoscopic study:
Fulmer BR, Sakamoto K, Turk TM et al. Acute and long-term outcomes of radiofrequency bladder neck suspension. *J Urol* 2002; 167: 141-145.Ross JW, Galen DI, Abbott K. et al. A prospective multisite study of radiofrequency bipolar energy for treatment of genuine stress incontinence. *J Am Assoc Gynecol Laparosc* 2002; 9: 493-499. See Evidence Table.

The use of Transurethral Radiofrequency Energy Tissue Remodeling in the treatment of Stress Urinary Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/20/2011: MTAC REVIEW
Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETRTSUI)
Evidence Conclusion: A randomized controlled trial that included 173 women evaluated the safety and efficacy of transurethral radiofrequency micro-remodeling for the treatment of female stress urinary incontinence compared to sham treatment. There were two primary outcomes for this study – quality of life and leak pressure point (LPP). An improvement in quality of life was defined as a 10 point or greater increase on the Incontinence Quality of Life (I-QOL) score. After 12 months of follow-up, 48% of subjects in the intervention group and 44% in the control group experienced an improvement in quality of life (P=0.07). However, in patients with moderate to severe stress urinary incontinence (I-QOL score of 0 to 60 points), 74% of subjects in the intervention group compared to 50% in the control group experienced an improvement in quality of life (P=0.03). There was no significant difference in the percent of subjects with mild stress urinary incontinence (I-QOL score of 61 to 90 points) who experienced an improvement in quality of life (intervention=22% vs. control=35%, P=0.02). Women in the intervention group experienced an increase in LPP at 12 months (13.2 ± 39.2 cmH_2O), while women in the control group experienced a decrease in LPP (-2.0 ± 33.8 cmH_2O) (P=0.02). There was no significant difference in adverse events between the two treatment groups. The most commonly reported adverse events were wet overactive bladder and dysuria (Appell 2006). This trial had several methodological limitations: an intent-to-treat analysis was not performed; it is not clear if the investigators were blinded; power was not assessed; and it is not stated if the subgroup analyses were planned. An interim analysis from a prospective case-series that included 139 women with stress urinary incontinence who had failed conservative treatments and had not undergone surgery or bulking agent treatment also evaluated the safety and long-term efficacy of transurethral radiofrequency micro-remodeling for the treatment of female stress urinary incontinence. After 18 months, patients experienced significant reductions in the median number of leaks per day (-0.43, range -34.3 to 18.9, P=0.006) and per week (-3.0 range -240.0 to 132.0, P=0.006) compared to baseline. Additionally, 46.7% of patients had at least 50% fewer leaks (P<0.0001) compared to baseline. With regard to quality of life, 65 patients (47.8%) experienced at least a 10-point improvement in I-QOL score. During the first three days post-treatment, the most common adverse events were dysuria (N=7, 5.2%), urinary retention (N=6, 4.4%), post-procedure pain
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(N=4, 2.9%), and urinary tract infection (N=4, 2.9%). At 12 months, one patient reported an increase in leakage, which was probably treatment related. Between 12 and 18 months one patient experienced a myocardial infarction, which was determined to be unrelated to the treatment (Elser 2009). Results from this study should be interpreted with caution as this study is a case-series and therefore more prone to bias. Additionally, 73 subjects (53%) discontinued the study for various reasons. *Conclusion*: Transurethral radiofrequency micro-remodeling: Results from a randomized controlled trial with several methodological limitations suggest that transurethral radiofrequency micro-remodeling may be safe and effective for the treatment of female stress urinary incontinence. More studies are needed to address the durability of the effect and whether women who undergo transurethral radiofrequency micro-remodeling can subsequently undergo other procedures such as retropubic colposuspension (Burch suspension) or tension-free vaginal tape without undo complications. Transvaginal radiofrequency bladder neck suspension: There is insufficient information to determine the safety and efficacy of transvaginal radiofrequency bladder neck suspension for the treatment of female stress urinary incontinence. **Articles**: *Assessment objective* to determine the safety and efficacy of transurethral radiofrequency micro-remodeling for the treatment of stress urinary incontinence. To determine the safety and efficacy of transvaginal radiofrequency bladder neck suspension for the treatment of stress urinary incontinence. Only one randomized controlled trial was identified that evaluated the safety and efficacy of transurethral radiofrequency micro-remodeling for the treatment of stress urinary incontinence. It was selected for review. Since the 2003 MTAC review, two retrospective cohort studies were identified that evaluated transvaginal radiofrequency bladder neck suspension for the treatment of stress urinary incontinence. As both of these studies included less than 25 participants, neither of them was selected for review (Buchsbaum 2007, Ismail 2008). The following study was critically appraised: Appell RA, Juma S, Wells WG, et al. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *Neurourol Urodyn 2006;* 25: 331-336. See Evidence Table.

The use of Transurethral Radiofrequency Energy Tissue Remodeling in the treatment of Stress Urinary Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of transvaginal radiofrequency bladder neck suspension in the treatment of Stress Urinary Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

SPARC® Sling for Treatment of Urinary Incontinence

BACKGROUND

Stress urinary incontinence (SUI) is defined as leakage of urine during activities that cause increased abdominal pressure such as exercise or coughing in the absence of a detrusor contraction. It is the most common form of urinary incontinence in women and is estimated to affect about 6.5 million women in the United States. Current understanding is that urinary continence during stress events requires both intact supportive structures (i.e. endopelvic fascia) and functioning neurological control of the muscles of the pelvic floor and urethra (Agarwala & Liu, 2002). Treatments for stress urinary incontinence include conservative therapies such as strengthening the pelvic floor muscles with Kegel exercises and devices such as electrical stimulation devices and pessaries. There are also medications such as estrogen and various surgical treatments. Surgical procedures for stress incontinence attempt to provide support to the bladder neck and/or urethra to limit the movement of these structures. Sling procedures are a surgical option for treating common stress urinary incontinence secondary to intrinsic sphincteric deficiency and urethral hypermobility. The sling procedure involves using abdominal fasci, cadaveric fasci or polypropylene mesh as sling material. The piece of muscle fiber or synthetic material is attached under the urethra and bladder neck and secured to the abdominal wall and pelvic bone. When the patient's abdominal fasci is used, an abdominal incision is required. Synthetic slings are generally inserted through a vaginal approach. Newer sling procedures include SPARC and tension-free vaginal tape (TVT). Both procedures place the sling under the urethra without tension that is intended to minimize disruption of normal urethral mobility. In addition, both use a sling made of loosely woven polypropylene mesh, require a relatively short operating time and can be performed under local anesthesia with sedation (Staskin & Plzak, 2002). The SPARC system differs from TVT in the way in which the sling is placed under the urethra. TVT passes the sling anchoring trocars from below, using a rigid catheter guide. In contrast, SPARC uses small diameter needles that are passed from above through two small suprapubic incisions". In addition, unlike TVT, the SPARC mesh has a knotted "tensioning suture" that allows adjustment of the sling (Staskin & Plzak, 2002).

08/13/2003: MTAC REVIEW

SPARC® Sling for Treatment of Urinary Incontinence

Evidence Conclusion: There is insufficient evidence to determine the effectiveness of the SPARC sling for the treatment of stress urinary incontinence in women. The single published empirical study reports only on 4 patients who experienced vaginal erosion after the SPARC procedure.

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Articles: The search yielded 27 articles. Most of these were on related procedures such as tension-free vaginal tape. There was one empirical article on SPARC. This was a case series that presented data on 4 patients who experienced vaginal erosion of the mesh after the sling procedure. Due to the small sample size and the lack of data on the patients in the series who did not experience vaginal erosion, this study was not critically appraised.

The use of SPARC Sling in the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)

BACKGROUND

Overactive bladder (OAB) is defined by the International Continence Society as the presence of urinary urgency with or without urge incontinence that is usually accompanied by frequency and nocturia, in the absence of urinary tract infection or other obvious pathology. Urgency, the hallmark of OAB, is defined as the sudden compelling desire to urinate, a sensation that is difficult to defer. Urinary frequency is defined as voiding 8 or more times in a 24-hour period. Nocturia is defined as the need to wake up one or more times per night to void. The National Overactive Bladder Evaluation (NOBLE) epidemiologic study estimated that 16.9% of adult women in the US had OAB syndrome; 9.3% with incontinence, and 7.6% without incontinence (Abrams 2002, Stewart 2003, Martinson 2013). OAB is not a disease but a symptom complex that is generally not life-threatening but has a significant impact on the quality of life, sleep, work productivity, social relationships, mental health, sexual and physical activity. Treatment options for overactive bladder can be divided into 1. Conservative measures as behavioral interventions and pharmacotherapy, and 2. More invasive procedures. Most treatments may improve patient symptoms but are unlikely to eliminate all symptoms. A successful treatment requires a participant who is motivated and well informed about the variable and chronic course of the condition. The first line treatment of OAB is typically behavioral interventions, which consist of bladder training, bladder control, pelvic floor muscle exercises, fluid management, and weight loss. Behavioral interventions may not eliminate all symptoms but lead to significant reductions of symptoms and improve the quality of life of most patients. Pharmacological therapy may be used in combination with behavioral intervention or as a second line treatment. Antimuscarinic drugs or anticholinergics lead to significant improvement in the patient symptoms but are commonly associated with side effects as dry mouth, blurred vision, urinary retention and infection, dyspepsia, and impaired cognitive function. Patients who fail behavioral and pharmacological therapy, who do not tolerate its side effects, or are not candidates for conservative therapy and still have bothersome symptoms, may be offered alternative invasive measures. These include invasive surgical procedures e.g. bladder denervation, detrusor myomectomy, urinary diversion, bladder augmentation, neobladder construction, and others. Surgical procedures have variable cure rates and adverse events. Other less invasive options include detrusor injection with botulinum toxin (BTX), and pelvic neuromodulation therapy (Ridout 2010, Peters 2009, 2010, 2012, Gormley 2012). Pelvic neuromodulation utilizes electrical stimulation to target specific nerves in the sacral plexus that control the pelvic floor and bladder functions. Neuromodulation is either invasive using implantable sacral nerve stimulation (SNS), or minimally or noninvasive using a removable device such as transvaginal or transanal electrostimulation, magnetic stimulation, or percutaneous tibial nerve stimulation (PTNS). The specific mechanism of action is unknown, but it is thought that neuromodulation may have a direct effect on the bladder or a central effect on the micturition centers in the brain. Neuromodulation of the sacral nerve, also known s pacemaker for the bladder, uses mild electrical pulse to activate or inhibit neural reflexes by continuously stimulating the sacral nerves that innervate the pelvic floor and lower urinary tract. A unilateral lead is implanted in the vicinity of S3 nerve root and attached to a small pacemaker placed within a subdermal pocket in the buttock region. SNS therapy was found to be effective for refractory OAB but is invasive and associated with adverse events related to the implant procedure, the presence of the implant, or due to undesirable stimulation. In addition, SNS requires reoperation to replace the implantable generator due to the limited longevity of the neurostimulator. The SNS technology continues to evolve (Peters 2009, 2010, 2012, Al-Shaiji 2011, Mossdoeff-Steinhauser 2013). PTNS, also known as Stoller afferent nerve stimulation (SANS), developed by Stoller in the late 1990s, is a form of peripheral neuromodulation. It is a minimally invasive, office-based procedure that involves percutaneous insertion of a fine (34-guage) needle at the level of the posterior tibial nerve, slightly above the medial alveolus of the ankle (the insertion point for the needle corresponds with an acupuncture point used for a variety of urinary disorders). The needle is connected to a low voltage (6V) stimulator device with 0-10mA at a fixed frequency of 20Hz. The amplitude is increased until the toes are seen to fan or the big toe to flex. The current is set at the highest tolerated level and the stimulation is continued for 30 minutes. Neuromodulation to the pelvic floor is delivered through the S2-S4 junction of the sacral nerve plexus through the posterior tibial nerve. During the initial therapy, treatment is delivered for 30 minutes and repeated weekly for 12 weeks. OAB is a chronic disease and patients who respond to PTNS may need to receive long-term therapy in order to sustain the benefit of PTNS therapy (Peters 2009, Shaiji 2011, Burton 2012, Martinson 2013, Mossdddorff-Steinhauser 2013).

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PTNS was approved by the FDA in 2000 as an office-based therapy for OAB.

10/01/2007: MTAC REVIEW
Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)
Evidence Conclusion: There is insufficient evidence to determine the safety and efficacy of percutaneous tibial nerve stimulation (PTNS) for treating urinary urgency, urinary frequency and urge incontinence. No published randomized or non-randomized controlled trials were identified. This is particularly problematic because there is known to be a high placebo effect in studies evaluating treatments for urinary incontinence. Only case series were available. A team based in the Netherlands published several case series that used either the Urgent PC Neuromodulation System (Uroplasty) or a precursor of this device. The studies were conducted before FDA approval. Results of the case series on the Urgent PC were similar. Vandoninck et al. (2003), for example, reported a substantial reduction in incontinence episodes and voiding frequency at the end of treatment among patients for whom data were available. Two other case series were evaluated. Both of these utilized the PerQ Sans (UroSurge), a device similar to the Urgent PC. It is not known whether the PerQ Sans is currently commercially available in the U.S. The Ruiz (2004) and Govier (2001) case series found significant improvement in urinary incontinence symptoms. One study was conducted in the United States; two of the five authors in the U.S. study reported financial relationships with the device manufacturer. Other limitations of the case series include missing data and lack of long-term follow-up.
Articles: The ideal study is a randomized controlled trial comparing PTNS to a placebo and/or alternative established intervention. No randomized controlled trials or non-randomized comparison studies were identified. The search yielded only case series. Sample sizes ranged from 11 to 132, most were in the range of 35 to 55 patients. Seven out of the 10 case series identified were conducted by the same research group in the Netherlands. The articles differed on the indications for treatment (urge incontinence, overactive bladder syndrome, etc.) and the outcomes reported. The largest case series from the Netherlands team, and two other case series (one conducted in Spain, the other in the U.S.) were critically appraised. The remaining case series was excluded because they did not report clinical outcomes. A news release from Uroplasty in July 2006 stated that the company is initiating a randomized controlled trial comparing Urgent PC to anticholinergic medication for patients with symptoms of urge incontinence and urgency and frequency. The announcement did not report the expected date of study completion. *The studies critically appraised in evidence tables are:*
Vandoninck V, van Balken MR, Agro EF et al. Percutaneous tibial nerve stimulation in the treatment of overactive bladder: Urodynamic data. Neurol Urodynam 2003; 22: 227-232. See Evidence Table. Ruiz BC, Outeirino P, Martinez PC et al. Peripheral afferent nerve stimulation for treatment of urinary tract irritative symptoms. Eur Urol 2004; 45: 65-67. See Evidence Table. Govier FE, Litwiller S, Nitti V et al. Percutaneous afferent neuromodulation for the refractory overactive bladder: Results of a multicenter study. J Urol 2001; 165: 1193-1198. See Evidence Table.

The use of Percutaneous Tibial Nerve Stimulation in the treatment of overactive bladder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/15/2013: MTAC REVIEW
Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)
Evidence Conclusion: The larger published randomized controlled trials on the use of PTNS for overactive bladder syndrome were mainly supported by the manufacturer of the PTNS system and conducted by the same group of researchers who had financial interest and/or other relationships with the manufacture. PTNS was compared either to sham therapy or to antimuscarinic drugs. No comparisons were made versus behavioral therapy or other methods of neuromodulation as sacral nerve stimulation. There were variations between published studies in the inclusion criteria, gender, severity and duration of symptoms, previous treatments, treatment protocol, number of sessions per week during therapy, and treatment intervals during maintenance therapy. Outcome measures were mainly subjective and based on reported patient diaries. No well-conducted trials with long term follow-up and objective urodynamic outcomes were identified. Definition of response or treatment success varied between studies. Burton et al (2012), meta-analysis of randomized and prospective trials showed that the success rate varied from 37-82%. Two of the published RCTs (ORBIT and SUmiT) were followed by reports on mid-term follow-up (12 months for ORBIT and up to 36 months for SUmiT), but only the responders to PTNS (60-70% of those receiving the PTNS therapy) were included in the follow-up studies. Studies showed that OAB symptoms worsen after discontinuation of treatment, and that maintenance therapy, is needed to avoid recurrence of symptoms.
Comparison of PTNS vs. Sham therapy

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Peters and colleagues (2010) compared the efficacy of PTNS to sham therapy in 220 adult men and women with OAB (SUmiT trial, evidence table 1). The results showed a statistically significant improvement in bladder symptoms in the PTNS group compared to sham therapy group, with some non-serious adverse events. However, only just over half the patients (54.5%) who received the PTNS therapy showed moderate or marked response to the therapy, almost two third of the patients still had urinary urge incontinence after 12 weeks of PTNS, and more than half still complained of urinary urgency and frequency.

In another sham-controlled, but small and single-blinded trial, Finazzi-Agro and colleagues (2010) randomized 35 women with OAB who did not respond to antimuscarinic therapy to receive PTNS or a sham therapy for 12 sessions. The sessions were performed for 30 minutes three times weekly. Patients with a 50% or greater reduction in urge incontinence episodes were considered responders. The primary outcome was the percent of responders in the two groups. The results of the trial showed that 12/17 (71%) of the patients randomized to PTNS reported a 50% or greater reduction in incontinence episodes compared to none of those in the sham therapy. Improvement in the number of incontinence episodes, number of voids, voided volume, and incontinence quality of life score were statistically significant in the PTNS group but not in the sham therapy group.
Comparison of PTNS vs. active therapy with extended-release tolterodine
In the OrBIT trial (evidence table 2), Peters and colleagues compared the effectiveness of PTNS to extended-release tolterodine (Detrol LA) in reducing OAB symptoms. The trial included 100 adults with OAB symptoms, at least 8 voids/24 hours, and with or without a history of anticholinergic drug use. The primary outcome of the trial was the reduction in frequency of urinary voids /24 hours. The study was randomized and controlled, but it was not blinded, and the outcomes were subjective, which does not allow ruling out the placebo effect of PTNS. The patients in the two arms were observed differently during follow-up (visits were made in person for the PTNS group and by phone for the Detrol La group). The duration of follow- was only 12 weeks, the dropout rate was >15%, and analysis was not based on ITT. The study was supported by the manufacturer, and the authors had financial interest with the industry. The results of the OrBIT trial showed a significantly higher improvement in the Global Response Assessment rate with PTNS compared to Detrol LA when self-reported, but not when assessed by the investigator. There was no significant difference in the OAB symptom improvement between the two treatment groups.
Articles: The literature search for studies published after the 2007 MTAC review of PTNS for the treatment of overactive bladder in adults revealed four randomized controlled trials, two of which were conducted by the same group of authors (SUmiT and OrBIT trials) and two had additional publications with extended follow-up data (2 and 3 years follow-up of SUmiT were published as STEP trial). The search also identified two systematic reviews (one with a meta-analysis) of studies on the effect of PTNS for overactive bladder, and an updated Cochrane review that compared anticholinergic drug vs. non-drug active therapies for OAB in adults. The two larger trials and the meta-analysis on the effectiveness of PTNS for OAB were selected for critical appraisal: Burton C, Sajja A, Latthe PM. Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systematic review and meta-analysis. *Neurourol Urodyn.* 2012 ;31 :1206-1216. See Evidence Table. MacDiarmid SA, Peters KM, Shobeiri SA, et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Uro*l.2010; 183:234-240. See Evidence Table. Peters KM, Carrico DJ, Perez-Marrro RA, et al. Randomized trial of percutaneous tibial nerve stimulation versus Sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. *J Uro*l.2010; 183:1438-1443. See Evidence Table. Peters KM, Carrico DJ, *MacDiarmid SA,* et al Sustained therapeutic effects of percutaneous tibial nerve stimulation: 24-month results of the STEP study. *Neurourol Urodyn* 2013; 32:24-29. See Evidence Table. Peters KM, Carrico DJ, Woolridge LS Percutaneous Tibial Nerve Stimulation (PTNS) for the Long-Term Treatment of Overactive Bladder: Three-Year Results of the STEP Study. *J Urol.* 2012*;* Dec. See Evidence Table. Peters KM, MacDiarmid SA, Woolridge LS, et al. Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. *J Uro*l.2009; 182:1055-1061. See Evidence Table

The use of Percutaneous Tibial Nerve Stimulation in the treatment of overactive bladder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
BACKGROUND
Urinary incontinence (UI) refers to an involuntary leak of urine. There are several types of UI. Stress UI, the most common form, is an involuntary leak on effort or exertion and urge UI is an involuntary leak accompanied or immediately preceded by a sense of urgency. Mixed UI is a combination of stress and urge UI. A related condition is urinary retention, the inability to completely empty the bladder. Another diagnosis is overactive bladder syndrome (OAB), an urge that occurs with us without a leak of urine, and usually occurs with increased urinary
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frequency and nocturia. The condition is often categorized as either OAB dry (without incontinence) or OAB wet (with incontinence). The prevalence of urinary incontinence in women is approximately 50% when defined as any urine loss and is 8-36% when limited to bothersome urine loss. About half of all cases are stress incontinence. Urinary incontinence that is severe enough it cannot be easily concealed can have a major impact on quality of life, especially if it includes urinary urgency. Severe urinary incontinence has been found to increase the risk of urinary tract infections in post-menopausal women, and the risk of falls and hip fractures in elderly women (Gray, 2005). Treatments for urge incontinence include the use of absorbent pads, bladder training/pelvic floor muscle exercises, treatment with medications (anti-cholinergic agents, antispasmodics, tricyclic antidepressants), topical estrogen, pelvic floor electrical stimulation, and surgery. The most common treatment for urinary retention is self-catheterization. Sacral nerve stimulation using an implantable device (bladder pacemaker) is proposed as an additional alternative to surgery for patients with urge incontinence, urgency-frequency symptoms or urinary retention. (It is not proposed for stress incontinence, the most common form of urinary incontinence). The InterStim Therapy for Urinary Control is an FDA-approved device developed by Medtronic. Consistent with the protocol in clinical trials, patients undergo percutaneous test stimulation in an outpatient setting before implantation. This involves insertion of an electrode into a sacral foramen. An external device produces continuous stimulation. The implantable InterStim system uses an implanted lead stimulating the appropriate sacral nerve root, most commonly S3. The proximal part of the lead is tunneled under the skin and connected to the neurostimulator which is placed in a subcutaneous pocket in the lower abdomen. The physician can use a microprocessor-based console programmer to set stimulation settings. There is also a handheld programmer that patients can use to turn the stimulator on and off, and to adjust the voltage output amplitude. The battery operating the device is expected to last 7 to 9 years. It is challenging to evaluate the efficacy of treatments for urinary incontinence because there is no gold standard for outcome assessment. In addition, there is a high placebo effect in randomized incontinence studies; as many as 30-40% of patients in placebo groups report success. The high placebo effect has been attributed to several factors including the strong subjective component in voiding dysfunction, and potentially therapeutic effects of study design components such as keeping a voiding diary and interacting with study personnel (Dmochowski, 2001). Because of the high placebo effect, in order to show that an intervention is effective, it is necessary to show that it has an impact beyond that of a placebo. Sacral nerve stimulation for urinary incontinence was reviewed by MTAC in February 1999 and February 2001. The technology did not meet MTAC evaluation criteria. An evidence update was conducted outside of MTAC in October 2002. The GHP Urology Department has requested an updated review.

01/2001: MTAC REVIEW
Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Evidence Conclusion: The Schmidt et al. study found a significant improvement in urinary incontinence symptoms at 6 months among patients who received an InterStim device compared to patients receiving standard medical treatment. This study has several threats to validity including substantial selective loss to follow-up, self-report data and lack of blinding or intention-to-treat analysis. Moreover, the research team had with financial ties to the manufacturer of the device. Due to the potential biases in this study, the existing data are insufficient to permit conclusions about the effectiveness of this technology.
Articles: Eleven articles were identified. Six articles were not directly relevant, did not include clinical outcomes or were review articles; five articles presented empirical data on clinical outcomes. Articles were selected based on study type. There were three randomized controlled trials (RCTs) and two case series. The three RCTs were done by a single group of investigators. Only one of the 3 RCTs were examining urinary incontinence as the outcome. An evidence table was created for this RCT: Schmidt RA, Jonas U, Oelson KA, Janknegt RA, Hassouna MM, Siegel SW, Kerrebroek for the Sacral Nerve Stimulation Study Group. J Urol 1999; 162: 352-57. See Evidence Table.

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/2002: MTAC REVIEW
Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Evidence Conclusion: The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the Interstim device to standard medical treatment for 6 months, among patients who demonstrated during a 3-7-day testing period that they responded to the Interstim device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only
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patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) Treatment was not blinded and did not allow for a placebo effect of the Interstim device and; 3) The intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing).
Articles: The search yielded 17 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were three articles on a single randomized controlled trial and five case series. The three RCT articles reported on different patient populations enrolled in the same trial (those with urge incontinence, urgency-frequency and non-obstructive urinary retention) and were all critically appraised. The Schmidt study was included in the February 2001 MTAC review. Evidence tables were created for the following articles: Schmidt RA, Jonas U, Oleson KA et al. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. *J Urol* 1999; 162: 352-357. See Evidence Table. Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. *J Urol* 2000; 163: 1849-1854. See Evidence Table. Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. *J Urol* 2001 165: 15-19. See Evidence Table.

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/01/2007: MTAC REVIEW
Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence
Evidence Conclusion: The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the InterStim device to standard medical treatment for 6 months, among patients who demonstrated in a 3-7-day testing period that they responded to the device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) treatment was not blinded and did not allow for a placebo effect of the InterStim device and; 3) the intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing). An alternative study design to evaluate the effectiveness of InterStim among patients who respond to a test trial would be to compare InterStim to a different treatment that patients had not already failed. Especially in a non-blinded study with some subjective outcomes, bias can be introduced if one group perceives that they are receiving a new and innovative treatment and the other group is receiving the same treatment they have already received. There are no new RCTs to supplement the above data.
Articles: The ideal study would be a randomized controlled trial comparing InterStim therapy to a placebo and/or established alternative intervention. At the time of the 2002 evidence review, conducted outside of the MTAC meeting, there were several RCTs by the same group of investigators. The RCTs compared InterStim to standard medical therapy. No new RCTs evaluating the efficacy and/or safety of the InterStim device were identified. There was one additional publication on the original RCT, evaluating psychosocial outcomes in a subset of the study population (Das et al., 2004; Urol). One new RCT was identified on a related topic, comparing two methods for predicting which patients would proceed to device implantation (Borawski et al., 2007). The study did not compare the effectiveness of InterStim treatment compared to placebo or an alternative treatment and was thus not reviewed further. In addition, there were several new case series with sample sizes of approximately 30 patients. Since higher grade evidence has been published, the small case series were not reviewed. *The RCTs on InterStim that have been critically appraised are* Schmidt RA, Jonas U, Oelson KA et al. for the Sacral Nerve Stimulation Study Group. J Urol 1999; 162: 352-57. See Evidence Table. Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. J Urol 2000; 163: 1849-1854. See Evidence Table. Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. J Urol 2001 165: 15-19. See Evidence Table.

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Sacral Nerve Stimulator

2/11/2013: MTAC REVIEW

Evidence Conclusion: Based on evidence from one randomized controlled trial and several observational studies, the Kaiser Medical Technology Assessment Team found that the evidence on the safety and efficacy of sacral nerve stimulation for treating severe fecal incontinence is of insufficient quality and quantity to determine whether sacral nerve stimulation is medically appropriate for the treatment of fecal incontinence. The best evidence comes from the randomized controlled trial conducted by Tjandra and colleagues (see below) (Kaiser 2011).

Results from a RCT that included 120 patients with severe fecal incontinence suggest that compared to optimal medical therapy patients who were treated with sacral nerve stimulation had significantly fewer incontinence episodes per week, days with incontinence, days with straining, and significantly better quality of life at 12 months. Adverse events included pain at implant site, seroma, and excessive tingling in the vaginal region. All patients in the sacral nerve stimulation group needed the program readjusted. The mean number of readjustments per person was three. Adjustments included changes in the electrode used for stimulation as well as changes in amplitude and rate. This study had several limitations: power was not assessed, results are only applicable to patients with severe incontinence, and patients included in the study were refractory to medical therapy and pelvic floor exercises, which was the control group treatment (Tjandra 2008).

Conclusion: There is limited evidence on the safety and efficacy of sacral nerve stimulation for the treatment of fecal incontinence.

Articles: In February 2011, Kaiser Permanente's Medical Technology Assessment Team reviewed implantable sacral nerve stimulators for fecal incontinence. The randomized controlled trial that was included in the Kaiser technology assessment was also selected for review as this was the highest quality study assessing the effects of sacral nerve stimulation for the treatment of fecal incontinence. Since the Kaiser Technology Assessment, several observational studies were identified that evaluated the effects of sacral nerve stimulation. None of these studies were selected for review as they did not compare sacral nerve stimulation to other treatments.

The following study and technology assessment were selected for review: Kaiser Permanente. Implantable sacral nerve stimulators for severe fecal incontinence. February 2011;
http://pkc.kp.org/national/cpg/intc/topics/03_19_125.html
Accessed November 6, 2012.

The use of Sacral Nerve Stimulation for Fecal Incontinence meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
E0740	Nonimplanted pelvic floor electrical stimulator, complete system
E0746	Electromyography (EMG), biofeedback device
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
L8604	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies

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L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

Biofeedback:

Non-Medicare—Considered Not Medically Necessary:
Medicare—Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
90901	Biofeedback training by any modality
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/1998	08/03/2010[MDCRPC], 04/05/2011[MDCRPC], 05/03/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 06/04/2013[MDCRPC], 08/06/2013[MPC], 11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	03/07/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008 and 34886
06/28/2015	Added coverage article A52965
03/07/2017	MPC approved criteria for PTNS
12/02/2022	Added Retired LCD 14443

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Clinical Review Criteria
Tumor Treatment Field Therapy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Tumor Treatment Field Therapy (TTFT) (L34823)
Local Coverage Article	Tumor Treatment Field Therapy (TTFT) (A52711)

For Non-Medicare Members

I. Tumor-treating fields (TTF) to treat primary (not recurrent) supratentorial glioblastoma multiforme (GBM) may be considered medically necessary when **ALL of the following** are met:
   A. Patient is 18 years of age or older; and
   B. Karnofsky Performance Status* is 70% or higher; and
   C. Documentation of histologically confirmed primary glioblastoma multiforme; and
   D. Patient has completed standard concomitant chemoradiation with temozolomide(TMZ); and
   E. Disease did not progress through chemo radiation (possible “pseudo progression” does not exclude patients from receiving TTF) and
   F. TTF will be administered concurrently with TMZ, unless TMZ has been ineffective, not tolerated, or is contraindicated and
   G. TTF must be started no later than 60 days from the end of chemo radiation

II. Continued treatment of TTF can be covered until the second radiological progression (meaning 2 consecutive images showing tumor progression) or clinical deterioration

All authorizations are for 90 days. Re-authorizations require updated clinical notes and imaging.

*Karnofsky Performance Status Scale

Condition	Value (%)	level of Functional Capacity
Able to carry on normal activity and to work; no special care needed	100%	No complaints; no evidence of disease
	90%	Able to carry on normal activity; minor signs or symptoms of disease
	80%	Normal activity with effort; some signs or symptoms of disease
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed	70%	Cares for self; unable to carry on normal activity or to do active work
	60%	Requires occasional assistance but is able to care for most personal needs

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	50%	Requires considerable assistance and frequent medical care
Unable to care for self; requires equivalent of institutional or hospital care; diseases may be progressing rapidly	40%	Disabled; requires special care and assistance
	30%	Severely disabled; hospital admission indicated although death not imminent
	20%	Very sick; hospital admission necessary; active supportive treatment necessary
	10%	Moribund; fatal processes progressing rapidly

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Glioblastoma (GBM), an incurable disease, has the highest incidence rate (3.19/100,000 population) amongst the central nervous system (CNS) tumors with an average survival of 15 months (Thakkar et al., 2014). Numerous genetic and environmental risk factors have been investigated but none is associated with a large population of GBM (Wrensch, Minn, Chew, Bondy, & Berger, 2002). The median age of diagnosis is 64 years and GBM is frequently found in the supratentorial region (Adams et al., 2013). GBM is an aggressive malignancy with poor prognosis and low survival. The first year relative survival rate is 35% and this estimate decreases over time (Ostrom et al., 2013) making the long term survival very harsh. Standard treatment consists of resection with combination of radiation and chemotherapy. These therapies, whether combined or utilized alone, do not significantly decrease mortality and do not lack adverse effects. Because GBM infiltrates the brain, it is prone to recurrence. Management of recurrence became challenging and therefore indispensable for better clinical outcomes. Different therapeutic options have been investigated but tumor treating fields (TTFields), a novel treatment, seems comparable to standard chemotherapy including Temozolomide and is less toxic (Roger Stupp et al., 2012).

TTFields, developed by NovoCure Ltd, is a medical device for the treatment of recurrent GBM. It is a portable, non-invasive, battery-operated and wearable device that disrupts the division of cancer cells and proliferation in the supratentorial region by delivering low-intensity and intermediate frequency (200 kHz) alternating electric fields via transducer arrays applied to the scalp by means of hypoallergenic ceramic disks, which are placed on the scalp using Hydrogel (Axelgaard Manufacturing Co, Ltd, Fallbrook, CA) as a conductor; It is believed that TTFields inhibits cytokinesis and microtubule assemble, and therefore inhibiting growth and causing death of cancer cells (Butowski, Wong, Mehta, & Wilson, 2013). The NovoTTF-100A received premarket approval from the Food and Drug Administration (FDA) on April 10, 2011 for treatment in adult patients with confirmed GBM, following confirmed recurrence in an upper region of the brain after receiving chemotherapy. The device is intended to be used independently and as an alternative to standard medical therapy after surgical and radiation options have been exhausted (FDA 2011).

The review of the safety and effectiveness of TTFields Therapy for the treatment of recurrent GBM in adults has been reviewed previously. However, it is being reviewed based on a request from the Clinical Review Unit with a focus on the combination of TTFields plus Temozolomide as maintenance therapy on newly diagnosed GBM. It is also being reviewed for coverage decision support.

Medical Technology Assessment Committee (MTAC)

Tumor Treatment Fields Therapy

08/19/2013: MTAC REVIEW

Evidence Conclusion: The randomized phase III trial sought to compare the overall survival of subjects treated with the NovoTTF-100A alone to subjects treated with the best standard of care (BSC) chemotherapy available for recurrent GBM (Stupp, Wong et al. 2012). In the clinical study, 237 subjects with previously diagnosed GBM who experienced recurrence of their tumor or their condition worsened despite conventional therapy (surgery and

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chemo-radiotherapy followed by chemotherapy) were randomly assigned to receive either NovoTTF-100A stand-alone treatment or the BSC chemotherapy (as determined by the local physician). The primary endpoint for the study was overall survival, as assessed by the log-rank test in the intent-to-treat population. In addition, the study examined the safety and tolerability of NovoTTF-100A treatment based on the incidence and severity of adverse events and toxicities. Secondary endpoints measured in the study included the progression free survival rate at 6 months, time to progression, one-year survival rate, quality of life and radiological response rate. The ITT population includes all subjects who were randomized to the trial. At a median follow up of 39 months 93% of patients had died. The analysis was performed by the treatment group to which the subject was randomized. The study results showed that overall survival with the NovoTTF-100A System was no superior to that seen with active best standard of care chemotherapy. There was a slightly higher incidence of neurological adverse events in the NovoTFF-100A treated group (43.1%) compared to the best standard of care control group (36.3%). Mild to moderate skin irritation beneath the device electrodes was seen in 16% of NovoTFF-100A-treated subjects. NovoTFF-100A treated subjects experienced a lower frequency of the classic adverse events as seen with chemotherapy (such as gastrointestinal, hematological and infectious adverse events) with the best standard of care. Quality of life surveys indicated an improved quality of life in the NovoTFF-100A recurrent GBM subjects compared to the best standard of care recurrent GBM subjects. The trial was generally well designed and conducted with recruitment from 28 different clinics, randomization and minimal loss to follow up. Limitations identified by the authors include the somewhat heterogenous patient population with patients included after progression of one or several lines of prior chemotherapy. The authors also observed that the study could have benefited from a placebo or treatment-free control arm. Some limitations that are not highlighted by the authors include the decreasing number of subjects remaining after 12 months which may limit the ability to reliably estimate the long-term survival outcomes. Furthermore, it is important to note that the primary investigator, as well as a number of other authors had financial and professional ties with the manufacturer of the device Novocure Ltd., Rye Beach, New Hampshire. Although the study failed to show that the NovoTTF-100A treatment is superior to chemotherapy with respect to overall survival the NovoTTF-100A treatment exhibits minimal toxicity, has clinically comparable primary and secondary effectiveness and better quality of life compared to the chemotherapies used in the control arm of the study.
Articles: A literature search was conducted revealing a small pilot trial and one larger pivotal study. The pilot study was an open-label prospective single arm study to assess the safety and effectiveness of TTFields for the treatment of GBM. The pivotal study was prospective, open label, best standard of care randomized control trial to compare the overall survival of subjects treated with NovoTTF-100A alone to subjects treated with the best standard of care chemotherapy available for recurrent GBM. In addition, the search revealed a case study illustrating one patient's success with TTFields therapy and one expert opinion article discussing the concept, evidence and future of TTFields. The clinical study that formed the FDA's basis for determining that the NovoTTF-100A System is safe and effective for its intended use was selected for review: Stupp R, Wong ET, Kanner AA, Steinberg D, Engelhard H, et al. NovoTFF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomized phase III trial of a novel treatment modality. *European Journal of Cancer*. 2012;48, 2192-2202. See Evidence Table.

The use of TT Fields Therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Tumor Treating Fields plus Temozolomide as maintenance therapy for Glioblastoma Multiforme (GBM)
03/21/2016: MTAC REVIEW
Evidence Conclusion: The previous review on TTFields, completed in 2013, aimed to determine the safety and efficacy of TTFields therapy compared to standard medical therapy, for the treatment of recurrent GBM for adult patients. The study evaluating NovoTTF-100A versus Physician Choice Chemotherapy in recurrent glioblastoma (Roger Stupp et al., 2012) was reviewed and no improvement in overall survival was identified. The author of the review concluded that there was insufficient evidence to determine the safety and effectiveness of TTFields Therapy. Stupp, R., S. Taillibert, et al. (2015). "Maintenance Therapy With Tumor-treating Fields plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial." See Evidence Table 1. This randomized phase 3 trial, open label, parallel design, multicenter, (R. Stupp et al., 2015) intended to assess the efficacy and safety of TTFields in combination with temozolomide for treatment of patients with GBM after initial treatment with chemoradiation. After patients were diagnosed, they were initially treated with chemoradiation comprised of Temozolomide and concomitant radiation. Brain MRI was required 2 weeks prior to starting the maintenance treatment (to exclude progression cases). After completion of the initial treatment, patients were randomized at a ratio of 2 to 1 to receive TTFields + Temozolomide (n=466) or Temozolomide alone (n=229).TTFields was initiated within 4-7 weeks from the last dose of concomitant chemoradiotherapy. While Temozolomide was given on a basis of 150-200 mg/m2/d for 5 days every 28 days for 6-12 cycles, TTFields was delivered continuously (>18 hours/day) via 4 transducer arrays placed on the shaved scalp and connected to a portable medical device. The primary outcome was progression-free survival (PFS) in the intent-
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to-treat population (significance level of 0.01) and the secondary outcome was the overall survival (OS) in the per-protocol population (significance level of 0.006). Safety and tolerability were also evaluated. A total of 695 patients were recruited but the trial was terminated after the interim analysis showed a benefit in Progression Free Survival. This interim analysis was conducted after the first 315 randomized patients reached a minimum of 18-month follow-up. Thus, data from 315 patients with 210 patients in the intervention group and 105 patients in the control group were analyzed. Baseline characteristics were nearly similar across the groups with median age of 57 years. The findings were based on the interim analysis. Patients who were treated with TTFields plus Temozolomide had longer PFS [7.1 months (CI, 5.9 – 8.2)] than those who were treated with Temozolomide alone [4 months (95%CI, 3.3 – 5.2)]. Likewise, patients who were treated with TTFields plus Temozolomide had longer OS [20.5 months (16.7 - 25)] than those who were treated with Temozolomide alone [15.6 months (CI, 13.3 – 19.1)]. In addition, no major increases in toxic effects were associated with the intervention. The most common adverse events were thrombocytopenia, mild to moderate skin irritation, and general disorders. In conclusion, the combination of TTFields plus Temozolomide prolonged PFS as well as OS compared to Temozolomide alone for the maintenance treatment of patients with GBM. However, this is an interim analysis with less than 50% of participation with exclusion of patients with early progression decreasing the quality of the evidence. MTAC will re-review the technology once full data are analyzed. Conclusion: The interim analysis with less than 50% participation suggests that TTF plus Temozolomide may prolong progression-free survival and overall survival versus Temozolomide alone. Nevertheless, the study failed to include patients with severe prognosis, therefore results should be interpreted with cautious. Other pitfalls remain in the open-label nature of the RCT leading to placebo effects and variation in the delivery of chemotherapy and radiochemotherapy.
Articles: A literature search was conducted revealing 13 articles (Please refer to appendix B) of which one meets inclusion criteria (studies involving histologically confirmed GBM, standard concomitant chemoradiation with Temozolomide, age >18 years with ≥ 70% on Karnofsky Performance Status (KPS) score and good renal and bone marrow function, received TTFields plus Temozolomide as maintenance therapy). The study on "Maintenance Therapy with tumor-treating fields plus temozolomide vs Temozolomide alone for Glioblastoma: A randomized clinical trial" will be critically appraised.

The use of Tumor Treating Fields (TTFields) plus Temozolomide as maintenance therapy for Glioblastoma multiforme (GBM) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

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Date Created	Date Reviewed	Date Last Revised
10/01/2013	10/01/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 05/03/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	09/06/2016

[MPC] Medical Policy Committee

Revision History	Description
03/21/2016	Added MTAC Review for of Tumor Treating Fields (TTFields) plus Temozolomide as maintenance therapy for Glioblastoma multiforme (GBM)
05/03/2016	MPC approved GH developed criteria for Tumor Treating Fields (TTFields)

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09/06/2016	Criteria added for continued treatment of TTF
06/28/2017	Added Medical Directors Comments
03/06/2018	MPC approved revised criteria for continued treatment of TTF

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Clinical Review Criteria
Ultrasound Guided Percutaneous Needle Release of Carpal Tunnel

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Ultrasound Guided Percutaneous Needle Release of Carpal Tunnel” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

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Background

Carpal tunnel syndrome (CTS) is a neuromuscular clinical condition caused by compression or irritation of the median nerve where it passes under the transverse carpal ligament in the wrist. Thickening of tendon sheaths or encroachment by other structures lead to a sustained rise in pressure within the canal. The pressure is further increased by flexion or extension of the wrist. The incidence of CTS in the United States has been estimated at 1-3 cases per 1,000 subjects per year, with a prevalence of 50 cases per 1,000 per year. CTS is more common in individuals 45-65 years of age and among females. The etiology of the syndrome is not well known and continues to be debated. It is believed that it may have a hereditary component and that physical occupational activity such as repeated and forceful movement of the hand and wrist or the use of handheld powered vibratory tools can predispose to the condition. Other predisposing causes included rheumatoid arthritis, pregnancy, obesity, and hypothyroidism (Nathan 2005, Verdugo 2008, Bickel 2010, Palmer 2011, Page 2013).

The most common symptoms of carpal tunnel syndrome are pain, tingling, and numbness within the median nerve distribution of the hand (thumb, index and middle, and radial half of the ring finger). Pain may radiate to the arm and is often worse at night and when gripping an object for a long duration of time. In advanced stages, thenar muscle weakness can occur. Based on symptoms alone, the British Society for Surgery of the Hand has classified carpal tunnel syndrome into mild, moderate and severe. In mild carpal tunnel syndrome, there is intermittent paresthesia which may be nocturnal or associated with certain hand positions or conditions such as pregnancy or

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hypothyroidism. In moderate carpal tunnel syndrome, there is constant paresthesia which interferes with activities of daily living and wakes the patients from sleep. It is associated with reversible numbness and/or pain. Severe cases have constant numbness or pain associated with weakness and/or wasting of the thenar muscles, but with small risk of damage to the nerve (McCartan 2012, Page 2013).

Carpal tunnel syndrome may be treated by surgical or non-surgical approaches. Non-surgical treatments are usually offered to patients with intermittent symptoms of mild to moderate CTS. These include the use of wrist splints, local steroid injections, oral steroid therapy, activity modification, ergonomic modification, or therapeutic ultrasound. The more severe or refractory cases may require surgical decompression of the median nerve. Surgery involves complete division of the flexor retinaculum to release the median nerve and can be performed through a number of different techniques as the standard open carpal tunnel release, the mini-open release, and the endoscopic carpal tunnel decompression. Each technique has its advantages and drawbacks (McCartan 2012, Figaro 2012, Page 2013).

The standard open carpal tunnel release (O-CTR), the oldest and most commonly used technique, involves releasing the flexor retinaculum under direct vision to ensure a complete release. The procedure is safe and simple, but is associated with painful and sensitive scars, decrease in grip strength, and long healing time. A less aggressive mini-open release (mini-OCTR) involves division of the retinaculum with limited access through a 1-1.5 cm incision at the distal wrist crease and the use of specially developed instruments. Carpal tunnel release can also be performed endoscopically (E-CTR) using single or double portal techniques to visualize the under surface of the flexor retinaculum and guide the surgeon's knife. The mini-open or endoscopic techniques cause less tissue trauma, have a smaller scar, less postoperative pain, faster recovery, and conserves the grip strength. However, these techniques with their limited approaches are associated with decreased visualization of the median nerve and its terminal branches (thenar muscular branch and palmar branch, vascular structures, and anatomic variations, all of which may increase the risk of neurovascular injury during the procedure. In addition, these techniques may carry the risk of incomplete release of the flexor retinaculum as a result of poor visualization, leading to persistent symptoms. (McCartan 2012, Nakamichi 2010, de la Fuente 2012).

Mini-open carpal tunnel release (Mini-OCTR) and percutaneous carpal tunnel release using ultrasonographic guidance are recently developed surgical techniques that allow combining the advantages of both the O-CTR and mini-OCTR i.e. the direct visualization of all the key anatomic structures including the variants together with the small incision. The size of the incision with percutaneous carpal tunnel release is 0.4-0.6 cm compared to 1-2 cm for the mini, and >4cm for the classic carpal tunnel release. These newly developed techniques may potentially lead to the same neurological and functional outcomes as O-CTR but with less scar sensitivity and pain, and better grip strength. The sonographically guided percutaneous needle technique is office-based and performed under local anesthetic. However, not all patients are legible for the procedure, and the results of hand surgeries performed under ultrasonography depend on the surgeon's experience with ultrasound, which is known to be examiner dependent, and involves a learning curve and interobserver variation in interpretation. In addition, there are many unanswered questions as regards the contraindications to the percutaneous procedure, the release extent at the deepest layer portions, best approach, best location, and best advancing direction of the instrument (Nakamichi 2010, de la Fuente 2012, McShane 2012, Rojo –Manuaute 2013).

Medical Technology Assessment Committee (MTAC)

Ultrasound Guided Percutaneous Needle Release of Carpal Tunnel

08/19/2013: MTAC REVIEW

Evidence Conclusion: There is a lack of published literature on ultrasound-guided percutaneous release of the carpal tunnel for individuals with carpal tunnel syndrome. The larger of two published studies to date, was a small non-randomized observational study that compared the outcomes of percutaneous carpal tunnel release vs. mini-open surgical release performed under ultrasonographic guidance. The technique was not compared to the standard open surgery, and the patients were not randomized to the procedures but were assigned to one versus the other according to the orthopedist's discretion based primarily on the safe zone that varied between the study participants and also on the patient's preference. In conclusion, there is insufficient published evidence to determine the efficacy and safety ultrasound-guided percutaneous release of the carpal tunnel for individuals with carpal tunnel syndrome.

Articles: The published literature on ultrasound-guided percutaneous release of the carpal tunnel is very limited. The search revealed only one nonrandomized study that compared the technique with mini-OCTR both performed under ultrasonographic guidance, and a very small retrospective case series with 17 patients. The following study was selected for critical appraisal: Nakamichi K, Tachibana S, Yamamoto S, et al. Percutaneous carpal tunnel

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release compared with mini-open release using ultrasonographic guidance for both techniques. *J Hand Surg Am*. 2010; 35:437-445. See Evidence Table

Ultrasound Guided Percutaneous Needle Release of Carpal Tunnel did not pass the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
With Diagnosis Codes	
G56.00	Carpal tunnel syndrome, unspecified upper limb
G56.01	Carpal tunnel syndrome, right upper limb
G56.02	Carpal tunnel syndrome, left upper limb
G56.03	Carpal tunnel syndrome, bilateral upper limbs

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Dates Reviewed	Date Last Revised
10/01/2013	10/01/2013[MPC], 08/05/2014[MPC],06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	11/06/2018

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
11/06/2018	Added language to use Kaiser Permanente criteria for Medicare members.

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Clinical Review Criteria
UltraCom Scan for Hypertension in Pregnancy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "UltraCom Scan for Hypertension in Pregnancy," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

Preeclampsia is a major cause of maternal and perinatal morbidity and mortality. Among pregnant women, cardiac output may be associated with increased risk of preeclampsia. UltraCom is a continuous-wave Doppler computer that measures cardiac output. Using UltraCom, at-risk women can be identified and treatment to reduce maternal and neonatal adverse outcomes can be initiated.

Medical Technology Assessment Committee (MTAC)

UltraCom Scan

2/14/2001: MTAC REVIEW

Evidence Conclusion: This review addresses three questions:

1. Does UltraCom accurately measure cardiac output?
2. Is high cardiac associated with preeclampsia?
3. Does treatment of women with high cardiac output reduce the risk of preeclampsia?

Question 1: There were two small studies evaluating the validity of the UltraCom test. Both studies found a high correlation between the results of UltraCom testing and thermodilution. However, the sizes of the samples (n=11 and n=12) are insufficient to show that the UltraCom test can accurately measure cardiac output compared to the best available alternative test. (Easterling 1987, 1990 Am J Perinatol)

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Question 2: There was one prospective cohort study that suggests an association between cardiac output and preeclampsia. However, this study did not control for confounding, particularly weight. The association between cardiac output and preeclampsia could be due to the weight differences between the two groups of pregnant women rather than cardiac output differences. (Easterling 1990)

Question 3: There was one small randomized controlled trial that found that women with high cardiac output who were treated with atenolol had a lower rate of preeclampsia than women with high cardiac output who were given placebo. Nulliparous women treated with atenolol also had babies that weighed significantly less than women treated with placebo. (Easterling, 1999). This single study provides insufficient evidence to draw conclusions about the effect of screening with UltraCom and subsequent treatment with atenolol on maternal and neonatal health outcomes. There is no evidence on the effectiveness of any other type of treatment.

All of the available studies on the use of UltraCom with pregnant women were done by a single group of researchers. Generally, replication by various groups of researchers in different settings provides stronger effectiveness data. Moreover, these researchers are based at University Hospital, University of Washington, which is marketing the UltraCom test for pregnant diabetic women; we cannot exclude the possibility of a conflict of interest that might bias the research methodology.

Articles: The Medline search only identified articles that were on related topics (Doppler technique, uterine artery Doppler ultrasound) but not on empirical studies evaluating UltraCom in pregnant women. Dr. Ruth Krauss listed the citation for one article. References in that article yielded 3 other relevant articles. Evidence tables were created for these four articles. Easterling TR, Brateng D, Schmucker B, Brown Z, Millard SP. Prevention of preeclampsia: A randomized trial of atenolol in hyperdynamic patients before onset of hypertension. Obstet Gynecol 1999; 93: 725-33. See Evidence Table. Easterling TR, Benedetti TJ, Schmucker BC, Millard SP. Maternal hemodynamics in normal and preeclamptic pregnancies: A longitudinal study. Obstet Gynecol 1990; 76: 1061-9. See Evidence Table. Easterling TR, Watts DH, Schmucker BC, Benedetti TJ. Measurement of cardiac output during pregnancy: Validation of Doppler technique and clinical observations in preeclampsia. Obstet Gynecol 1987; 69: 845-50. See Evidence Table. Easterling TR, Carlson KL, Schmucker BC, Brateng DA, Benedetti TJ. Measurement of cardiac output in pregnancy by Doppler technique. Am J Perinatol 1990; 7: 220-222. See Evidence Table.

The use of UltraCom Scan in the screening and treatment of hypertension in pregnancy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

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Date Created	Dates Reviewed	Date Last Revised
02/14/2001	04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 01/09/2018MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC	04/04/2011

MDCRPC Medical Director Clinical Review Policy Committee
MPC Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Ultrafiltration for the Treatment of Congestive Heart Failure

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Ultrafiltration, Hemoperfusion and Hemofiltration (110.15)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Heart failure (HF) is a major and growing health problem worldwide and is the leading cause of hospitalization in the Western world. In the United States more than 5 million patients suffer from HF, and more than one million are admitted annually to hospitals for acute decompensated heart failure (ADHF). The great majority of patients present with dyspnea and edema from the volume overload and pulmonary congestion driven by sodium and water retention, and many are discharged without clinical evidence of adequate decongestion. The prognosis of patients with ADHF is poor with an approximately 4% in-hospital mortality rate. 25% are readmitted within 30 days, and up to 23% die within 6 months. 25-33% of patients with ADHF develop acute cardiorenal syndrome which is defined as worsening renal function (often defined as an increase in creatinine $\geq$0.3 mg/dL from baseline). This results from a number of contributing factors and is usually associated with poor outcome (Chiong 2010, Giglioli 2011, Bart 2012, Felker 2012).

Standard therapy for decompensated HF consists predominantly of intravenous (IV) loop diuretics and vasodilators. Loop diuretics induce rapid diuresis that reduces lung congestion and edema. Intravenous administration of an effective dose of furosemide (a loop diuretic) typically results in a diuretic effect within 30 minutes and peaks at one hour. Heart failure patients require a higher dose to achieve this same effect. It was reported that in ADHF, renal responsiveness to loop diuretics may be decreased, and that patients with New York Heart Association (NYHA) class II or III HF have one third to one fourth the natriuretic response as compared with normal subjects. This response decreases further as the severity of HF increases, and higher doses are required. The effectiveness of the diuretics also declines with repeated exposure, and resistance to the therapy may

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develop as heart failure progresses. In some patients fluid overload persists despite the higher doses. Investigators described two types of diuretic resistance; short-term resistance, which is a decrease in response to the first administration, and long-term resistance that develops after long-term administration of loop diuretics. Approximately 25%-30% of HF patients develop diuretic resistance which is usually associated with worsened outcomes and higher risk of death. In some cases, the intravenous administration of diuretics to patients with ADHF may directly contribute to worsening of renal function, and its continued use for treating persistent congestion after the onset of worsening renal function, may lead to additional kidney injury. Despite the concerns about these potential harms associated with higher doses of diuretic therapy and the lack of proven survival benefit, diuretics remain the standard therapy for removing the excess extracellular fluid in patients with heart failure. Other therapeutic alternatives include inotropic therapy, IV nitroglycerine and natriuretic peptides. When these pharmacological approaches fail, or are unsuitable, the alternative means for fluid removal are dialysis, phlebotomy, or ultrafiltration (Costanzo 2005, 2007, Chiong 2012, Bart 2012, Felker 2009, 2012)

The concept of extracorporeal removal of fluid with ultrafiltration has been used for decades to treat refractory edema. The pump-driven extracorporeal ultrafiltration (UF) was described in the 1970s and was used for patients with heart failure in the mid-1980s. Ultrafiltration is accomplished by mechanically drawing blood from the patient either through peripheral or central venous access. Plasma is then filtered by means of the negative hydrostatic pressure generated by a second pump, and re-infused back into the patient. The ultrafiltrate is composed of water with electrolytes in the same concentration as in the serum without the cells or proteins which are too large to pass through the filter pores. Unlike dialysis, ultrafiltration operates by convection in eliminating iso-osmolar extracellular fluid resulting in a decrease in ventricular filling pressure without significant changes in the renal function, creatinine, or urea concentration. It is reported that ultrafiltration can improve cardiac hemodynamics by reducing both right and left sided filling pressure, increasing the stroke volume and cardiac output. Researchers also found that it restores diuretic responsiveness and improves natriuresis without changes in the heart rate, systolic blood pressure, intravascular volume, or electrolytes. A potential advantage of UF over loop diuretics is that the ultrafiltrate is isotonic, whereas the urinary output with loop diuretics is hypotonic, thus UF removes more sodium (and less potassium) than diuretics for an equivalent volume loss. Ultrafiltration is not a substitute for dialysis and will not lead to removal of accumulated toxins or potassium in hyperkalemic patients (Bourge 2005, Boyle 2005, Costanzo 2005).

Earlier, ultrafiltration required physician placement of a double-lumen central venous catheter and monitoring by a dialysis technician. Recently a simpler, smaller, and portable ultrafiltration device was introduced (System 100, CHF Solutions, Minneapolis, Minnesota). The device is less invasive and does not require intensive care unit monitoring or central intravenous access. It allows a technician to place the blood withdrawal and infusion catheters in peripheral veins, usually the brachial-cephalic system, with subsequent monitoring by a clinical nurse. The device removes water and non-protein-bound small and medium molecular weight solutes through a semipermeable membrane when hydrostatic pressure generated by blood pressure or external blood pump exceeds oncotic pressure. The fluid removal rate can range from 100 to 500 ml/hour and is set by the treating physician. UF requires systemic anticoagulation with the possibility of excess bleeding. Other potential complications include air embolism, and overly aggressive volume removal (Bourge 2005, Bart 2012).

The ACC/AHA clinical practice guidelines do not recommend the use of UF as a class I therapeutic option but as a class II recommendation (level B evidence) for the relief of fluid overload in patients with refractory congestion not responding to medical therapy.

CHF Solutions received marketing clearance from the FDA for System 100 in June 2002 and for central venous access with the system in December 2003. System 100 is indicated for temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload. In 2005, System 100 was renamed Aquadex FlexFlow™ and launched with several new features (according to the manufacturer).

Medical Technology Assessment Committee (MTAC)

Ultrafiltration in the Treatment of Congestive Heart Failure

08/07/2006: MTAC REVIEW

Evidence Conclusion: The RAPID-CHF trial (Bart 2005) was a randomized, controlled, non-blinded trial that compared usual care vs. usual care plus ultrafiltration (UF) in 40 patients admitted to hospital with acute decompensated heart failure and fluid overload. Patients randomized to the usual care group received the conventional heart failure therapy. Those in the UF group received an 8 hour UF treatment with a maximum fluid removal rate of 500 cc/hour. Diuretics were administered after the 8 hours of UF, and additional courses of UF were allowed after 24 hours. The results of the trial show that the weight loss (primary endpoint of the trial) was not

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significantly different between the two study groups. The average volume removal of fluid was significantly higher in the UF group at 24 and 48 hours. Patients in the two treatment groups experienced improvement in their symptoms during the treatment period. The improvement observed was significantly greater in the UF group compared to the usual care group at 48 hours but not at 24 hours. The significant difference may be due to the greater fluid removal or due to chance as the trial was small, un-blinded, and the outcome measure was subjective. Costanzo et al (2005) reported their experience with early initiation of UF in 20 selected HF patients admitted to hospital with manifest signs and symptoms of fluid overload. The patients underwent UF which was continued until the acute decompensation heart failure symptoms were resolved. The removal of fluid was aggressive (8,654 + 4,205 ml) and resulted in a mean decrease of 6 kg of weight at discharge, and improvement in the clinical signs of symptoms of fluid overload that seem to have lasted for the 90 days of follow-up. This was only an observational case series with no comparison or control group and subject to selection and observation bias. The results of the UNLOAD (or UltrafiltrationN versus IV diuretics for patients hospitalized for Acute Decompensated congestive heart failure) trial was presented at the 2006 ACC conference in Atlanta, but have not been published in a peer reviewed journal to date. The trial randomized 200 patients from 28 centers to receive the standard intravenous diuretic drug therapy or IV diuretics plus ultrafiltration to treat fluid overload. The study was not blinded, the primary outcomes were weight loss and dyspnea score at 48 hours, and the patients were followed up for 90 days. The unpublished results of the trial indicate that both treatments were associated with significant improvement in the dyspnea score at 48 hours, but with no significant difference between the two treatment groups. Patients in the UF group had significantly greater net fluid and weight loss at 48 hours, and a lower incidence of hypokalemia. The results also show that the hospital readmission rate, during the 3 months of follow-up, was significantly lower in the UF group, vs. the IV diuretic group. All three studies were funded or supported by the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota, which may introduce bias. In conclusion, there is insufficient evidence to date to determine the efficacy and long-term safety of ultrafiltration versus standard care in acute decompensated heart failure, or to determine who would benefit most from the intervention.

Articles: The search yielded around 280 articles most of which were review articles, opinion pieces, or dealt with the technical aspects of the procedures. There was one RCT, and several small case series, many of which dated back in the 1980s and 1990s. The RCT and the relevant case series using the new UF device (System 100, CHF Solutions, Minneapolis, Minnesota) were selected for critical appraisal: Bart BA, Boyle A, Bank AJ, et al. Ultrafiltration versus usual care for hospitalized patients with heart failure. The Relief for Acutely fluid-overloaded Patients with Decompensated Congestive Heart Failure (RAPID-CHF) trial. J Am Coll Cardiol 2005; 46:2043-2046. **See** Evidence Table. MR, Saltzberg M, O'sollivan J, et al. Early ultrafiltration in patients with decompensated heart failure and diuretic resistance. J Am Coll Cardiol 2005;46:2047-2051. **See** Evidence Table.

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/17/2013: MTAC REVIEW

Ultrafiltration in the Treatment of Congestive Heart Failure

Evidence Conclusion: All published trials on the use of ultrafiltration in patients with acute decompensated heart failure with or without renal dysfunction compared UF with IV diuretic-based therapy. No published RCT, to date, examined the efficacy and safety of ultrafiltration in patients with ADHF who refractory to diuretics were. This latter indication of ultrafiltration was only evaluated in a one retrospective study with no control group. Ultrafiltration as a first line therapy The UNLOAD (ultrafiltration versus Intravenous Diuretics for Patients Hospitalized for Acute Decompensated Congestive Heart Failure) trial compared ultrafiltration to diuretic therapy in patients hospitalized for acute decompensated heart failure. The trial examined UF as a first-line early therapy not as a rescue therapy (i.e. patients did not have to fail an initial diuretic therapy to be included in the trial). 200 patients were randomized to receive early UF (within 24 hours of hospitalization) or intravenous diuretic drug therapy. The co-primary outcomes were weight loss and patient self-assessed dyspnea score at 48 hours. The results show that both the UF and IV diuretic therapies were associated with significant improvement in the dyspnea score at 48 hours, with no statistically significant difference between the two treatment groups. Patients in the UF group had significantly greater fluid and weight loss at 48 hours, and a lower incidence of hypokalemia. This however, did not have an impact on the length of the index hospital stay. The rates of rehospitalization and unscheduled visits during the 90 days of follow-up were significantly lower in the UF group, vs. the IV diuretic group. The results also show a higher rise in serum creatinine levels in the UF group vs. the IV diuretic group (twice as many patients in the UF arm experienced an increase in sCr level >0.3 ml/dL during the first 24 hours of therapy) but the difference did not reach a statistically significant level. The authors considered the lack of significant difference between the two groups for this as well as other outcomes, as similar effects when the trial was not designed as equivalent study, and the lack of significant differences could results from insufficient statistical power. The study was a multicenter RCT but had several limitations many of which were acknowledged by the authors. The trial had a relatively small size and short follow-up duration, excluded

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patients with hypotension or hemodynamic instability, and used suboptimal dose and mode of administration of loop diuretics. The dose of the diuretic, duration, and rate of UF were all based on the discretion of the attending physician who was not blinded to the randomization groups and could be a source of bias. In addition, the authors did not present any data on low-salt diet compliance, or criteria for hospitalization. The study was supported by CHF Solution Inc., and the primary author as well as a number of other authors had financial ties to the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota. The Cardiorenal Rescue Study in Acute Decompensated Heart Failure (CARRESS-HF, sponsored by the NHLBI) investigated the role of UF as a treatment for patients with persistent congestion and worsening of kidney function (increase in serum creatinine ≥0.3 mg/dL within 12 weeks before or 10 days after index admission). 188 patients were randomized to undergo ultrafiltration (fluid removal at a rate of 200 ml/hour using Aquadex System 100; CHF Solutions), or to receive stepped pharmacological therapy involving increasing the doses of loop diuretics (with or without metolazone), vasodilators and inotropes (based on an algorithm that aimed at achieving urine output of 3-5 liters/ day). The assigned treatment was continued in the two groups until signs and symptoms of congestion were improved as possible. The primary endpoint was bivariate (simultaneous) change in serum creatinine level and body weight in 96 hours after randomization. The trial was not blinded, and the patients were followed-up for 60 days. Recruitment for the trial was stopped early before reaching the planned size of 200 subjects based on the advice of the data and safety monitoring board due to lack of benefit and excess adverse events with ultrafiltration. The results of CARRESS-HF show that stepped pharmacological therapy was superior to UF when the primary end point was assessed at 96 hours after randomization. There was a statistically significant reduction the serum creatinine (sCr) in the pharmacologic therapy group compared to the UF group. There was no significant difference between the groups in weight loss at 96 hours. At the 60 days of follow-up, there were no statistically significant differences in weight loss, or rate of hospitalization due to heart failure. There was a nonsignificant increase in the all-cause readmission rate in the UF group. UF, was also associated with a significantly higher rate of serious adverse events including kidney failure, bleeding complications, and catheter–related complications. The sixty-day mortality was17% for the UF group and 13% for the pharmacological therapy group with no significant difference between the groups, however, as indicated earlier, a lack of significant difference does not indicate equivalence due to the study design. These results should be interpreted with caution and cannot be generalized to patients with ADHF with better renal function than those included in the trial.

Other published trials Two other very small published RCTs (ULTRADISCO (Giglioli et al 2011), and Hanna and colleagues' trial (2012) also compared ultrafiltration versus intravenous diuretics inpatients hospitalized for ADHF. The trials had intermediate outcomes (hemodynamic variables in the ULTRADISCO trials, and time for pulmonary wedge pressure to be maintained at >18 mmHg for ≥4 consecutive hours in Hanna and colleagues' study). Their overall results showed greater fluid loss with UF vs. diuretic therapy with no significant difference between the groups in the serum creatinine levels. Ultrafiltration as a rescue therapy for patients with ADHF who are refractory to IV diuretic therapy The literature search did not identify any published RCT to date, that examined the efficacy and safety of ultrafiltration in patients with ADHF who were refractory to diuretics. In a retrospective observational study with no comparison group, Patarroyo and colleagues (2012) analyzed data from hospital records for adult patients with ADHF admitted to one heart failure intensive care unit in Cleveland Ohio ((2004-2009) and who required slow continuous ultrafiltration therapy (SCUF). The study population was a highly selected group of 63 adult patients with advanced HF, worsening renal function, and congestion refractory to hemodynamically guided intensive medical therapy. Their median age was 58 years, mean LV ejection fraction 26 ±15%, baseline serum creatinine (sCr) 1.9 ± 0.8 mg/dL and hemodynamics consistent with cardiogenic shock. SCUF was initiated after a mean of 8 days from admission, was performed at a rate of 200ml/hr. and for a mean duration of 8 days. At the initiation of SCUF therapy the sCr level was 2.2 ± 0.9 mg/dL. The mean duration of the UF therapy was 3+2 days, and the primary endpoint of the study was all-cause mortality and the secondary endpoint included number of readmissions for ADHF and dialysis-dependent status at time of discharge. The results of the analysis showed that after 48 hours of SCUF the overall cohort lost weight significantly compared to baseline (mean 4.4 kg). This was associated with significant improvement in hemodynamic variables but with no improvements in sCr levels or blood urea. 37 patients (59%) required conversion to continuous hemodialysis during their hospital stay and 9 (14%) were dependent on hemodialysis at hospital discharge. 34/37 (93%) of these patients were readmitted to the hospital within 60 days form discharge.19/63 patients (30%) died during the index hospitalization, and 4 were discharged to terminal care in hospice. The overall 1-year all-cause mortality was 70% and 2 of the surviving patients underwent heart transplantation. The results of the study should be interpreted with caution due to the study design and its inclusion of severely ill patients. Conclusion: There is insufficient evidence to support the use of ultrafiltration as a first-line treatment in hospitalized ADHF with volume overload. There is insufficient evidence to determine the safety and efficacy of ultrafiltration in patients with ADHF who are refractory to diuretic therapy. Results from UNLOAD trial, suggest, but do not provide good evidence, that ultrafiltration may provide better correction of volume overload than IV diuretics (given at the dose used in the trial) in patients hospitalized ADHF who are not resistant to diuretic therapy. The trial had its limitations and does not provide any evidence on the safest and most effective rates of fluid removal, duration of treatment, or the conditions for termination of ultrafiltration. There is evidence from the CARRESS-HF that IV loop diuretic-based therapy adding distal-acting

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diuretics, IV vasodilator and inotropic agents as needed is superior to ultrafiltration in patients with acute decompensated heart failure and worsening renal function. CARESS-HF results show increased incidence of worsening kidney function in the ultrafiltration group versus the stepped pharmacologic therapy group.
A large ongoing trial (AVOID-HF) (NCT01474200) involving 810 patients in 40 US centers is examining the effect of UF vs. intravenous diuretics in reducing hospitalization in patients with ADHF before worsening renal function.
Articles: UNLOAD trial (Costanzo et al 2007, evidence table 1) See Evidence Table. CARRESS-HF (Bart yet al 2012, evidence table 2) See Evidence Table

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
08/29/2006	04/04/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	08/06/2013

[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

UniSpacer Knee System

- McKeever Hemiarthroplasty Prosthesis
- MacIntosh Hemiarthroplasty Prosthesis
- Shabaro Tibial Plateau Prosthesis

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Criteria

For Medicare Members

This device is not called out by Medicare as separate from knee arthroplasty.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

The UniSpacer is a small, kidney shaped insert made of cobalt chrome that is intended to correct the knee alignment, decrease pain and improve joint stability for patients with early stages of osteoarthritis. It is a device that fits between the natural bone structures of the knee and stays in place without the aid of bone cement or screws. Not everyone is a candidate for the UniSpacer. It is suitable for patients with isolated, moderate degeneration of the medial compartment, patellofemoral compartment, or lateral condyle, and not suitable for patients with subchondral bone loss, significant patellofemoral disease, or significant lateral compartment disease. The anterior and posterior cruciate ligaments must be intact.

According to the manufacturer, the operation is conducted under general or regional anesthesia and takes about one hour to complete. After surgery patients need physical therapy for 6-8 weeks and may need to wear braces 1- 2 weeks or more. Recovery may take as long as one year.

The UniSpacer has been approved by FDA on 1/4/2001 as a Class II device.

Medical Technology Assessment Committee (MTAC)

UniSpacer Knee System

12/11/2002: MTAC REVIEW

Evidence Conclusion: Due to lack of scientific data, there is no evidence to determine the role of the UniSpacer Knee System in the treatment of osteoarthritis.

Articles: The search did not yield any articles on the UniSpacer knee system or its equivalents.

The use of UniSpacer Knee System in the treatment of osteoarthritis of the knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

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Date Created	Dates Reviewed	Date Last Revised
12/11/2002	04/04/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	04/04/2011

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

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Clinical Review Criteria
Myoelectric Upper Limb Prosthesis

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Myoelectric Upper Limb Prosthesis," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

1. Myoelectric upper limb prosthetic components may be medically necessary when **ALL of the following** criteria are met:
   A. The patient has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); AND
   B. Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing activities of daily living. The inadequacies of a standard device must be documented in detail by a physical or occupational or physiatrist therapist who is not employed by the vendor or prosthetist; **AND**
   C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device, as demonstrated by functional testing using a physical or computer model prosthesis; **AND**
   D. The patient has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; **AND**
   E. The patient is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); **AND**
   F. Functional evaluation by a qualified professional (e.g., prosthetist) indicates that with training, use of a myoelectric prosthesis is likely to meet the functional needs of the individual (e.g., gripping, releasing, holding, and coordinating movement of the prosthesis) when performing activities of daily living. This evaluation should consider the patient's needs for control, durability (maintenance), function (speed, work capability), and usability. **BOTH of the following** criteria must be met:
      i. The device is necessary for the patient to perform instrumental activities of daily (see B above)
      ii. The device is not primarily for the purpose of allowing the patient to perform vocational, leisure or recreational activities.
   G. Patient must be at least 1 year old.

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Prosthesis with individually powered digits, including but not limited to partial hand prosthesis, is considered investigational.

Repair and/or replacement of an external prosthetic device, including an upper limb myoelectric prosthetic device, is covered as follows:

- Repair is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and the repair will make the equipment usable.
- Replacement is covered only when anatomical change or reasonable wear and tear renders the item nonfunctional and non-repairable.

Repair or replacement of an external prosthetic device, including an upper limb myoelectric prosthetic device, made unusable or nonfunctioning because of individual misuse, abuse or neglect is not covered

If requesting this these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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Background

External prosthetic appliances, often referred to as prosthetic devices or prostheses, are devices used to replace the functions of missing body parts. A passive prosthesis is a type of device that must be moved manually, typically by the opposite arm. The standard prosthetic appliance for replacement of an upper extremity, either below or above the elbow, is a body-powered prosthesis with a terminal hook device. This type of prosthetic device is the most durable and requires gross body movement and sufficient strength for adequate use. It is attached to the user's body through a system of harnesses. The patient controls the hand, forearm and elbow by movement of the harness system. Gross body motion is required to pull the harness and thereby move the prosthesis. Usage of a body-powered prosthesis requires adequate space for compensation of movement; the user must be able to place his/her body in front of the object to be manipulated. This type of device allows voluntary closing or opening of the hand, but not both.

The myoelectric device functions by means of electrical impulses. It is a prosthetic device used as an alternative to a passive or conventional body-powered device which enables a patient to adjust the force of his/her grip and both open and closes the hand voluntarily. Myoelectric devices may be recommended for amputees who are unable to use body-powered devices or who require improved grip function/motion for performance of daily activities. Adults or children with above- or below-the-elbow amputations may use the device effectively, although for children there is some controversy regarding use because due to normal growth patterns the prosthesis may require multiple socket replacements over time.

Unlike body-powered prosthetic devices, myoelectric devices move the prosthetic limbs with small, electric, motorized controls, which allow more precise movement. Small electrodes are installed in the socket of the prosthesis. The electrodes sense electrical activity of the muscles, called electromyographic (EMG) signals. When amplified, the EMG signal stimulates the motors in the device to perform a function. The signal is very weak (i.e., 5–200 microvolts); an individual must be able to produce a strong enough EMG signal for the device to record and amplify; that is, the person must possess a minimum microvolt threshold in the remaining musculature of the arm. The user must also be able to isolate muscle contraction, so that if one muscle is contracted (e.g., flexion), the opposing muscle is relaxed (e.g., extension). Contraction of both muscles (co-contraction) would result in signals turning the motor on and off at the same time, causing the device not to function and eliminating its myoelectric capability.

Myoelectric devices operate on rechargeable batteries and require no external cables or harnesses. The myoelectric prosthetic device does not require gross body movements or added space for compensation of movement to provide adequate functional movement; it can be operated in any user position that allows muscle contraction. Instead of a suspension harness, the devices use one of two suspension techniques: skeletal/soft tissue lock or suction.

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Proponents suggest that myoelectric devices have many advantages over conventional ones. When designing prostheses to replace a hand, manufacturers attempt to replicate the grip function, the hand's major function. Other functions that are often replicated are pinch force, wrist rotation and elbow function. Investigators assert that a myoelectric device offers greater grip capabilities and more improved rotational function than conventional devices. Furthermore, because no control cable or harness is associated with the myoelectric device, cosmetic skin can be applied to the device to enhance cosmetic appearance. More recent control systems incorporate programmable microprocessors allowing various ranges of adjustment, performance of multiple functions and sequential operation of elbow, wrist and hand motions. In some cases, a combination of myoelectric and body- powered technology (i.e., hybrid prosthesis) is used to enhance the amputee's overall functionality, depending on the level and location of amputation. Patients with amputations above the transhumoral level may elect a body- powered device to control shoulder and elbow movement and a myoelectric device to control hand and wrist motion, allowing control of two joints at once. There are also devices that are similar to the normal wrist, enabling the terminal device to be rotated, thus allowing more natural movement or placement. More recently, hand devices have become available with five individual powered digits and separately powered prosthetic digits are available for individuals who have lost a part of the hand or finger.

Medical Technology Assessment Committee (MTAC)

Controlled Upper Limb Prosthesis

08/11/2004: MTAC REVIEW

Evidence Conclusion: There is minimal published data on the microprocessor- controlled upper limb prosthesis. These data do not provide evidence on the benefit of using these more sophisticated prostheses in improving health outcomes of the amputees, their impact on their physical and social activities, or to suggest which patients will benefit more with using them.

Articles: The search yielded 35 articles. The majority dealt with the technical aspects and mechanisms of action of the prostheses. The search did not reveal any randomized controlled trials. Only one case series (N=18) that investigated the satisfaction level of young users of myoelectric prosthesis was identified. This was a small case series and did not involve a microprocessor.

Controlled upper limb prosthesis in the treatment of members with missing or amputated upper limb does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)
L6611	Addition to upper extremity prosthesis, external powered, additional switch, any type
L6677	Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow
L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)
L6881	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
L6882	Microprocessor control feature, addition to upper limb prosthetic terminal device
L6925	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6935	Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6945	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6955	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger,

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	myoelectronic control of terminal device
L6965	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6975	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L7007	Electric hand, switch or myoelectric controlled, adult
L7008	Electric hand, switch or myoelectric, controlled, pediatric
L7009	Electric hook, switch or myoelectric controlled, adult
L7045	Electric hook, switch or myoelectric controlled, pediatric
L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
L7259	Electronic wrist rotator, any type

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Dates Reviewed	Date Last Revised
08/11/2004	04/04/2011[MDCRPC], 02/07/2012 [MDCRPC], 12/04/2012 [MDCRPC],10/01/2013 [MPC], 08/05/2014 [MPC], 06/02/2015 [MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC] , 10/05/2021[MPC] , 10/04/2022[MPC]	08/28/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/05/2016	Developed criteria to expand coverage for service
02/07/2017	Medicare is silent; MPC approved to adopt KPWA criteria for Medicare members
08/28/2020	Removed deleted HCPC code L6025; Added HCPC codes L6026, L6925 and L7259

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Uvulopalatopharyngoplasty (UPPP)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**Uvulopalatopharyngoplasty**", for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Uvulopalatopharyngoplasty (KP-0245) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

MCG* are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 12 months of clinical notes from requesting provider and/or specialist (pulmonary, ENT)
- Most recent sleep study results

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Sleep-disordered breathing includes a spectrum of disorders ranging from primary snoring to obstructive sleep apnea (OSA). Obstructive Sleep Apnea Syndrome (OSAS) is defined as an apnea-hypopnea index of more than five events per hour, and often also have mental or physical effects such as excessive daytime sleepiness. Potential health consequences of OSAS are cardiovascular diseases, neuropsychiatric problems, injuries and increased mortality. Obstructive sleep apnea results from a combination of a structurally small upper airway and a loss of upper airway muscle tone.

Methods of treating OSA include weight loss, nasal continuous positive airway pressure (CPAP), surgical or laser resection of the uvula, tonsils or soft palate, or tracheostomy when all other treatments fail. Surgical treatment

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approach varies, and the results are affected by age, cause of obstruction, and severity of the disease. The best method of treatment remains controversial.

Uvulopalatopharyngoplasty (UPPP) is a surgical procedure used to treat sleep apnea or snoring. It removes excess tissue in the throat in an attempt to widen the airway. The soft tissue removed may include the uvula, tonsils, adenoids, tongue or roof of the month. It takes 2 to 3 weeks to recover from the surgery.

Medical Technology Assessment Committee (MTAC)

1997 Literature Search

Articles: Based on the literature below there is limited evidence of the value of LAUP or UPPP in the treatment of OSAS (Obstructive Sleep Apnea Syndrome). While there is strong evidence supporting the value of CPAP in the treatment of OSAS, compliance in the use of the CPAP device remains a problem. Anand-V-K, Ferguson-P-W, Schoen-l-S, Obstructive sleep apnea: comparison of continuous positive airway pressure and surgical treatment, Otolaryngology-Head-Neck Surgery. Sept: 105(3) 382-90. Retrospective review, 400 cases of patients diagnosed with OSA (Obstructive Sleep Apnea). A comparative analysis with polysomnography revealed superior cures with CPAP, although long term compliance remains problematic. Conclusion was use of CPAP as initial therapy in-patients with no clinically apparent causes for obstruction: nasal polyps, deviated nasal septum, or obstructive tonsillar hypertrophy. Mickelson, SA., Laser-Assisted Uvulopalatoplasty for Obstructive Sleep Apnea, Laryngoscope: 106(I Pt 1): 10-3, 1996 Jan. Study Size 34, Consecutive prospective patients; Improved RDI by at least 50% in 53.8% of the study group. Snoring was reduced by 92.3%. Conclusion: Results suggest that LAUP MAY be efficacious in management of OSAS. Vaidya AM. Petruzzelli GJ., McGee D., Gopalsami C., Identifying obstructive sleep apnea in patients presenting for laser-assisted uvulopalatoplasty, Laryngoscope: 106(4): 431-7 1996 Apr. 850 patients with snoring evaluated. While body mass index, falling asleep while driving, snoring every night, and stopping breathing during sleep were found to correlate strongly with increasing RDI (Respiratory Disease Index), it was strongly recommended that a referral for PSG (polysomnography Study) be initiated if there is any suspicion of OSAS. Walker RP. Grigg-Damberger MM. Gopalsami C, Totten MC., Laser-assisted uvulopalatoplasty for snoring and obstructive sleep apnea: results in 170 patients, Laryngoscope. 105(9 Pt 1): 938-43, 1995 Sept July 1993 - December 1994, 541 consecutive patients referred for treatment of snoring. 274 had LAUP treatments. As of January 1995 LAUP, treatment courses were completed for 170 patients.105 had diagnosis of snoring and 65 had diagnosis of OSAS based on preoperative polysomnography. Of the 65 OSAS patients 16 cases achieved success as measured on post-op polysomnography. Conclusion: LAUP may be a viable surgical option for patients with snoring and mild sleep apnea. Schecthtman KB. Sher AE., Piccirillo JF., Methodological and statistical problems in sleep apnea research: the literature on Uvulopalatopharyngoplasty.

Sleep 18(8): 659-66 1995 Oct. A comprehensive review of the literature on surgical treatment of sleep apnea found 37 appropriate papers (total n = 992) on UPPP. Problems identified: 1) There were no randomized studies and few (n=4) with control groups. 2) Median sample size was only 21.5; thus statistical power was low and clinically important associations were routinely classified as "not statistically significant". 3) Only one paper presented the confidence bounds that might distinguish between statistical and clinical significance. 4) Because of short follow-up times and infrequent repeat follow-ups, little is known about whether UPPP results deteriorate in time. 5) In at least 15 papers, bias caused by retrospective designs and nonrandom loss to follow-upraised questions about generalizability of results. 6) Few papers associated polysomnography data with patient-based quality of life measures. 7) Missing data and inconsistent definitions were common. 8) Baseline measures were often biased because the same assessment was inappropriately but routinely used for both screening and baseline. LU SJ. Chang SY., Shiao GM., Comparison between short-term and log-term post-operative evaluation of sleep apnea after Uvulopalatopharyngoplasty. Journal of Laryngology & Otology. 109(4): 308-12 1995 Apr. Sample 15 OSAS patients who had UPPP with pre-operative, initial post-operative and long-term post-operative polysomnography studies (more than 5 years after surgery). The subjective improvement after operation is not adequately correlated to the PSG results. Suggestion that long- term follow-up for patients after UPPP is necessary. Watson, Robert K., Thompson, A. Siobhan: Treatment Outcome of Sleep Apnea. CONN Med. 56: 125-129, 1992. 101 patients. Interviewed over 12-24-month period. CPAP most often treatment used with results of improved daytime alertness (84%). Patients with moderate OSA often had surgery which led to 85% improved daytime sleepiness, and patients with mild OSA were treated with sleep position change and weight loss with 64 - 66% improved daytime alertness.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT® or HCPC Codes	Description
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
12/15/1997	07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC], 11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC], 12/06/2022[MPC]	01/09/2018

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
01/09/2018	Adopted Kaiser Permanente criteria for MA members

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Clinical Review Criteria

UroVysion FISH Test

- Assay Tests for the Diagnosis of Bladder Cancer

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Bladder/Urothelial Tumor Markers (L36680)
Local Coverage Article	Billing and Coding: Lab: Bladder/Urothelial Tumor Markers (A55029)

For Non-Medicare Members

UroVysion FISH test is covered for members with a suspected new diagnosis of bladder cancer or known prior history of bladder cancer, who have an atypical cytology in spite of normal cystoscopy and upper tract imaging.

A negative test will preclude further evaluation and a positive test either increases the frequency of surveillance or prompts urothelial biopsy.

The FISH test is not covered when used for all other indications, such as, screening for bladder cancer or for the evaluation of hematuria. The tests below are not covered for any indication:

- BTA Stat test
- NMP22 test
- Aura-Tek FDP test

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In 2012, cancer of the urinary bladder accounted for 73,510 new cases and 14,880 deaths in the USA, making it the sixth most common and tenth most lethal malignancy in the country (Siegel, Naishadham et al. 2012). Most patients present with superficial low-grade transitional cell carcinoma which is readily resectable and, in some cases, requires additional chemotherapy or immunotherapy (Rouprêt, Babjuk et al. 2013). Although these tumors have a high recurrence, they usually do not invade the bladder wall or metastasize. One third of incident bladder cancers, however, progress into invasive cancer presenting as solid, nonpapillary tumors with a high propensity for metastasis

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requiring radical therapy. The five year survival rate for these tumors is only 30-50% (Arentsen, de la Rosette et al. 2006). Thus, patients with a history of bladder cancer are routinely monitored for recurrence

At present, the diagnosis of both primary and recurrent bladder tumors relies upon both cystoscopy and cytology, of which, neither is completely accurate (Mian, Lodde et al. 2003). Cystoscopy is an efficient method; however, it is invasive, causes patient discomfort, may be associated with a risk of urethral and bladder neck stricture and might not detect flat tumors or carcinoma in situ (false negative rate of 30%) (Daniltchenko, Riedl et al. 2005; Denzinger, Burger et al. 2007). Cytology, often used as an adjunct to cystoscopy, has a poor sensitivity for low grade tumors and frequently the results are inconclusive for malignancy (Nabi, Greene et al. 2004). In addition, patients with atypical cytology pose a challenging problem due to uncertainty about the presence of cancer.
Options for management of this predicament include observation with the possibility of missing a diagnosis or biopsying every patient.

Due to the limitations of cytology, molecular-based detection techniques represent potentially attractive strategies for noninvasive detection of aggressive bladder cancer using urine as the specimen source. Among these is the UroVysion™ Kit, a multi-target, multicolor FISH assay designed to detect aneuploidy for chromosomes 3, 7, 17 or the loss of the 9p21 locus (Sarosdy, Schellhammer et al. 2002). Better performance has been reported in detecting carcinoma in situ and high-grade tumors (Lokeshwar, Habuchi et al. 2005).

UroVysion (Abott-Vysis, Wiesbaden, Germany) was approved by the FDA in January 2005 for the cytologic detection of cancer cells in voided urine specimens.

Medical Technology Assessment Committee (MTAC)

UroVysion FISH Test

10/13/2004: MTAC REVIEW

Evidence Conclusion: The studies reviewed compared the performance of the UroVysion FISH test to the other noninvasive tests used to detect new or recurrent urinary bladder carcinoma, using voided urine specimens. Cystoscopic evaluation (or bladder resection) with histopathologic studies for the suspicious cases was used as gold standard. All studies were conducted among patients referred to cystoscopy for a history of bladder carcinoma, or urinary signs/symptoms. Sarosdy's study only included patients with a history of transitional cell carcinoma, and Halling as well as Placer included patients with either a history of urothelial carcinoma or other genitourinary symptoms and signs. The ages of the study subjects ranged from 28 to 98 years, and the majority were men. Patient characteristics and inclusion criteria provided were insufficient, exclusion criteria were not discussed, and except for one study with consecutive patients, the authors do not explain how the subjects were selected for the studies. None of the studies evaluated the test as a screening tool, and none evaluated its role in improving the management of urothelial carcinomas. Overall, the studies reviewed showed that FISH test was more sensitive than urine cytology in detecting new or recurrent bladder carcinomas among the patients studied. The specificity of the two tests was similar. Compared to the gold standard of cystoscopy/histopathologic evaluation, the overall sensitivity of FISH assays ranged from 71% to 81%, and the overall specificity ranged from 66% in Sarosdy et al's study to 96% in Halling et al's study. The test appears to be more sensitive in detecting later stages, and higher grades of the disease however; the numbers of patients in the subgroups were too small.
Articles: The search yielded 29 articles. There were 14 studies that compared the FISH test with cytologic analysis and/or other tests. In five of these studies the urine specimens were obtained from bladder washings during cystoscopy. These studies were excluded as this review deals specifically with the noninvasive UroVysion FISH test using voided urine specimens. Nine studies on UroVysion FISH test in voided urine were identified. Sensitivity and/or specificity of the test was/were not reported in three of the studies. Four of the remaining studies that had a gold standard, and reported sensitivity and specificity were critically appraised. Selection of these studies for critical review was based on the sample size and validity of the study methodology. *The following articles were critically appraised*:*Sarosdy MF, Schellhammer P, Bokinsky, et al. Clinical evaluation of a multi-target fluorescent in situ hybridization assay for the detection of bladder cancer. *J Urol* 2002; 168:1950-1954. See Evidence Table Halling KC, King W, Sokolova I, et al. A comparison of cytology and fluorescence in situ hybridization for the detection of urothelial carcinoma. *J Urol* 2000; 164:1768-1775. See Evidence Table Halling KC, King W, Sokolova I, et al. A comparison of BTA stat, hemoglobin dipstick, telomerase and Vysis assays for the detection of urothelial carcinoma in urine. *J Urol* 2002; 167:2001-2006. See Evidence Table Placer J, Espinet B, Salido M, et al. Clinical utility of a multiprobe FISH assay in voided urine specimens for the detection of bladder cancer and its recurrence, compared with urinary cytology. *Eur Urol* 2002; 42:547-552. See Evidence Table

The use of UroVysion FISH test in the evaluation of new or recurrent urinary bladder carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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UroVysion FISH Test

6/17/2013: MTAC REVIEW

Evidence Conclusion: The accuracy of the UroVysion FISH assay for the diagnosis of bladder cancer in patients with atypical cells has two major components, validity and precision. In this context, the validity of the UroVysion FISH assay refers to the degree to which it does what it is designed to do (i.e. detect urothelial carcinoma of the bladder) and the precision refers to its reliability or it's consistency from one application to the next. In both of the selected studies, the validity of the FISH assay was measured by testing every patient who underwent cystoscopy and cytology with atypical cells within a certain time frame and then reviewing the clinical and pathological data on each patient for congruence. The end result, in both studies, was sensitivity and specificity which allows us to measure how well the test classifies people with the cancer as sick and those without cancer as healthy. In addition, two other measures, positive and negative predictive values, were determined to measure how well the test performed in the given population. Both of the selected studies employed similar methodologic techniques. The UroVysion test was performed on all patients presenting with atypical cytology, both with and without cancer history, within a certain time frame. Results were reviewed comprehensively to evaluate the clinical and pathological data on each patient. Clinical stage was assigned by the operative surgeon and all cytology results were interpreted by an experienced cytopathologist, who was blinded to clinical findings. Cytology results were considered atypical if it was not unequivocally positive or negative. The results of both studies show that the use of the UroVysion test is beneficial in patients with equivocal and negative cystoscopy. Lotan and colleagues found in patients with no cancer history the sensitivity was 77.8% and the specificity was 100% and in patients with cancer history the sensitivity and specificity were both 100%. These findings were validated by Schlomer and colleagues results which show that in patients with cystoscopically visualized lesions UroVysion had a positive predictive value of 100% but there were false negative results. In patients with equivocal cystoscopy and a history of cancer all four high grade tumors were detected and there were no false negative findings. In patients with equivocal cystoscopy and no prior cancer the positive predictive value was 100% and there were no false negative results. In patients with negative cystoscopy the UroVysion test detected all cancers but the positive predictive value was 10% and 29% in patients with and without a history of cancer, respectively. Although these prospective studies indicate that the use of UroVysion in patients with atypical cytology is beneficial in identifying cancer in patients with atypical results they come with limitations. First and foremost, both studies are working with relatively small samples threatening the generalizability of the study. In addition to the small samples, both studies yielded and excluded uninformative UroVysion results. Furthermore, both studies employed more than one diagnostic technique which leads to potential bias. It should also be noted that the UroVysion FISH assay has been approved by the FDA as a noninvasive tool for the detection of cancer cells through voided urine. A portion of the sample collections described in the two prospective studies included specimens that were obtained via bladder washings during cystoscopy which makes comparison difficult with studies that solely used voided urinary samples.

Articles: Lotan Y, Bensalah, Ruddell T, Shariat S, Sagalowsky A, Ashfaq R. Prospective evaluation of the clinical usefulness of reflex fluorescence in situ hybridization assay in patients with atypical cytology for the detection of urothelial carcinoma of the bladder. The Journal of Urology 2008; 179:2164-2169. See Evidence Table Schlomer BJ, Ho R, Sagalowsky A, Ashfaq R, Lotan Y. Prospective Validation of the clinical usefulness of reflex fluorescence in situ hybridization assay in patients with atypical cytology for the detection of urothelial carcinoma of the bladder. The Journal of Urology 2010; 183:62-67. See Evidence Table

The use of UroVysion FISH test in the evaluation of new or recurrent urinary bladder carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
88120	Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual
88121	Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/13/2004	04/04/2011 [MDCRPC], 02/07/2012 [MDCRPC], 12/04/2012 [MDCRPC], 08/06/2013[MPC], 09/03/2013 [MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC]	09/01/2020

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34067
09/01/2020	Removed CPT code 88271

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KAISER PERMANENTE®

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Clinical Review Criteria
Vertebral Axial Decompression (VAX-D System)

- Internal Disc Decompression (IDD)
- Spinal System Therapy
- Traction, Spine

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	National Coverage Determination (NCD) for Vertebral Axial Decompression (VAX-D) (160.16) *This service is not covered per Medicare criteria.*
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Traction, Spine (A-0345) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Chronic lower back pain is a major health problem and cause of disability in Western countries. The cause of the persistent pain is not well understood for the majority of patients. It generally occurs without specific damage or signs that can be revealed by imaging or other neurophysiological techniques. It is believed that the pain starts as acute pain of muscle and connective tissue and persists among approximately one third of the patients (Rittweger 2002). Mechanical low back pain may have various causes including degenerative disc disease, degenerative spondylosis, disc herniation, facet arthropathy, and others. Patients with low back pain may also experience reduced lumbar flexibility, reduced flexion-relaxation and static balance. The pain is aggravated by sitting, standing and lifting, which increase axial loading on the spine. Walking may relieve some of the pain, but patients experience more relief by lying down as it unloads the spine and reduces intradiscal pressure (Gose 1998).

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Conservative medical care for chronic back pain includes bed rest, steroid injection, anti-inflammatory drugs, muscle relaxants, conventional physiotherapy, exercises, stretching, manipulative techniques, ultrasound treatments, electric stimulation techniques and others. These measures ease the pain for some patients but are ineffective, intolerable, or unsuitable for others. Patients not responding to conservative therapy may be offered conventional or percutaneous surgical procedures such as disc space decompression, epidural blocks, and spinal instrumentation. These interventions play an important role in treating patients with low back pain due to herniated disc and degenerative disc problems. However, surgery may not relieve all the pain, and could permanently disrupt the biomechanical and physiological function of the disc. Moreover, not all patients are candidates for surgery.

Some researchers have found that lumbar traction, if adequately applied, may alleviate many of the conditions that cause low back pain. Conventional traction involves simple mechanical stretch which when applied continuously, or by certain techniques, may lead to paravertebral muscle recruitment and increase the intradiscal pressure (Ramos 1994). This observation led to the continuous development of devices and equipment that would achieve decompression of the lumbar discs at a force that the patients can tolerate without stimulating the reactive reflexes of the lumbar musculature (Gose 1998), i.e. without an increase in the resistance to the applied force.

Several systems for vertebral axial decompression have been introduced including the VAX-D equipment, and the Decompression Reduction Stabilization (DRS) System later developed to the Spina System then the Accu-spina Logic System. According the manufacturer's web site, the latter system provides lumbar decompression, cervical decompression, and high-tension oscillation all in one machine, which is also certified to administer IDD therapy treatments.

The VAX-D applies distraction tensions to the patient's lumbar spine in order to non-surgically decompress the spine and intervertebral discs. The patient lies prone on the VAX table that has a split design and is restrained by holding on to adjustable handgrips with the arms extended above the head to stabilize the shoulder girdle and upper body. Patients are allowed to release the handgrips at any time during the treatment. The upper body lies over a stationary portion, and a special harness designed to apply forces to the lateral pelvic alae is fitted and tightened around the patient and connected to a tensionometer at the caudal end of the table. The distraction- relaxation cycles are automated, and continuous feedback from the tensionometer is captured on a chart printout, which allows the operator to constantly monitor the patient. The therapy consists of an average of 20 sessions comprising 15 cycles of decompression and relaxation. The cycles are characterized by one minute of distraction and one minute of relaxation. The therapeutic range of tension is 50-95 pounds, which is reduced by 10-15 pounds when the patients are asymptomatic, or the symptoms have reached a plateau. The investigators of this technology indicate it for patients with low-back pain associated with herniated discs, or degenerative disc disease, and contraindicate it for patients with cauda equine syndrome, infection, tumor severe osteoporosis, fractures, bilateral pars defect, spondylolisthesis Grade 2, and the presence of surgical hardware (Ramos 2004).

The Spina IDD System is also a non-invasive procedure that provides static intermittent and cyclic distraction forces to relieve the pressure on structures causing chronic neck or lower back pain. The system consists of a table split into two cushions, and a controller unit. The patient is anchored by means of a pelvic harness to the traction connector for the prescribed period of time. The therapy is provided in 20 treatment sessions over a period of 35 days. Each session lasts for approximately 30 minutes.

Both the VAX-D System and the Spina System were cleared by the FDA as Class II Medical devices 510 (k). The technology is being reviewed based on requests for coverage of the Internal Disc Compression Therapy.

Medical Technology Assessment Committee (MTAC)

Internal Disc Decompression Therapy in the Treatment of Pain from Spinal Disc Problems

06/09/1999: MTAC REVIEW

Evidence Conclusion: The published scientific evidence reporting clinical outcomes from VaxD treatment consists of a case series of 778 patients diagnosed with herniated or degenerated lumbar discs or facet syndrome. This study reports improvements in pain, mobility, activity and satisfaction following treatment. The validity of these results are uninterpretable however because no statistical analysis was reported and no information on the length and completeness of patient follow up was presented. Another small retrospective case series of 17 patients reports some changes in sensory nerve function as measured by a Current Perception Threshold neurometer following VaxD but the relationship between these changes and clinical improvement is unclear. The published evidence is not sufficient to determine if the benefits of Vax-D outweigh the harms of treatment. No studies which compare benefits and harms of Vax-D to the natural history of disc related low back pain have been published. Data from the large case series was obtained from 22 medical centers in the US. However, a lack of statistical analysis of this data

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does not permit conclusions to be made regarding the effect of Vax-D on back pain. The best published evidence is insufficient to demonstrate that Vax-D is effective and therefore Vax-D does not represent an efficient use of healthcare resources.
Articles: Gose, EA, et al, Neurological Research, 1998, 20:186-190 See Evidence Table.

The use of internal disc decompression therapy in the treatment of pain from spinal disc problems does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/06/2006: MTAC REVIEW
Internal Disc Decompression Therapy in the Treatment of Pain from Spinal Disc Problems
Evidence Conclusion: The literature search did not reveal any published studies on the IDD Therapy or the Spina System. The latter received FDA Clearance, in July 2000 based on its equivalence to the vertebral axial decompression device (VAX-D). There was one randomized trial and few case series published on the VAX-D. The RCT and a large series were critically reviewed. Sherry et al randomized 44 patients, 18-65 years old, with chronic low-back pain to receive either vertebral axial decompression (VAX-D) or transcutaneous electrical nerve stimulation (TENS) therapy. The primary outcome was the difference in proportion of successfully treated patients in the two treatment groups. Success of treatment was defined as 50% decrease in pain on the visual analogue scale and improvement in disability. The trial was small, poorly randomized, un-blinded, and had a high dropout rate. The authors did not conduct an intention to treat analysis but calculated their results on data for patients who completed therapy and follow-up, and concluded that VAX-D therapy was associated with a significant reduction in pain and disability. They compared the therapy to TENS, which seems to have a negative effect. A recent Cochrane Systematic Review (Khadilkar 2005) of published RCTs evaluating the effect of TENS on lower back pain, showed that the efficacy of TENS therapy was limited and inconsistent. Gose et al, reported the results of 778 patients with low back pain who had received at least 10 sessions of VAX-D therapy in 22 centers in the USA. The primary outcome was reduction in pain, improvement in mobility, ability to walk and sit, and patient satisfaction with the treatment. The study was only observational and had no control or comparison group. Moreover, all outcomes were subjective, and apparently there was no extended follow-up after the end of treatment. Overall, the results show that the treatment was successful among 71% of cases, with treatment success defined as a reduction in pain to 0 or 1 on a 0-5 scale. In conclusion, the current literature does not provide sufficient evidence to recommend the use of the VAX-D therapy, or the Spina System for the management of chronic low back pain. Larger, multi-center randomized controlled trials are needed to determine the effectiveness and long-term net health outcomes of the therapy. The published scientific evidence reporting clinical outcomes from VaxD treatment consists of a case series of 778 patients diagnosed with herniated or degenerated lumbar discs or facet syndrome. This study reports improvements in pain, mobility, activity and satisfaction following treatment. The validity of these results is uninterpretable however because no statistical analysis was reported and no information on the length and completeness of patient follow up was presented. Another small retrospective case series of 17 patients reports some changes in sensory nerve function as measured by a Current Perception Threshold neurometer following VaxD but the relationship between these changes and clinical improvement is unclear.
Articles: The search yielded 20 articles several of which were not related to the devices. Four studies on the vertebral axial decompression therapy using the VAX-D device were identified. One was an RCT comparing it to TENS, and the other three were case series with patient sizes varying from 5 to 778 patients. The RCT and the largest case series were selected for critical appraisal. No articles on the Spina System were identified. *The following articles were critically appraised:* Sherry E, Kitchener P, and Smart R. A prospective randomized controlled study of VAX-D and TENS for the treatment of chronic low back pain. Neurol Res 2001; 53:780-784. See Evidence Table. Gose EE, Naguszewski WK, and Naguszewski RK. Vertebral axis decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study. Neurol Res 1998; 20:186-190. See Evidence Table.

The use of internal disc decompression therapy in the treatment of pain from spinal disc problems does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
S9090	Vertebral axial decompression, per session

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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
12/1998	04/04/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015 MPC, 04/05/2016 MPC, 02/07/2017 MPC, 12/05/2017 MPC, 11/06/2018 MPC, 11/05/2019 MPC, 11/03/2020 MPC, 11/02/2021 MPC, 11/01/2022 MPC	08/05/2014

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Vectra DA (Multiple Biomarker Disease Activity [MBDA])

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Billing and Coding: MolDX: Vectra™ DA (A54505)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

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Background

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder that primarily involves synovial joints. It is debilitating disease that if uncontrolled, may lead to joint destruction, functional disability, and premature death. It is thus important to detect RA early, and to control the disease as soon as possible after diagnosis to delay its progression and preserve physical function.

Treatment of RA has shifted from symptom management, to reducing the disease activity and delaying its progression. Recent guidelines recommend treating RA promptly and aggressively aiming for remission as a therapeutic target (tight control or treatment-to-target strategy). Tight control may be defined as a treatment strategy tailored to the disease activity in individual patients with RA with the aim of achieving a predefined level of low disease activity, or preferably remission within a reasonable period of time. The availability of an increasing number of biologic and non-biologic effective disease-modifying anti-rheumatic drugs (DMARDs) has allowed the achievement of this treatment goal, but requires close monitoring of the disease activity, which is the cornerstone of tight control (Bakker 2007, Anderson 2012, Curtis 2012, Peabody 2013, Segurado 2014, Michaud 2015).

There are a number of composite tools available for assessing RA disease activity, six of which have been recommended by the American College of Rheumatology (ACR): Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (DAS28), Patient Activity Scale (PAS), PAS-II, Routine Assessment of Patient Index Data with 3 measures (RAPID-3), and Simplified Disease Activity Index (SDAI). These indices are based on information obtained from clinical, laboratory, and physical measures that include quantitative joint counts, patient

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reported outcomes, physician examination, and laboratory test including erythrocyte sedimentation rate (ESR) and C- reactive protein (CRP). These composite measurements are of great importance, but are complicated, may have intra- and inter-observer variability, are unable detect subclinical synovial damage, and may be influenced by cumulative damage and other conditions unrelated to RA (Anderson 2012, Curtis 2012, Owens 2015).

More recently, researchers have been investigating biomarkers to complement the clinical assessment of RA and improve the evaluation of disease activity. No single biomarker has been found to accurately assess RA activity, and it is hypothesized that a combination of biomarkers that measure diverse pathways to RA may have the potential of providing objective information on disease activity (Curtis 2012, Hirata 2013).

Vectra DA (Crescendo Bioscience, South San Francisco, CA), is a commercially available blood test that measures the serum concentration of 12 biomarkers and combines them into an algorithm to generate a multibiomarker disease activity (MBDA) score. The biomarkers included in Vectra DA test are: VCAM-1 (vascular cell adhesion molecule-1), EGF (epidermal growth factor), VEGF-A (vascular endothelial growth factor A), IL-6 (interleukin-6), TNF-RI (tumor necrosis factor receptor, type 1), MMP-1 (matrix metalloproteinase-1 or collagenase-1), MMP-3 (matrix metalloproteinase-3 or stromelysin-1), YKL-40, SAA (serum amyloid), CRP (C-reactive protein), leptin, and resistin. The score generated by the test is believed to represent the level of RA disease activity on a scale of 1 (lowest activity) to 100 (greatest activity). According to the manufacturer a score between 45 and 100 indicates high level of disease activity; 30 to 44 indicates moderate disease activity; and 1 to 29 indicates a low level of disease activity. Vectra DA test is not intended or validated to diagnose RA, but as an aid in the assessment of disease activity in adults RA patients when used in conjunction with standard clinical assessment (Curtis, 2012, Peabody 2013, Michaud 2015, Vectra.com).

Medical Technology Assessment Committee (MTAC)

12/21/2015: MTAC REVIEW

Vectra DA Test for Rheumatoid Arthritis

Evidence Conclusion: *Analytic validity* **-** Eastman and colleagues (2012), evaluated the analytical performance of each of the individual biomarker assays that comprise the MBDA test and the generated MBDA score. The investigators quantified the 12 serum biomarkers and found that all 12 individual assays exhibit a high level of precision with minimal cross-reactivity and interference by substances commonly seen in RA patients. The total MBDA score had good reproducibility over time with a median coefficient of variation of <2% across the score range. The same MBDA score was observed in different subjects with different biomarker profiles (Eastman 2012). *Clinical validity* **-** The published literature on the clinical validity of the MBDA Vectra DA test consists of observational cohort studies and posthoc analyses of randomized controlled trials performed for other reasons and among patients for whom serum samples were available to retrospectively evaluate the Vectra DA test. The studies correlated the MBDA score with other validated measures used for disease activity (mainly DAS28-CRP), radiographic joint progression, or response to therapy, and had no long-term follow-up to determine the test ability to predict clinical outcomes. Curtis and colleagues (2012), prospective cohort study (Evidence table 1): The authors used blood samples for 371 patients from 3 diverse RA cohorts in North America and Europe to validate the MBDA scores against DAS28-CRP (Disease Activity Score in 28 joints using the C-reactive protein level) as the reference measure for disease activity. The analysis of the results showed that MBDA score was positively, but moderately correlated with DAS28-CRP in both seropositive and seronegative patients (correlation coefficient r=56 and 43 respectively). The area under the receiver operating characteristic curve (AUROC) for discriminating low disease activity from moderate disease activity was 0.77 for seropositive patients and 0.70 for seronegative patients. The analysis also showed that changes in the MBDA scores at 6-12 weeks were significantly correlated with the corresponding changes in DAS28-CRP (Spearman's correlation coefficient r_s = 0.51). The study did not adjust for confounding factors, and did not evaluate the ability of the test to predict long-term outcomes of RA. In addition, it was partially supported by Crescendo Bioscience, the company manufacturing the laboratory test, and the authors had financial ties to the company. Bakker, et al (2012), Posthoc analysis of a completed randomized controlled trial (Evidence table 2): The investigators evaluated the performance of individual biomarkers and a MBDA (Vectra DA) test score in a subset of RA patient population enrolled in the Computer Assisted Management in Early Rheumatoid Arthritis (CAMERA) tight control study. Only patients with available serum samples were included in the study evaluating the performance MBDA test (72 patients out of the 299 enrolled in CAMERA trial). There were significant differences between the patients with available samples versus those without. Blood samples were obtained from 72 patients at baseline and from 46 patients after treatment. MBDA scores were calculated and the performance of the Vectra DA test was evaluated relative to DAS28-CRP. The analysis showed that MBDA score had a significant correlation with DAS28-CRP (r=0.72; p<0.001) and an area under the receiver operating characteristic curve for distinguishing remission/low from moderate/high disease activity of 0.86 (p<0.001) using a DAS28-CRP cut-off of 2.7. The agreement of MBDA score with DAS28-CRP for classifying disease activity was fair (kappa score =0.34, 95% CI 0.19-0.49). The results also showed that MBDA score decreased from 53±18 at baseline to 39 ±16 at 6 months in response to study therapy (p<0.0001). Neither MBDA

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score nor DAS28-CRP was predictive of radiographic progression. The study was based on posthoc analysis of data from a completed trial, did not adjust for confounding factors, and did not evaluate the ability of the test to predict long-term outcomes of RA. The study was supported by Crescendo Bioscience, and the authors had financial ties to the company. Hirata and colleagues (2013) evaluated MBDA score in 125 patients with RA from the Behandel Strategieën (BeSt) study. Data and serum samples were available from 179 visits (91 at baseline and 88 at year 1). The results showed that the MBDA scores was significantly correlated with DAS28-ESR (Spearman's rank correlation coefficient r_s=0.66). It was also correlated with simplified disease activity index (SDAI), clinical disease activity index (CDAI). Changes in MBDA between baseline and year 1 were also correlated with changes in DAS28-ESR (assessed in a subgroup of 54 patients, r_s=0.55). The study was also a posthoc analysis of patients enrolled in BeSt study, was supported by Crescendo Bioscience, Inc., and the authors had financial ties to the company. *Prediction of radiographic joint progression* - Posthoc analyses of two RCTs: SWEFOT (Hambardzumyan et al, 2015) and BeSt [Markusse et al, 2014) suggest that MBDA scores may predict radiographic damage progression in patients with RA. These analyses had their limitations including, but not limited to the use of data obtained from RCTs designed primarily to compare different RA therapies, the patients included in the trials do not represent all RA patients as those with low DAS28 were excluded, patients were not randomized to therapy based on their MBDA scores, these scores were only available at baseline, and after 1 year (in one trial). In addition, patients in SWEFOT trial switched from one drug to another during the trial, which could affect radiographic outcomes, and the treatment-to-target strategy in BeSt trial suppressed inflammation and progression of radiographic joint damage in the majority of patients. A more recently published retrospective observational study (Li, 2015) with its limitations also suggest that MBDA score may enhance the ability to predict radiographic progression in patients with RA treated with non-biologic DMARDs. In conclusion, the published studies on the relationship between MBDA and radiographic joint damage had their limitations and do not provide sufficient evidence to determine the value of MBDA in predicting progression of radiographic joint damage in patients with rheumatoid arthritis. *Clinical utility*- There are no published RCTs, to date, that that compared a management strategy using the MBDA score versus another established measure of disease activity, and reported clinical outcomes such as disease progression, functional statue, or quality of life. The studies that evaluated the impact of Vectra DA test on clinical-decision making used simulated cases or physician surveys and did not report outcome data. Li and colleagues (2013), assessed the impact of MBDA, Vectra DA blood test on RA treatment decisions in 101 patients with RA. The health care providers (HCP) completed surveys before and after viewing the MBDA test result, recorded the dosage and frequency for all planned RA medications and the physician global assessment of disease activity. Frequency and types of change in treatment plan that resulted from viewing the MBDA test result were determined. The results of the study showed that, after reviewing MBDA test results treatment decisions were changed in 38 cases (38%), of which 18 involved starting, discontinuing, or switching a biologic or non-biologic DMARD. Other changes involved drug dosage, frequency or route of administration. The total frequency of use of the major classes of drug therapy changed by <5%. Treatment plans changed 63% of the time when the MBDA test result was perceived as being not consistent or somewhat consistent with the HCP assessment of disease activity. The study had its limitations including the small sample size, lack of a control group, and absence of follow-up to determine the impact on patient outcomes. Rech and colleagues (2015) analyzed the role of MBDA score in predicting disease relapse in patients with RA in sustained remission with tapered disease modifying antirheumatic drug (DMARD) therapy in RETRO trial. This was a RCT that evaluated the possibility of tapering or stopping DMARDs in patients fulfilling classification criteria for RA. The participants were randomized to 3 arms: 1. continuing DMARDs for 12 months, 2. Tapering the treatment by 50%, or 3. Reducing the dose by 50% for the first 6 months before entirely discontinuing the treatment. MBDA scores were calculated from the analysis of baseline serum samples of 94 patients participating in the RETRO trial. Retrospective analysis of data showed that baseline MBDA levels were significantly higher in patients experiencing a relapse vs. those in sustained remission. The analysis was retrospective and does not provide sufficient evidence to determine utility of MBDA in predicting the disease relapse and tapering or discontinuing the use of DMARDs accordingly. Conclusion There is insufficient evidence to determine whether MBDA is as good as or better than other established indices used to measure RA disease activity. The published studies show a moderate correlation between Vectra DA and DAS28-CRP in classifying patients into low vs. moderate to high disease. There is insufficient evidence to determine the clinical validity of Vectra DA test and its ability to predict outcomes. There is insufficient evidence to determine that Vectra DA test results have an impact on the management of patients with rheumatoid arthritis and/or improve their health outcomes.
Articles: The literature search revealed a study on the analytic validity of MBDA test score, four studies on the clinical validity of the MBDA Vectra Da test, and few small simulating studies or surveys on the clinical utility of the test. The following two studies on the clinical validity of MBDA test studies were selected for critical appraisal: Bakker MF, Cavet G, Jacobs JW, et al. Performance of a multi-biomarker score measuring rheumatoid arthritis disease activity in the CAMERA tight control study. *Ann Rheum Dis.* 2012 Oct; 71(10):1692-1697. See Evidence Table 1. Curtis JR, van der Helm-van Mil AH, Knevel R, et al. Validation of a novel multibiomarker test to assess rheumatoid arthritis disease activity. *Arthritis Care Res (Hoboken).* 2012 Dec; 64(12):1794-1803. See Evidence

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Table 2.

The use of Vectra DA (Multiple Biomarker Disease Activity [MBDA]) test for monitoring disease activity in patients with rheumatoid arthritis does not meet the *Kaiser Permanente Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/06/2016	01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	01/06/2016

[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Treatment of Varicose Veins

- Radiofrequency Catheter Closure
- Sclerotherapy
- Surgical Stripping
- Trivex System for Outpatient Varicose Vein Surgery
- VenaSeal Closure System
- VNUS Closure Device

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Treatment of Varicose Veins of the Lower Extremities (L34010)
Local Coverage Article	None

For Non-Medicare Members

I. For great saphenous vein or small saphenous vein ligation, stab phlebectomy, division, stripping, radiofrequency endovenous occlusion (VNUS procedure), Endovenous Radiofrequency Ablation Treatment (ERFA) and endovenous laser ablation of the saphenous vein (ELAS) (also known as endovenous laser treatment (EVLT) **ALL of the following** criteria must be met:

A. The patient is symptomatic and has one or more of the following:
   1. Pain or burning in the extremity
   2. Recurrent episodes of superficial phlebitis
   3. Non-healing skin ulceration
   4. Bleeding from a varicosity
   5. Stasis dermatitis
   6. Refractory dependent edema

B. Vein size is 4.5 mm or greater in diameter (not valve diameter at junction) or with exception of short saphenous vein 3.5 mm or greater can be ablated

C. Pre-operative doppler demonstrates reflux (reflux duration of 500 milliseconds (ms) or greater in the vein to be treated).

D. In addition, all of the following are true for ERFA and laser ablation:
   1. Absence of aneurysm in the target segment.
   2. Maximum vein diameter of 12 mm for ERFA or 20 mm for laser ablation.
   3. Absence of thrombosis or vein tortuosity, which would impair catheter advancement.
   4. The absence of significant peripheral arterial diseases.

E. Microfoam sclerotherapy (e.g. Varithena) can be used if patient meets criteria B (above) when laser ablation is not an option, per criteria D3 (above).

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II. Sclerotherapy is covered for up to 6 months after a covered stab phlebectomy, endovenous ablation or a vein stripping. Sclerotherapy can be approved at these same venous sites if symptoms persist associated with persistent varicosities. Also, sclerotherapy can be approved for 4.0 mm or greater superficial varicosities associated with spontaneous bleeding or a poorly healing ulcer.
III. VenaSeal Closure System
Can be covered if all criteria above are met.

No evidence to support coverage for:
A. Treatment of reticular veins, spider veins or superficial telangiectasias by any technique (considered cosmetic)
B. Procedures with devices not FDA-approved

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Background

Superficial venous reflux occurs when the valves that keep blood flowing out of the veins in the leg become damaged or diseased. Primary symptoms are pain, swelling and varicose veins. The basic treatment is to re-route blood flow through other healthy veins. This can be done using several techniques: stripping the greater damaged vein, using radiofrequency energy to heat and occlude the vein, and using irritant solution to obliterate the vein.

The conventional treatment is stripping of the greater damaged vein. This procedure has favorable clinical outcomes (REF), but is associated with substantial post-operative morbidity, particularly pain and bruising. Recurrent reflux is possible with the existing treatments and the risk of recurrence increases over time.

Rather than vein stripping, radiofrequency (RF) energy to heat and occlude the damaged vein. RF energy is delivered via collapsible catheter electrodes that are introduced into the vein lumen. The operator sets the target temperature, usually 85°C. The temperature is monitored using a microprocessor-controlled bipolar generator. The procedure is performed on an outpatient basis, using either local or regional anesthesia.

Sclerotherapy is the treatment of veins that are distended, lengthened and tortuous (i.e. varicose veins) by the injection of an irritant solution to encourage obliteration of the veins by thrombosis and subsequent scarring.

The treatment of varicose veins and spider veins can be for either cosmetic purposes or for the improvement of clinical symptoms related to these conditions. In order to identify when the care will be covered a common set of clinical appropriateness criteria were developed.

Evidence and Source Documents

Radiofrequency Catheter Closure
Trivex
VenaSeal Closure System

Medical Technology Assessment Committee (MTAC)

Radiofrequency Catheter Closure in the treatment of varicose veins

BACKGROUND

Superficial venous reflux occurs when the valves that keep blood flowing out of the veins in the leg become damaged or diseased. Primary symptoms are pain, swelling and varicose veins. The basic treatment is to re-route blood flow through other healthy veins. The conventional treatment is stripping of the greater damaged vein. This procedure has favorable clinical outcomes (REF), but is associated with substantial post-operative morbidity, particularly pain and bruising. Recurrent reflux is possible with the existing treatments and the risk of recurrence increases over time. The VNUS Closure System was proposed as a minimally invasive treatment for superficial venous reflux. Rather than vein stripping, the Closure system uses radiofrequency (RF) energy to heat and occlude the damaged vein. RF energy is delivered via collapsible catheter electrodes that are introduced into the vein lumen. The operator sets the target temperature, usually 85o C. The temperature is monitored using a microprocessor-controlled bipolar generator. The procedure is performed on an outpatient basis, using either local or regional anesthesia. The VNUS Closure System received FDA approval March 1999.

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08/13/2003: MTAC REVIEW
Radiofrequency Catheter Closure in the treatment of varicose veins
Evidence Conclusion: The best, published evidence on the VNUS Closure system is a small RCT with n=33 (Rautio et al., 2002). This study found that patients had less pain and fewer sick days a mean of 50 days after the Closure procedure than patients who received the stripping operation. There was no significant difference in quality of life variables. Potential sources of bias in the Rautio RCT include lack of blinding, lack of intention to treat analysis and potential confounding. In addition, the RCT did not have long-term follow-up and did not address the issue of recurrent reflux. Also available are case series data from a multi-center registry (Merchant et al., 2002). 93% of patients had complete the use of Radiofrequency Catheter Closure in the treatment of varicose veins does not meet the Kaiser Permanente Medical Technology Assessment Criteria. Occlusion after the VNUS Closure procedure. Twelve months after treatment, among the patients with data available, 94% of those with complete occlusion had varicose veins absent and 100% had reflux absent. These findings could be biased because data were missing on 20% of the patients at 12 months. Although the Rautio study suggests short-term benefit of the Closure system compared to the stripping procedure, there is insufficient evidence on long-term effectiveness.
Articles: The search yielded 12 articles. The best evidence was a recent case series taken from a multi-center registry and a small randomized controlled trial. The following studies were critically appraised: Rautio T, Ohinmaa A, Perala J. et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: A randomized controlled trial with comparison of the costs. *J Vasc Surg* 2002;35: 958-65. See Evidence Table. Merchant RF, DePalma RG, Kabnick LS. Endovascular obliteration of saphenous reflux: A multicenter study. *J Vasc Surg* 2002;35: 1190-1196. See Evidence Table.

The use of Radiofrequency Catheter Closure in the treatment of varicose veins does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

TriVex System for Outpatient Varicose Vein Surgery
BACKGROUND
Because there are no published studies on the TriVex transluminated powered phlebectomy for outpatient varicose vein surgery, this was documented. Transilluminated phlebectomy is a minimally invasive surgical technique for removing varicose veins. The TriVex system was introduced by Smith & Nephew in 2000. The TriVex resector and TriVex illuminator are placed under the skin through small 2mm vertical incisions on either side of the varicosity. According to Smith & Nephew, “one of the key features of the TriVex system is its ability to light the area beneath the skin. For the first time, the vein is clearly visible, allowing the surgeon to quickly and accurately remove it using a powered resector and then visually confirm its complete extraction.”

08/08/2001: MTAC REVIEW
TriVex System for Outpatient Varicose Vein Surgery
Evidence Conclusion: There are no published studies on the TriVex System Transilluminated Powered Phlebectomy for outpatient varicose vein surgery. We were not given any unpublished data of sufficient quality to review as evidence. In conclusion, there is no evidence on which to base conclusions about the effect of this technology on health outcomes.
Articles: No published articles were found. Literature from the manufacturer included conference abstracts that cannot be evaluated as evidence. Conclusion: There is no evidence on which to base conclusions about the effect of this technology on health outcomes.

The use of TriVex in the treatment of Varicose Veins does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

VenaSeal Closure System for Varicose Veins
BACKGROUND
Chronic venous disorders of the lower limb affect approximately 30 million adults or 35% of screened adults in the United States (McLafferty et al., 2008) and manifest most frequently like varicose veins. The mechanism underlying varicose veins can be explained by a defective valve inside the veins. The valves of the superficial veins and those of the Great Saphenous Vein (GSV) transferring blood toward the heart are dysfunctional leading to venous dilation and stasis. The accumulation of blood in the vein causes the swelling, pain, chronic skin changes, spontaneous hemorrhage, leg ulcers and fatigue. Evolution of the condition is marked by a reduction of quality of life (QoL) (Nick Morrison et al., 2015).

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The management of varicose veins has undergone a shift and several treatment options have been described. These include surgery and minimal invasive therapies. Surgery which is represented by ligation, stripping and various other techniques are described and involve saphenous vein inversion and removal, high ligation of the saphenous vein, ambulatory phlebectomy, trans illuminated phlebectomy, conservative venous ligation (CHIVA), and perforator ligation. Although surgery improves symptoms and leads to patient satisfaction (Baker, Turnbull, Pearson, & Makin, 1995; MacKenzie et al., 2002; Nelzén & Fransson, 2013; Smith, Garratt, Guest, Greenhalgh, & Davies, 1999), it can be complicated by hematoma, paresthesia and high recurrence rate (Ostler, Holdstock, Harrison, Price, & Whiteley, 2015). Other treatments encompass thermal-based techniques including endovenous thermal ablation (EVTA) by radiofrequency ablation (RFA) or laser ablation. These techniques are believed to have long-term success (vein closure) rates of 78 to 84% (Carroll et al., 2014; Nesbitt, Bedenis, Bhattacharya, & Stansby, 2014; Pan, Zhao, Mei, Shao, & Zhang, 2014) and necessitate tumescent anesthesia. In contrast, new technique such as venaseal closure system (VSCS) does not seem to require tumescent anesthesia, and has recently been approved for treatment of the incompetent GSV in the European Union, Hong Kong, and Canada (Nick Morrison et al., 2015).

The VenaSeal Closure System (VSCS) treats symptomatic varicose veins of the legs by closing the affected superficial veins with a cyanoacrylate-based adhesive. The VenaSeal System is composed of a catheter, guidewire, dispenser gun, dispenser tips, and syringes. A catheter is introduced through the skin into the varicose vein and a clear liquid (adhesive) is also injected. The insertion of the catheter and the delivery of adhesive are performed under ultrasound guidance. After the delivery of the adhesive, manual compression of the affected area begins and the adhesive changes into a solid to seal the varicose vein. The system is used for patients with venous reflux disease and it seals superficial varicose veins of the legs. Treating the diseased veins generally relieves symptoms. The VenaSeal System should not be used in patients with a known hypersensitivity to the VenaSeal adhesive or cyanoacrylates, patients who have acute inflammation of the veins due to blood clots and patients with acute whole-body infection (FDA, 2015).

06/20/2016: MTAC REVIEW
VenaSeal Closure System
Evidence Conclusion:
Conclusion:

- Based on low quality evidence, manufacturer sponsored trial, cyanoacrylate embolization (CAE) performed with the VSCS was non-inferior to radiofrequency ablation (RFA).
- There is a lack of evidence to determine whether the VenaSeal Closure System (VSCS) for varicose veins treatment is effective and safe compared to other alternative treatments.

Articles: The following article was selected for critical appraisal: Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose) See Evidence Table 1.

The use of VenaSeal Closure System of Varicose Veins does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

01/04/2019: MTAC REVIEW
VenaSeal Closure System
Evidence Conclusion: Moderate evidence shows that VenaSeal is non-inferior and comparable to RFA in patients with moderate to severe varicosities and incompetence of the great saphenous vein on the short-term and long-term (36 months).
Articles: PubMed was searched from May 2016 through June 6, 2018 with the search terms venaseal OR venaseal closure system OR venaseal system. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded 18 articles. After screening, 12 articles were retained and assessed. See Evidence Tables.

The use of VenaSeal Closure System of Varicose Veins does meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are

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met:

Endovenous Laser Ablation

CPT® or HCPC Codes	Description
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Ligation and Excision

CPT® or HCPC Codes	Description
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
37718	Ligation, division, and stripping, short saphenous vein
37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
37735	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
37780	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg

Sclerotherapy Telangiectasias

CPT® or HCPC Codes	Description
36468	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk

Radiofrequency Ablation

CPT® or HCPC Codes	Description
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Laser Ablation

CPT® or HCPC Codes	Description
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Sclerotherapy

CPT® or HCPC Codes	Description
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)

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36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
S2202	Echosclerotherapy

Stab Phlebectomy

CPT® or HCPC Codes	Description
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions

Subfascial Endoscopic Perforator Surgery (SEPS)

CPT® or HCPC Codes	Description
37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
37760	Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open,1 leg
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg

VenaSeal (chemical adhesive)

CPT® or HCPC Codes	Description
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

Varithena

CPT® or HCPC Codes	Description
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
1992	05/04/2010 [MDCRPC], 03/01/2011 [MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 01/07/2014[MPC], 07/01/2014[MPC], 06/02/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC]	10/01/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34010
01/13/2016	Added CPT codes and stab phlebectomy language
06/20/2016	Added VenaSeal Closure System MTAC review
04/03/2018	MPC approved to adopt the revised indication for varicose veins: *Vein size is 4.5 mm or grater in diameter (not valve diameter) & Sclerotherapy can be approved for 4.0 mm or greater superficial varicosities associated with spontaneous bleeding or a poorly healing ulcer.*
02/05/2019	MPC approved to adopt coverage criteria for VenaSeal Closure System; added 01/2019 MTAC review
10/01/2019	MPC approved to add coverage for Varithena
12/06/2022	Care Delivery Medical Necessity Review for Varicose Veins audit has been reviewed; prior authorization with no medical review has been awarded for another year.

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Clinical Review Criteria
Vertebral Artery Angioplasty / Stenting

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Percutaneous Transluminal Angioplasty (20.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Vertebral Artery Angioplasty, with or without Stent Placement (A-0233) MCG* for medical necessity determinations. This service is not covered per MCG. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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Background

Vertebral artery angioplasty for stroke prevention, with or without stenting (also called endovascular intervention), has had high technical success for patients sustaining recurrent vertebrobasilar transient ischemic attacks or strokes; however, long-term outcome data are limited. (per MCG)

Applicable Codes

Considered not medically necessary:

CPT® or HCPC Codes	Description
0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel
0076T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel (List separately in addition to code for primary procedure)

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[MPC] Medical Policy Committee

Revision History	Description

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Clinical Review Criteria
Virtual Colonoscopy or CT Colonography

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Colorectal Cancer Screening Tests (210.3)
Decision Memo	Decision Memo for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)*
Local Coverage Determinations (LCD)	None
KPWA Medical Policy	**Screening** Per Medicare, for Virtual Colonoscopy or CT Colonography: The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under §1861(pp) (1) of the Social Security Act. However, for Kaiser Permanente Medicare Advantage members, virtual colonoscopy or CT colonography for colorectal cancer screening after a positive fecal immunochemical (FIT) or fecal occult blood test (FOBT) may be considered medically necessary if the patient meets the non-Medicare criteria below. **Diagnostic** Virtual Colonoscopy or CT Colonography: Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, ***Virtual Colonoscopy or CT Colonography*** for medical necessity determinations. Use the non-Medicare criteria below.

For Non-Medicare Members

Computed tomographic (CT) colonography, also known as virtual colonoscopy, utilizes helical computed tomography of the abdomen and pelvis to visualize the colon lumen, along with 2D or 3D reconstruction. The test requires colonic preparation similar to that required for fiberoptic colonoscopy, and air insufflation to achieve colonic distention.

CT colonography is indicated only in patients having **ONE of the following** qualifying conditions:

1. Instrument colonoscopy of the entire colon is incomplete and/or contraindicated due to colon obstruction;
2. A coagulation disorder known to increase bleeding risk;
3. Lifetime anticoagulation or long-term anticoagulation therapy with increased patient risk if discontinued;
4. Significant medical or surgical complications from previous standard colonoscopy;
5. Medical condition that places the patient at increased risk with use of conscious sedation;
6. CT colonography is not a covered service when utilized in preoperative cancer staging, and in this clinical situation as standard CT or MRI is the preferred imaging study, or for screening or diagnostic evaluation in the absence of one of the indications 1-5 above.

Patient personal preference or patient refusal to undergo colonoscopy, in the absence of one of the qualifying

conditions noted above, even if signs or symptoms of colon disease are present, is not a covered indication for CT colonography. *Per the USPSTF, upon a patient request virtual colonoscopy can be covered for *"screening purposes"* (not diagnostic).

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Background

Colorectal cancer is the third most common cancer and the second leading cause of cancer-related deaths in the United States. A majority of cases can be prevented with colonoscopic removal of the precursor adenomatous polyp. With early detection, patients with cancer limited to the colonic wall will have a corrected 5-year survival of around 90%, whereas for those with lymphatic spread this figure drops to 30%. Although standard colonoscopy is a total colonic examination that allows lesion biopsy and resection, it is an invasive procedure, may fail to demonstrate the entire colon in up to 5% of cases examined by an experienced gastroenterologist, and could miss up to 20% of all adenomas. (Yee J, 2001).

Computed tomography colonography, commonly referred to as virtual colonoscopy, is a new method of imaging the colon. It uses data from thin sections helical computed tomography of the clean, air-distended colon, combined with advanced imaging software to create two-dimensional and three-dimensional images of the colon that simulate the endoluminal view seen at endoscopy. Since first introduced by Vining and colleagues in 1994, its performance has improved due to the development of fast helical CT scanners, and advances in the computer software for image reconstruction.
A variety of techniques have been described, but all share the same basic principles: Full bowel cleaning, air distension of the colon using a rectal enema tube, taking thin-section images of the colon in the supine and prone positions, and image interpretation using a combination of axial and multiplanar or endoluminal reconstructions.

The concept of virtual colonoscopy is appealing and appears to many as a potentially attractive method of screening for colorectal cancer. Compared to the standard optical colonoscopy, virtual colonoscopy is less invasive, does not require sedation, analgesia, or recovery time, and allows the entire colon to be visualized in the majority of patients. It might also provide additional information by evaluating colonic wall thickness and imaging abdominal structures outside the colon and may be more acceptable to patients.

However there are a number of potential limitations to this procedure. First of all, it requires a complete and thorough colon cleansing. Poor colonic preparation or distension limits the accuracy of CT colonography. Colonic lavage preparation often results in excess residual fluid or stools in the colon, that may simulate or cover the presence of a lesion. Another significant limitation is that virtual colonoscopy may be less effective at detecting smaller polyps and flat adenomas. In addition, unlike conventional colonoscopy, virtual colonoscopy is only a diagnostic test; the detected polyps cannot be resected during the procedure. If suspicious lesions are detected, the patient undergoes further testing, usually by conventional colonoscopy. (Hawes 2002).

The original MTAC review in June 2001 evaluated virtual colonoscopy as a screening tool, and for evaluation of high-risk patients. The second review in October 2002 focused on virtual colonoscopy for detecting of colorectal polyps among high risk, elderly or frail patients. At both meetings, virtual colonoscopy failed MTAC diagnostic test criteria. The current review is on virtual colonoscopy as a screening method for average risk asymptomatic individuals and was initiated in response to the publication of the Pickhardt study on virtual colonoscopy in a screening population.

Medical Technology Assessment Committee (MTAC)

Virtual Colonoscopy

06/13/2001: MTAC REVIEW

Evidence Conclusion: The available evidence suggests that virtual colonoscopy is not yet as effective as conventional colonoscopy at identifying colorectal polyps and carcinomas. Virtual colonoscopy may be relatively effective at identifying lesions ≥ 10 mm in size, but further study is needed to verify this. No studies to date have examined the use of virtual colonoscopy for general screening or compared the acceptability of virtual compared to conventional colonoscopy.
Articles: The literature search yielded 57 articles. Articles that were opinion pieces, reviews, dealt with technical

aspects of virtual colonoscopy, or had small sample sizes were excluded. There were 4 empirical studies with sample sizes ≥ 50. The two studies with the strongest methodologies were reviewed. Fenlon HM, Nunes DP, Schroy PC, Barish MA, Clarke PD, Ferrucci JT. A comparison of virtual and conventional colonoscopy for the detection of colorectal polyps. N Engl J Med 1999; 341: 1496-503. See Evidence Table. Spinzi G, Belloni G, Martegani A, Sangiovanni A, Del Favero C, Minoli G. Computed tomographic colonography and conventional colonoscopy for colon diseases: A prospective, blinded study. Am J Gastroenterol 2001; 96: 394-400. See Evidence Table.

The use of Virtual Colonoscopy for colon cancer screening failed Kaiser Permanente *Medical Technology Assessment Criteria*

10/09/2002: MTAC REVIEW
Virtual Colonoscopy
Evidence Conclusion: Previously, virtual colonoscopy did not meet GHC Medical Technology Assessment Committee as a screening tool for colorectal polyps and carcinomas. The purpose of the current re-review is to evaluate the use of the technology among high-risk patients, the frail, and the elderly. The available literature does not provide evidence for the use of virtual colonoscopy for the elderly and frail patients. The study (Laghi 2002) currently reviewed, as well as the Fenlon study reviewed for MTAC in June 2001, show that the sensitivity of virtual colonoscopy was good for colorectal carcinomas and large colorectal polyps in the selected symptomatic or high-risk patients. The two studies were appropriate for comparison of diagnostic tests and measured the performance of CT colonography relative to conventional colonoscopy. Virtual colonography was able to detect 100% of the colorectal carcinomas identified by conventional colonoscopy in the two studies. In Laghi's study the sensitivity was 92% for the detection of polyps 10 mm diameter or larger, 82% for those 6-9 mm, but as low as 50% for those less than 5 mm diameter, with an overall sensitivity of 78%. The corresponding values in Fenlon's study were almost similar with a slightly less overall sensitivity most probably because of the higher rate of the smaller polyps in the population studied. The sensitivity in Fenlon's study was (91%, 82%, 50% and 71% respectively). In bothstudies the sensitivity of virtual colonoscopy dropped considerably for polyps with a diameter of 5 mm or less. There is no clear consensus as to the importance of identifying and removing such tiny polyps. The per-patient specificity was 97% in Laghi's study and 84% in Fenlon's study. These high-risk patients with detected lesions may still need to undergo conventional colonoscopy for biopsy or removal of lesions. Neither study examined the impact of CTC on colorectal cancer morbidity, mortality or patient management. The inter-observer variability was not examined or discussed.
Articles: The literature search yielded 84 articles. The majority were opinion pieces, reviews, or dealing with technical aspects of virtual colonoscopy. There were 5 empirical studies, one had a very small sample size and poor methodology, and two were conducted in the same center by the same researchers but one included more patients. The study with the larger size was selected for critical appraisal. The remaining two were retrospective studies conducted on frail or elderly patients, one used non-helical CT scan, and the other was conducted to evaluate the accuracy of CT scans in detecting caecal carcinomas using oral contrast media and minimal preparation. *The study critically appraised is:* Laghi A, Iannaccone R, Carbone I, et al. Detection of colorectal lesions with virtual computed colonography. *Am J Surg* 2002; 183:124-131. See Evidence Table.

The use of virtual colonoscopy in colorectal screening for the frail elderly does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/11/2004: MTAC REVIEW
Virtual Colonoscopy
Evidence Conclusion: The two best new studies were evaluated. Pickhardt found a higher sensitivity and specificity of virtual colonoscopy than Johnson. Both included asymptomatic populations, but individuals in the Johnson study were at higher than average risk of colorectal neoplasia (i.e. personal or strong family history of colorectal neoplasia). The difference in the study population does not explain the lower sensitivity in Johnson because any bias introduced by having a higher risk sample would tend to increase, not decrease the sensitivity. The populations in the Pickhardt and Johnson studies may actually have been quite similar. The prevalence of adenomatous polyps ≥1 cm was 4% in Pickhardt and 5% in Johnson. The better performance of virtual colonoscopy in the Pickhardt study may be due in part to the routine use of 3-D CT images by Pickhardt. Johnson generally used 2-D images, and 3-D images were used for regions with suspected abnormalities. In addition, Johnson used conventional colonoscopy as the reference standard whereas Pickhardt used a reference standard developed for the study—conventional colonoscopy enhanced by information from the virtual colonoscopy. Neither of the new studies included polyps < 5mm which many experts believe are not clinically significant. Previous studies of virtual colonoscopy evaluated by MTAC have found low sensitivity for these smaller polyps. In summary, the Pickhardt study is the first to suggest that virtual colonoscopy has comparable sensitivity and specificity to conventional colonoscopy in asymptomatic individuals. The Johnson study suggests that the sensitivity of virtual

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colonoscopy is relatively low and that interobserver variability is high. Replication of the findings obtained in the Pickhardt study would strengthen the evidence.

Articles: The search yielded 103 articles, many of which were reviews, opinion pieces or dealt with technical aspects of the procedure. There were five prospective blinded studies comparing the diagnostic accuracy of virtual colonoscopy to conventional colonoscopy in asymptomatic populations. The two largest studies, each of which had samples larger than 700 individuals, were critically appraised. The others had sample sizes of 205, 158 and 80. The following articles were reviewed: Johnson CD, Harmsen WS, Wilson LA. Prospective blinded evaluation of computed tomographic colonography for screen detection of colorectal polyps. *Gastroenterol* 2003; 125: 311-319. See Evidence Table. Pickhardt PJ, Choi JR, Hwang I. et al. Computed tomographic virtual colonoscopy to screen for colorectal neoplasia in asymptomatic adults. *N Engl J Med* 2003; 349: 2191-2000. See Evidence Table.

The use of virtual colonoscopy in colorectal screening does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/18/2009: MTAC REVIEW
Virtual Colonoscopy

Evidence Conclusion: Diagnostic accuracy in the Regge et al., 2009 study is not dramatically different than previous studies, particularly when considering that it was conducted in a population at increased risk of CRC. There is still no high-grade evidence on the impact of screening with CT colonography on CRC mortality. Although it is not invasive like colonoscopy, CT colonography requires the same colonic preparation and involves exposure to radiation, and patients who test positive still require a colonoscopy for polyp removal.

Articles: Regge D, Laudi C, Galatola G et al. Diagnostic accuracy of computed tomographic colonography for the detection of advanced neoplasia in individuals at increased risk of colorectal cancer. JAMA 2009; 301: 2453-2461. See Evidence Table 6 and Evidence Table 7.

Update of evidence but the evidence does not change the previous review.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
74261	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material
74262	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed
74263	Computed tomographic (CT) colonography, screening, including image postprocessing

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
06/13/2001	05/04/2010[MDCRPC],03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 02/04/2014[MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC],03/07/2023[MPC]	12/05/2022

[MPC] Medical Policy Committee

Revision History	Description
07/25/2016	Changed NCD to (210.0)
06/06/2017	Adopted KPWA policy for Medicare members

09/25/2017	Added Decision Memo language
08/31/2021	Added NCD 210.3. Effective January 1, 2022, virtual colonoscopy or CT colonography for colorectal cancer screening after a positive fecal immunochemical (FIT) or fecal occult blood test (FOBT) may be considered medically necessary for Medicare members when the patient meets the non-Medicare clinical review criteria.
12/05/2022	Clarified USPSTF language with Director of Clinical Knowledge & Implementation.

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Clinical Review Criteria
Vitrectomy Chair or Support Face Down Positioning Device

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Durable Medical Equipment Reference List (280.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Joint DME MAC Publication	Correct Coding – Face Down Positioning Devices

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Background

The macula is the small area of the retina that provides the sharp central vision that is needed for reading, driving, and seeing fine details. A macular hole is a small break in the macula, which can cause blurred and distorted central vision. Macular holes are related to aging; fifty percent of macular holes occur in patients 65-74 years old. Only three percent were found to occur in patient under the age of fifty-five. The majority of holes are idiopathic; however, they can occur from eye disorders, such as high myopia (nearsightedness), macular pucker, and retinal detachment; eye diseases, such as retinopathy and Best's disease; and trauma to the eye (Solebo 2010; American Academy of Ophthalmology 2008).

The pathogenesis of idiopathic macular holes is not fully understood; however, recent histopathological and high resolution imaging studies have increased current understanding of the natural history of this condition. One theory of macular hole formation suggests that as we age, the vitreous, a gel-like substance that fills about 80 percent of the eye, shrinks and pulls away from the retinal surface creating tractional forces on the retinal and leading to macular holes (Solebo 2010). If left untreated, approximately three percent to eleven percent of macular holes close spontaneously (American Academy of Ophthalmology 2008). The treatment for macular hole is vitrectomy, which involves the surgical removal of the vitreous gel from the middle of the eye and is thought to relieve vitreofoveal traction and reactivate reparative healing mechanisms (Gupta 2009). Some surgeons instruct their patients to postoperatively maintain a face-down position from one day to three weeks to tamponade the macular hole. However, a recent study demonstrated that approximately 77% percent of macular holes close as soon as twenty-four hours after surgery (Solebo 2010). Research is lacking regarding the appropriate duration of postoperative face-down posturing and as to whether face-down positioning is needed at all.

Medical Technology Assessment Committee (MTAC)

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Vitrectomy Chair
04/19/2010: MTAC REVIEW
Evidence Conclusion: There is limited evidence regarding the effect of duration of face-down posturing on macular hole closure. The best available evidence was provided by the Tatham and Banerjee (2009) meta- analysis of five studies. This meta-analysis attempted to determine whether decreasing or eliminating face-down position time would affects surgical outcomes. Posturing for 5 to 10 days was compared to posturing for 24 hours or less. The results from the analysis suggest that there is a 34% increased risk of anatomical failure (macular hole non-closure) when face-down posturing is reduced from 5 to 10 days to less than 24 hours. However, this difference was not statistically significant. Within the studies that comprise the meta-analysis there is diversity of study design, surgical technique used, follow-up periods, and patient characteristics. This diversity reduced the validity of the meta-analysis. Additionally, non-randomized studies were included in the analysis making it more prone to bias. Conclusion: There is insufficient evidence to determine whether the duration of face-down posturing after macular hole surgery affects macular hole closure rates. There is insufficient evidence to determine whether a vitrectomy chair will improve outcomes after surgery.
Articles: The literature search yielded over 100 articles. The majority of the articles were unrelated to the current review. There was only one meta-analysis regarding face-down posturing. This article was selected for critical appraisal. The search did not reveal any evidence pertaining to the use of a vitrectomy chair after surgery.
Tatham A., Banerjee S. Face-down posturing after macular hole surgery: A meta-analysis. British Journal of Ophthalmology 2009. Advance online publication. doi:0.1136/bjo.2009.163741 See Evidence Table.

The use of a Vitrectomy Chair for the treatment of post-operative recovery from macular surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
05/10/2010	05/04/2010[MDCRPC], 04/05/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MDCRPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	11/03/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
11/03/2020	Added Correct Coding reference from Noridian

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Clinical Review Criteria
Vagus Nerve Stimulation

- Adjunctive Treatment for Partial Onset Epileptic Seizures
- Medical Diagnoses
- Treatment Resistant Depression
- gammaCore Sapphire non-invasive vagus nerve stimulator

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Vagus Nerve Stimulation (VNS) (160.18)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

I. Implantable Vagus Nerve Stimulator
   A. Adjunctive Treatment for Epilepsy
      - No medical necessity review is required for this service
   B. Mental Health Diagnoses
      - MCG* B-821-T, Vagus Nerve Stimulation, Implantable: Behavioral Health Care. This service is not covered per MCG Guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
   C. All other non-Mental Health Diagnoses

II. MCG* A-0424, Vagus Nerve Stimulation - Implantable. This service is not covered for any diagnoses besides epilepsy per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

III. Non-Invasive Vagus Nerve Stimulator
   A. gammaCore Sapphire
      - MCG* A-0998, Vagus Nerve Stimulation- Transcutaneous. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

MCG* manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

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The Cyberonics Vagus Nerve Stimulator (VNS) Therapy System is a device similar in design and function to a cardiac pacemaker. It consists of a constant current pulse generator implanted in the anterior chest wall and a bipolar stimulating electrode that is wrapped around the left vagal nerve in the neck. A magnet controlled by the patient can turn off the device.

In 1985, there were initial animal studies to test VNS, and devices were implanted in humans beginning in 1988. The first clinical application was to treat epilepsy. Research on epilepsy treatment suggested that VNS might reduce dysphoria in some patients. Moreover, VNS has been found to increase levels of a metabolite of serotonin in epilepsy patients, an effect similar to that seen after successful treatment of depression. These findings led to an interest in using VNS for patients with treatment-resistant depression (Goodnick et al., 2001).

In July 1997, the FDA granted pre-market approval for the Cyberonics VNS device to be used as an adjunctive treatment for medically refractory partial onset seizures in patients over 12 years of age. In July 2005, the FDA approved the device for patients 18 and older with treatment-resistant depression who failed to respond to at least 4 courses of adequate medication or electroconvulsive therapy (ECT).

Evidence and Source Documents

Adjunctive Treatment for Partial Onset Epileptic Seizures Vagus
Nerve Stimulation for Treatment-Resistant Depression

Medical Technology Assessment Committee (MTAC)

Vagal Nerve Stimulation (VNS) as an Adjunctive Treatment for Partial Onset Epileptic Seizures

BACKGROUND

Repetitive stimulation of the vagal nerve has been shown to reduce the frequency of seizures in various animal models of epilepsy. Epilepsy is typically treated with anti-epileptic medications and in some cases surgical resection of the epileptic focus. Despite the efficacy of these treatments, 25-50% of patients with epilepsy continue to experience seizures and/or suffer harms from continued use of anti-epileptic medications. The NeuroCybernetics Prosthesis (NCP) Vagal Nerve Stimulator (VNS) is a device (similar in design and function to a cardiac pacemaker) which consists of a constant current pulse generator implanted subcutaneously in the anterior chest wall and a bipolar stimulating electrode which is wrapped around the left vagal nerve in the neck. A magnet controlled by the patient can initiate stimulation (when the patient senses the onset of a seizure) or can turn off the device depending on how it is placed against the device. The mechanism by which the VNS reduces epileptic seizures is still unknown, however it has been shown that stimulation of the vagal nerve has the ability to affect brain wave activity.

02/10/1999: MTAC REVIEW

Vagal Nerve Stimulation (VNS) as an Adjunctive Treatment for Partial Onset Epileptic Seizures

Evidence Conclusion: Recently published evidence from a large, well designed, multicenter trial of 254 patients randomized to high or low Vagal nerve stimulation demonstrates that the use of VNS in the treatment of medically refractory patients reduces seizure frequency by approximately 28% compared to baseline and 13% compared to an active control group receiving low stimulation. This translates into an average reduction of 3 seizures per week. Adverse events such as voice alteration, cough and pharyngitis during stimulation are reported to occur in 25-60 percent of subjects but are generally well tolerated. Patients receiving high VNS also reported significant improvement in their perception of well-being. A randomized controlled trial of 114 patients reports a similar beneficial effect of VNS. Data from an open extension trial of the first 67 patients exiting the RCT demonstrates that all patients chose to either continue high stimulation or switch from low to high stimulation for up to 15 months. Four out of five patients in this group demonstrated continuing clinically significant reductions in seizure frequency over 15 months with 5 drop-outs (8%) due to lack of efficacy and no drop-outs due to side effects from stimulation. **Articles**: Handforth, A et al. Vagus Nerve Stimulation Therapy for Partial Onset Seizures: A Randomized Active- Control Trial. Ne*urology*1998; 5:48-55 See Evidence Table**.** The Vagus Nerve Stimulation Group, A Randomized Controlled Trial of Chronic Vagus Nerve Stimulation for Treatment of Medically Intractable Seizures. *Neurology, 1995; 45:224-230.* See Evidence Table**.** Vagus Nerve Stimulation for Treatment of Partial Seizures: 3. Long-Term Follow-Up on First 67 patients exiting a Controlled Study. *Epilepsia, 1994;35:637-643.* See Evidence Table.

The use of the NeuroCybernetics Prosthesis (NCP) Vagal Nerve Stimulator (VNS) for treating patients with medically refractory partial onset seizures has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria*.

Vagus Nerve Stimulation for Treatment-Resistant Depression

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BACKGROUND

The Cyberonics Vagus Nerve Stimulator (VNS) Therapy System is a device similar in design and function to a cardiac pacemaker. It consists of a constant current pulse generator implanted in the anterior chest wall and a bipolar stimulating electrode that is wrapped around the left vagal nerve in the neck. A magnet controlled by the patient can turn off the device.

In 1985, there were initial animal studies to test VNS, and devices were implanted in humans beginning in 1988. The first clinical application was to treat epilepsy. Research on epilepsy treatment suggested that VNS might reduce dysphoria in some patients. Moreover, VNS has been found to increase levels of a metabolite of serotonin in epilepsy patients, an effect similar to that seen after successful treatment of depression. These findings led to an interest in using VNS for patients with treatment-resistant depression (Goodnick et al., 2001).

In July 1997, the FDA granted pre-market approval for the Cyberonics VNS device to be used as an adjunctive treatment for medically refractory partial onset seizures in patients over 12 years of age. In July 2005, the FDA approved the device for patients 18 and older with treatment-resistant depression who failed to respond to at least 4 courses of adequate medication or electroconvulsive therapy (ECT). VNS passed MTAC evaluation criteria in 1999 for epilepsy. In 2005, it was reviewed for treatment-resistant depression and failed MTAC evaluation criteria. At that time, all of the major studies were conducted by the same group of researchers (A. John Rush and colleagues) with links to the device manufacturer. There was one published RCT (Rush et al., 2005), with negative findings. A post-hoc sub-group analysis of the Rush RCT with a historical control group (George et al., 2005), a design subject to bias, found a benefit of the treatment for a selected group of patients. FDA approval of the VNS device for depression remains controversial. Citing a lack of efficacy data and concerns about safety, an FDA review team decided not to approve the new indication for the Cyberonics device. Instead, the team recommended additional data from RCTs. The Director of the FDA's Center for Devices and Radiological Health (CDRH) overruled the team and granted pre-market approval. The Director agreed with Cyberonics researchers that it would be unethical to conduct a blinded treatment study with patients with major depression.

The FDA approval in 2005 included a request to Cyberonics for additional post-marketing controlled studies (Shuchman, 2007).

12/05/2005: MTAC REVIEW

Vagus Nerve Stimulation for Treatment-Resistant Depression

Evidence Conclusion: There is insufficient evidence that VNS is effective therapy for treatment-resistant depression. All of the major studies were conducted by the same group of researchers. This research team has close financial links with the device manufacturer which could bias study methodology, analysis and/or results reporting. The single published RCT (Rush et al., 2005) had negative findings. There was not a statistically significant between-group difference in the primary outcome, 3-month HAM-D response, between groups receiving active and placebo VNS therapy. A subsequent non-randomized study (George et al., 2005) followed-up a portion of the RCT study patients, and compared findings to a group of depressed patients who were participating in a different study. The George study found a significant difference in the primary outcome, change in the Inventory of Depressive Symptomatology (IDS) score, favoring the VNS therapy group. The study is subject to selection bias due to the use of different patient populations, and the exclusion of patients who responded to sham treatment in the RCT. It is also subject to observation biases because patients did not receive a consistent intervention e.g. those in the VNS group had different lengths of treatment, and possible bias in the selection of the primary outcome (IDS score was the only significant efficacy outcome in the RCT). A limitation of all of the published studies was that the eligibility for participation did not match the FDA definition of treatment-resistant depression. The studies required patients to have failed a minimum of 2 courses of medication whereas the FDA approved VNS therapy for depressed patients who have failed at least 4 treatments.

Articles: The published empirical studies on VNS therapy for depression were conducted by a single research group with close links to the manufacturer, A. John Rush and colleagues. As described in the recent BlueCross BlueShield review (2005), these studies were: D01: Case series with n=50 patients, D02: 3-month randomized controlled trial with n=233, D02 extension arm. 12 month follow-up of selected patients who participated in study D02, D04: Case series of patients not receiving VNS. This study was used to form a comparison group to the 12- month extension of study D02. *Articles critically appraised were:* Publication reporting the results of the RCT, D02: Rush AJ, Marangell LB, Sackeim HA et al. Vagus nerve stimulation for treatment-resistant depression: A Publication comparing 12-month outcomes in the D02 extension and the D04 comparison group: George MS, Rush AJ, Marangell LB et al. A one-year comparison of vagus nerve stimulation with treatment as usual for treatment-resistant depression. Biol Psychiatry 2005; 58: 364-373. See Evidence Table

The use of Vagus nerve Stimulation in the treatment of treatment-resistant depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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06/01/2009: MTAC REVIEW
Vagus Nerve Stimulation for Treatment-Resistant Depression
Evidence Conclusion: Conclusions of the 2005 MTAC review were as follows: There is insufficient evidence that VNS is an effective therapy for treatment-resistant depression. All of the major studies were conducted by the same group of researchers that had close financial links with the device manufacturer. The single published RCT (Rush et al., 2005) had negative findings. There was not a statistically significant between-group difference in the primary outcome, 3-month HAM-D response, between groups receiving active and placebo VNS therapy. A subsequent non-randomized study (George et al., 2005) followed-up a portion of the RCT study patients and compared findings to a group of depressed patients who were participating in a different study. The George study, which was subject to selection and observation biases, found a significant difference in the primary outcome, change in the Inventory of Depressive Symptomatology (IDS) score, favoring the VNS therapy group. As of May 2009, there is still insufficient evidence to determine whether VNS is effective for depressed patients who have failed antidepressant treatment. There were no additional RCTs or non-randomized comparative studies. A new case series (Schlaepfer) with 74 patients recruited from 9 sites in Europe found a 34% response rate at 3 months (end of active treatment period), which increased to 47% at the 12 month follow-up. The Schlaepfer case series represents a low grade of evidence. There was no comparison group, so response with a different treatment or no treatment is not known. Also, patients were not blinded, and they had regular clinic visits, both of which could affect responses to a subjective outcome measure like the HAMD.
Articles: The Pubmed search yielded 13 articles. Only 9 of these were actually on depression (the rest addressed epilepsy, Alzheimer's disease or rapid-cycling bipolar disorder). Of the 9 articles on depression, 3 were reviews or opinion pieces, 3 were basic research on brain changes during VNS and 3 were empirical studies. Two of the 3 empirical studies were subanalyses of the Rush et al. (2005) RCT. On closer inspection, neither of these analyses was eligible for MTAC review. The Nierenberg et al. (2008) study did not compare outcomes associated with active vs. sham VNS; instead the investigators compared the effects of VNS on bipolar vs. unipolar depressed participants within the Rush RCT. The other sub-analysis, Burke et al. (2006) evaluated the effect of concomitant VNS and electroconvulsive therapy (ECT) in the 14 participants in the Rush RCT who received both treatments. This was a descriptive analysis of a small number of individuals and does not aid our understanding of the effectiveness of VNS. The third new empirical study was a case series (n=74) conducted in Europe. This study was critically appraised. A Blue Cross Blue Shield technology assessment report, used for the first MTAC review, has not been updated since August 2006. No additional published articles were identified on the Cyberonics website. The citation for the new European study is as follows:
Schlaepfer TE, Frick C, Zobel A et al. Vagus nerve stimulation for depression: efficacy and safety in a European study. Psychol Med 2008; 38: 651-661. See Evidence Table.

The use of Vagus Nerve Stimulation in the treatment of treatment-resistant depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/12/2020: MTAC REVIEW
gammaCore Sapphire non-invasive vagus nerve stimulator
Evidence Conclusion:
- Cluster headache
  - Although results are promising, there is insufficient evidence to determine the efficacy of nVNS for the acute treatment of patients with cluster headache.
  - Results are promising from one RCT. More studies are needed. There is insufficient evidence to determine the efficacy of nVNS as prophylactic treatment for the prevention of episodic or chronic cluster headache.
- Migraine
  - Acute treatment of migraine: A randomized controlled trial with moderate quality shows that nVNS was effective for aborting migraine attacks at 30 and 60 minutes after treatment and for relieving pain 2 hours after treatment. More studies are warranted to confirm these findings.
  - Prevention of migraine: there is insufficient evidence to determine the efficacy of nVNS in preventing migraine with or without aura.

Articles: PubMed was searched through August 2020 with the search terms (gammaCore Sapphire OR non-invasive vagus nerve stimulator) AND (cluster headache OR episodic cluster headache OR chronic cluster headache OR migraine) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Only RCTs were included in the search. Studies with no comparison group were not reviewed. Key trials were selected and reviewed.

Applicable Codes

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Vagus Nerve Stimulation, Implantable- Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or rec
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

Vagus Nerve Stimulation, Transcutaneous (gammaCore Sapphire non-invasive vagus nerve stimulator): Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
E1399	Durable medical equipment, miscellaneous

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
10/08/1999	07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC], 11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	11/02/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
11/03/2020	Added MTAC review for gammaCore Sapphire non-invasive vagus nerve stimulator
11/02/2021	MPC approved to adopt MCG* B-821-T criteria for medical necessity determinations for VNS for Mental Health Diagnoses. Requires 60-day notice, effective 04/01/2022.

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KAISER PERMANENTE®

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Clinical Review Criteria

Left Atrial Appendage (LAA) Closure Therapy

- Watchman, Amplatzer Amulet (percutaneous)
- AtriClip (non-percutaneous, used during surgical procedures)

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Criteria

**Please send all cases to Medical Director for review.*

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Percutaneous Left Atrial Appendage Closure (LAAC) (20.34)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N)
KPWA Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for non-percutaneous left atrial appendage closure devices, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Left Atrial Appendage (LAA) Closure Therapy***, for medical necessity determinations. Refer to the Non-Medicare criteria **II.B.** below regarding **non-percutaneous** closure.

For Non-Medicare Members

I. Percutaneous LAA appendage closure using a device approved by the FDA (e.g., the Watchman or Amplatzer Amulet) is approved for patients with atrial fibrillation who meet **ALL of the following criteria**:
   - A CHA2DS2-VASc score ≥ 3
   - Patient is suitable for short-term warfarin but deemed unable to take long term oral anticoagulation (neither Warfarin nor DOACs) following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants.
   - The patient is formally evaluated by a multidisciplinary Heart Team of medical professionals who document a collaborative recommendation for LAA occlusion.
   - The procedure must be furnished in a hospital with established cardiac surgery, structural heart disease, and electrophysiology (EP) programs.
   - A formal shared decision-making interaction with an independent non-interventional cardiologist (not part of procedural treatment team) using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision-making interaction must be documented in the medical record.
   - The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s) or cardiovascular surgeon(s) that meets accepted CMS criteria for training/implantation (see Medicare NCD)
   - The patient is enrolled in, and the MDT and hospital must participate in a prospective, national, audited registry.

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II. The use of any other left atrial appendage devices are considered investigational, including but not limited to any of the following:

- Devices not approved by the FDA for percutaneous LAA closure (e.g., LARIAT or PLAATO devices).
- Devices used during surgical procedures (**non-percutaneous**) to occlude the LAA (e.g., AtriClip is not medically necessary).

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting more than 5.5 million individuals in the US, and its prevalence is increasing with the aging population. AF leads to loss of organized atrial contractions, which results in blood stasis in the atrium and thrombus formation with the potential for embolization leading to stroke. It is reported that the risk of ischemic stroke is up to 5 times higher in patients with AF. This risk of cardioembolic stroke varies from one individual to the other based on other risk factors and comorbidities, but overall it increases considerably with age from 1.5% in patients 50-59 years of age to 23.5% for those 80-89 years of age. Stroke prophylaxis is thus an important component in managing patients with non-valvular AF (Holmes 2009, Reddy 2013, Bode 2015).

Antiarrhythmic drugs, and catheter ablation of AF may provide relief of symptoms, but do not sufficiently prevent the occurrence of thromboembolic events. Long-term oral anticoagulant therapy is the standard of care for effective stroke prevention in AF patients at high risk for thromboembolism according to clinical risk scores such as the CHADS2 and the CHA2DS2-VASc models. Warfarin is highly effective in reducing stroke in at-risk patients with AF, but is often not well tolerated by all patients, has a very narrow therapeutic range, and is associated with a high risk of bleeding. In addition, its effectiveness may vary due to its interactions with some foods and medications resulting in the need for frequent monitoring and dose adjustments. It is reported that 50% of the patients' blood test results are outside the therapeutic range. These limitations as well as intolerance or contraindications to warfarin in some patients have led to the non-use or discontinuation of the drug in a large proportion of AF patients, particularly the older patients who are at an increased risk of stroke. The more recently developed oral anticoagulant agents (NOACs) have overcome many of warfarin's limitations, but also need lifelong use and carry the potential risk of bleeding at similar or lower rates than warfarin, depending on the agent used (Sick 2007, Holmes 2009, Alli 2013, Reddy 2013, Price 2014).

Researchers have been investigating non-pharmacological alternatives for patients with intolerance or contraindication to anticoagulant therapy. It is believed (based on echocardiography and autopsy studies) that more than 90% of the atrial thrombi in patients with non-valvular AF, originate in the left atrial appendage (LAA), which is an embryonic remnant of the original embryonic left atrium. LAA is a long tubular trabeculated structure continuous with the atrial cavity. The location and the discrete nature of the LAA have led to the development of a number of techniques for excluding it from the systemic circulation. These include its surgical excision or obliteration by surgical ligation, or by the use of implantable devices via mini thoracotomy or percutaneously.
These devices include the St Jude Amplatzer® cardiac plug, Coherex WaveCrest® LAA occlusion system, LARIAT® device, the PLAATO system, and the WATCHMANTM LAA system. The latter is the focus of the current review (McCabe 2009, Holmes 2009, Alli 2014).

The WATCHMANTM (WM) left atrial appendage closure (LAAC) system (Boston Scientific Corp., Maple Grove, Minnesota) is the most intensely studied for LAA occlusion. It is a 3-part system consisting of a trans-septal access sheath, a delivery catheter, and an implantable nitinol (nickel titanium) device. The system is designed to facilitate the device placement through femoral venous access via transseptal route into the LAA. The implantable device is parachute-shaped and comprises a self-expanding nitinol frame structure with fixation barbs to secure it in the LAA, and a permeable polyester membrane that covers the atrial facing surface of the device. The WM

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implant is available in 5 sizes (21, 24, 27, 30, and 33 mm) and is typically chosen 10-20% larger than the LAA body to have sufficient compression for stable positioning to minimize the risk of device embolization. The procedure is performed in the cardiac catheterization laboratory under general anesthesia. Transseptal access is obtained using standard techniques guided by fluoroscopic or transesophageal echocardiography (TEE). Once access is gained into the left atrium (LA), a variety of approached can be used to place the guidance sheath. A pigtail angiographic catheter is then inserted into the sheath which is advanced into the distal portion of the LAA. Once this catheter is placed, the sheath is advanced over it into the LAA. Positioning of the sheath is of critical importance as the LAA is thin-walled and fragile and may be damaged or perforated. Anticoagulation is necessary and it is also important to avoid the potential for air embolism during the procedure. WM is permeable to blood and thus the patients require post-procedure warfarin therapy for 45 days with INR between 2.0 and 3.0 for those who are legible for warfarin or other equivalent. A TEE is performed for device assessment at 45 days after which a decision is made to discontinue warfarin. After warfarin is discontinued, the patient is treated with clopidogrel 75 mg and aspirin 81-325 mg for 6 months following the implantation, after which the clopidogrel is discontinued and aspirin is used indefinitely (Sick 2007, Alli 2014, Holmes 2015).

As with other invasive procedures, the techniques and devices used for LAA closure including WATCHMANTM have potential complications including pericardial effusion, procedure-related stroke, device thrombosis, device embolization, bleeding, arrhythmia, access site complications, arteriovenous fistula, and pseudoaneurysm formation (Alli 2014). More recently on April 23, 2015, the FDA recalled the TigerPaw II (Maquet, Rastatt, Germany) LAA closure device following reports that the device could cause tearing of the left atrial wall and bleeding.

The WATCHMANTM device received FDA approval in 2015 as an alternative to commonly-used blood thinners to prevent stroke in patients with atrial fibrillation who are at an increased risk of stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc and are recommended for anticoagulation therapy; are deemed by their physicians to be suitable for warfarin; and have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin. The FDA had initially declined the approval of the device twice before the final approval due of concerns about its safety and effectiveness, including the complications while implanting the device.

Medical Technology Assessment Committee (MTAC)

Watchman

08/17/2015: MTAC REVIEW

Evidence Conclusion: The published evidence does not support the use of Watchman LAA occlusion device for the prevention of stroke in in patients with nonvalvular atrial fibrillation. Ideally a new therapy or intervention would be at least equivalent or noninferior (if not superior), to the gold standard treatment with regard to safety, efficacy, and long term outcomes. To date, LAAC closure with Watchman system in patients with nonvalvular atrial fibrillation has not fulfilled the safety requirement in the two pivotal trials, nor the efficacy requirement in the PREVAIL trial. The PROTECT AF trial showed that occluding the LAA with the Watchman device is feasible and with noninferior efficacy than warfarin in reducing the composite risk of stroke, cardiac death, or systemic embolism as primary prevention therapy in patients with CHADS2 >1. In the PREVAIL trial that included higher risk patients, the device did not reach the noninferiority level for the primary efficacy composite endpoint of ischemic or hemorrhagic stroke, cardiovascular or unexplained death, or systemic embolism. More recent long-term follow-up data from PROTECT AF show that the device remained noninferior to warfarin use as regards its efficacy but not its safety. More recent long-term follow-up data from PREVAIL trial show that the 2 first primary endpoints of the trial do not meet the prespecified noninferiority end point of the study. There is evidence from the published RCTs that the occlusion of the LAA with the Watchman device is associated with high risk of procedure-related ischemic stroke and device embolism, as well as other adverse events including serious pericardial effusion and major bleeding. There is insufficient evidence from well-designed RCTs to determine the efficacy and safety of Watchman in patients with a contraindication or intolerance to warfarin or other blood thinners.

There is insufficient published evidence from well-designed RCTs to determine the efficacy and safety of Watchman device to other LAA occluding devices or surgical interventions in patients with nonvalvular atrial fibrillation. There is no published study to date, that compared the efficacy and safely LAA occlusion to any of the NOACs, that demonstrated (from large RCTs) to be either noninferior or superior to warfarin in reducing stroke or systemic embolism with similar or lower rates of major hemorrhage. There are currently 11 ongoing trials on LAA occlusion/excision that may add more information on the safest and most effective intervention for the prevention of stroke in patients with non-valvular atrial fibrillation. WATCHMAN LAA closure device was reviewed by the Kaiser Interregional New Technologies Committee (INTC) in June 1st, 2015. The Committee used the Blue Cross Blue Shield TEC Assessment Program as their primary evidence source and updated the review with new

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evidence that would change the TEC results or conclusions. Both TEC and INTC concluded that the evidence was insufficient to determine that WATCHMAN LAAC is medically appropriate for stroke prevention for patients with nonvalvular atrial fibrillation.

Articles: The literature search identified two randomized controlled trials (PROTECT AF and PREVAIL), a nonrandomized prospective study, and a pilot observational study on Watchman LAA occlusion system. All studies were conducted mainly by the same group of principal investigators. The literature search also identified a more recent meta-analysis of the two RCTs also conducted by the same investigators, and another meta-analysis of observational studies (with no control groups) that examined different devices used in the percutaneous occlusion of the left atrial appendage. The two RCTs on Watchman LAA closure device and the meta-analysis pooling their results were selected for critical appraisal. Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial. Lancet. 2009; 374 (9689):534-542. See Evidence Table 1. Holmes DR Jr, Kar S, Price M, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. J Am Coll Cardiol. 2014 Jul 8; 64 (1):1-12. See Evidence Table 2. Holmes DR Jr, Doshi SK, Kar S, et Al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient-Level Meta-Analysis. J Am Coll Cardiol. 2015 Jun 23; 65(24):2614-23. See Evidence Table 3. Bode WD, Patel N, Gehi AK. Left atrial appendage occlusion for prevention of stroke in nonvalvular atrial fibrillation: a meta-analysis. J Interv Card Electrophysiol. 2015 June; 43:79-89.

The use of the Watchman does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

Considered not medically necessary:

CPT® or HCPC Codes	Description
33267	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)
33269	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Creation Date	Review Dates	Date Last Revised
08/17/2015	09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	02/01/2022

[MPC] Medical Policy Committee

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Revision History	Description
02/07/2017	MPC approved to adopt criteria for commercial members
03/14/2017	Added AtriClip
04/02/2019	MPC approved to update criteria to include Warfarin and DOACs
01/18/2022	Updated applicable coding with new codes effective 1/1/22 (33267, 33268, 33269) for non-percutaneous left atrial appendage exclusion/closure.
02/01/2022	MPC approved to update criteria to clarify that only FDA approved percutaneous devices such as the Watchman or Amplatzer Ampule are covered. Any other LAA devices are considered not medically necessary, and no device inserted during an open procedure are currently covered. Requires 60-day notice, effective date 07/01/2022.

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Clinical Review Criteria
Mobility Assistive Devices

- Associated Special Parts
- Manual Wheelchairs
- Power Wheelchairs
- Scooters

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Mobility Assistive Equipment (280.3)
Local Coverage Determinations (LCD)	Manual Wheelchair Bases L33788 Power Mobility Devices L33789 Wheelchair Seating L33312 Wheelchair Options/Accessories L33792
Local Coverage Articles	Manual Wheelchair Bases A52497 Power Mobility Devices A52498 Wheelchair Seating A52505 Wheelchair Options/Accessories A52504

For Non-Medicare Members

Wheelchair, 2-Gear (aka MAGICWHEELS® 2-Gear Wheelchair Drive)

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Documentation Requirements:

See 45 Day Visit Documentation Requirements

MANUAL WHEELCHAIRS (new or replacement)

Kaiser Permanente has elected to use the Manual Wheelchair (KP-0354) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Most recent note from requesting provider
- Most recent Physical Therapy mobility assessment (for a patient 18 and under, therapy evaluation cannot be solely done by a school-based therapist. Wheelchairs are only covered for use inside the home and the therapist must complete an onsite visit in the home to determine accessibility requirements.)
- If recent discharge from SNF/IPR, include therapy notes

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- Specialty evaluation as indicated in the criteria above
- Vendor assessment and itemized codes if applicable

POWER OPERATIVE VEHICLES (POV)/SCOOTERS (new or replacement)
Kaiser Permanente has elected to use the Scooter (KP-0352) (MCG)* for medical necessity determinations.
For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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If requesting this service, please send the following documentation to support medical necessity:

- Most recent comprehensive note from requesting provider in which the power mobility device is discussed. The note should provide pertinent information about the following elements but may include other details. Each element would not have to be addressed in every evaluation.
  - History of the present condition(s) and past medical history that is relevant to mobility needs
    - Symptoms that limit ambulation
    - Diagnoses that are responsible for these symptoms
    - Medications or other treatment for these symptoms
    - Progression of ambulation difficulty over time
    - Other diagnoses that may relate to ambulatory problems
    - How far the beneficiary can walk without stopping
    - Pace of ambulation
    - What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used
    - What has changed to now require use of a power mobility device
    - Ability to stand up from a seated position without assistance
    - Description of the home setting and the ability to perform activities of daily living in the home
  - Physical examination that is relevant to mobility needs
    - Weight and height
    - Cardiopulmonary examination
    - Musculoskeletal examination
      - Arm and leg strength and range of motion
    - Neurological examination
      - Gait
      - Balance and coordination

The evaluation should be tailored to the individual beneficiary's conditions. The history should paint a picture of the beneficiary's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the beneficiary's ambulatory difficulty or impact on the beneficiary's ambulatory ability.

- Most recent Physical Therapy mobility assessment if available
- If recent discharge from SNF/IPR, include therapy notes
- Vendor assessment and itemized codes if applicable

I. POWER WHEELCHAIR (new or replacement)

A. Mobility Assistive Device (MAE) is reasonable and necessary for patients who have a personal mobility deficit sufficient to impair their performance of Mobility-Related Activities of Daily Living (MRADL) such as toileting, feeding, dressing, grooming, and bathing in customary areas in the home and coverage is considered when the following has been applied:
   1. The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more MRADLs in the home. A mobility limitation is one that:
      - Prevents the patient from accomplishing the MRADLs entirely, or,
      - Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to participate in MRADLs, or,
      - Prevents the patient from completing the MRADLs within a reasonable time frame.

B. These other limitations can be ameliorated or compensated sufficiently such that the additional provision of MAE will be reasonably expected to significantly improve the patient's ability to perform or obtain

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assistance to participate in MRADLs in the home.

1. A caregiver**, for example a family member, may be compensatory, if consistently available in the patient's home and willing and able to safely operate and transfer the patient to and from the wheelchair and to transport the patient using the wheelchair. The caregiver's need to use a wheelchair to assist the patient in the MRADLs is to be considered in this determination.
2. The amelioration or compensation requires the patient's compliance with treatment, for example medications or therapy, substantive non-compliance, whether willing or involuntary. This can be justification for denial of wheelchair coverage if it results in the patient continuing to have a significant limitation. It may be determined that partial compliance results in adequate amelioration or compensation for the appropriate use of MAE.

C. The patient or caregiver demonstrates the capability and the willingness to consistently operate the MAE safely.
   1. Safety considerations include personal risk to the patient as well as risk to others. The determination of safety may need to occur several times during the process as the consideration focuses on a specific device.
   2. A history of unsafe behavior in other venues may be considered.

D. If a manual wheelchair or POV does not meet the mobility needs of the patient, and all of the following features provided by a power wheelchair are needed to allow the patient to participate in one or more MRADLs,
   1. The pertinent features of a power wheelchair compared to a POV are typically controlled by a joystick or alternative input device, lower seat height for slide transfers, and the ability to accommodate a variety of seating needs.
   2. The type of wheelchair and options provided should be appropriate for the degree of the patient's functional impairments.
   3. The patient's home should provide adequate access, maneuvering space and surfaces for the operation of a power wheelchair.
   4. Assess the patient's ability to safely use a power wheelchair.
   5. The patient has had a face-to-face evaluation by the prescribing physician within the past 45 days which assesses his/her mobility status, and the need for the power wheelchair.

E. Due to the complexity of determining whether a power wheelchair or power scooter is the best device for a patient, any requests for either of these devices must be submitted by a physiatrist who has examined the patient and done a thorough evaluation.

**Note: If the patient is unable to use a power wheelchair, and if there is a caregiver who is available, willing, and able to provide assistance, a manual wheelchair is appropriate. A caregiver's inability to operate a manual wheelchair can be considered in covering a power wheelchair so that the caregiver can assist the patient.

Home Assessment:
Coverage for the use of an electric wheelchair is determined solely for the needs within the home.
An on-site evaluation of the member's home is necessary to verify that the member can adequately maneuver the device that is provided considering the physical layout, doorway width, doorway thresholds, and surfaces. There must be a written report of this evaluation available upon request.

Associated Special Parts:
The options/accessories are necessary for the patient to perform one or more of the following activities:
1) Function in the home.
2) Perform instrumental activities of daily living.

An option/accessory that is beneficial primarily in allowing the patient to perform leisure or recreational activities is non-covered.

Anti-rollback device (E0974)	• The patient propels himself/herself and needs the device because of ramps.
Arm of Chair	• Adjustable arm height option (E0973, K0017, K0018, K0020) is covered if the patient requires an arm height that is different than that available using nonadjustable arms and the patient spends at least 2 hours per day in the wheelchair. • An arm trough (E2209) is covered if patient has quadriplegia, hemiplegia, or uncontrolled arm movements.
Fully reclining back (E1226)	• Quadriplegia

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Has one or more:	• Fixed hip angle • Trunk or lower extremity casts/braces that require the reclining back feature for positioning • Excess extensor tone of the trunk muscles and/or • The need to rest in a recumbent position two or more times during the day and transfer between wheelchair and bed is very difficult
Elevating Leg Rests (E0990, K0046, K0047, K0053, K0195)	• The patient has a musculoskeletal condition or the presence of a cast or brace which prevents 90-degree flexion at the knee or • The patient has significant edema of the lower extremities that requires having an elevated leg rest or • The patient meets criteria for and has a reclining back on the wheelchair
Mechanically linked leg elevation feature (E1009) Power leg elevation feature (E1010)	• Meet criteria for elevating leg rest • And is receiving a **covered** power seating system
Hook-on headrest extension	• Has weak neck muscles and needs headrest for support OR • Meets criteria for and has reclining back on wheelchair
Non-standard seat frame (E2201-E2204, E2340-E2343)	• A nonstandard seat width and/or depth is covered only if the patient's dimensions justify the need.
Electronic Interface (E2351)	• An electronic interface to allow a speech generating device to be operated by the power wheelchair control interface is covered if the patient has a **covered** speech generating device.
Swingaway, retractable, or removable hardware (E1028)	• Needed to move the component out of the way so the patient can perform a slide transfer AND • The sole reason is not to allow the patient to move close to desks or other surfaces
Tilt-in-space seat Power tilt seating system (E1002) Power reclining seat system (E1003-E1005) Power tilt and reclining seat system (E1006-E1008)	• Has documented weak upper extremity strength or a disease that will lead to weak upper extremities. AND • Is at risk for skin break down because of inability to reposition body in chair to relieve pressure areas.
Power Assist Device (E0986)	A push-rim activated power assist device for a manual wheelchair(E0986) may be considered medically necessary when the criteria for a wheelchair (noted above) are met and **ALL of the following** criteria are met: • The patient has been self-propelling in a manual wheelchair for at least one year but no longer has sufficient upper extremity function to self-propel a manual wheelchair in the home to perform MRADLs. **AND** • The patient has had a specialty evaluation performed by a physiatrist who has specific training and experience in rehabilitation wheelchair evaluations **AND** • The wheelchair is provided by a supplier that specializes in wheelchairs with a specialist who has direct, in-person involvement in the wheelchair selection for the patient **AND** • The evaluation documents the need for the device to perform mobility related activities *in the patient's home* *Note: In some circumstances, a group 2 power wheelchair would meet mobility needs.
The following are not covered because they are not primarily medical in nature	• Power seat elevation feature (E2300) • Power standing feature (E2301) • Attendant control (E2331) • Electrical connection devices (E2310 or E2311) with the sole function of connection for a power seat elevation or power stand feature. • Electrical interface used to control lights or other electrical devices
E1399, K0108	• Any part that is requested using either of these miscellaneous codes is subject to review for medical necessity.

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The following wheelchair options are not covered:	• "Ability to balance on two wheels" feature for a PWC • Any wheelchair, option, or accessory that is primarily for the purpose of allowing the individual to perform leisure or recreational activities • Articulating (telescoping) elevating leg rests: considered for patients with long legs • Back support systems: Back support systems have a plastic frame which is padded and covered with cloth or other material; they are designed to be attached to a wheelchair base, but do not completely replace the wheelchair back. These back-support systems are considered convenience items, because they are not generally necessary to provide trunk support in members in wheelchairs. An adequate seating system would allow the member to function appropriately in the wheelchair. • Battery charger: A battery charger for a power wheelchair is included in the allowance for a power wheelchair base. A dual mode battery charger for a power wheelchair is considered a convenience item and is not covered. • Canopies • Clothing guards to protect clothing from dirt, mud, or water thrown up by the wheels (similar to mud flaps for cars) • Commode seat, wheelchair (HCPCS code E0968) • Crutch or cane holder: May need to help safely transfer • Electronic balance feature for a PWC • Flat-free inserts (zero pressure tubes): Flat free inserts have a removable ring of firm material that is placed inside of a pneumatic tire. Flat free inserts are intended to allow the wheelchair to continue to move if the pneumatic tire is punctured. • Home modifications: Modifications to the structure of the home to accommodate wheelchairs are not considered treatment of disease and are not covered. Examples of home modifications and installations that are not covered include wheelchair ramps, wheelchair accessible showers, elevators, and lowered bath or kitchen counters and sinks. • Identification devices (such as labels, license plates, name plates) • Lighting systems • Powered seat elevator attachments for electric, powered, or motorized wheelchairs (HCPCS code E2300) • Power or manual standing options or standing wheelchairs (HCPCS code E2301, E2230) • Powered wheelchair seat cushions (HCPCS code E2610) • Remote operation feature for a PWC • Rental or purchase of more than one mobility assistive device at a time • Seat elevator wheelchairs (HCPCS code K0830, K0831) • Shock absorbers • Speed conversion kits • Stair-climbing wheelchairs, computerized or gyroscopic mobility systems (e.g., INDEPENDENCE™ IBOT™ Mobility System, Independence Technology, LLC, Warren, NJ) (K0011) • Transport chairs or rollabout chairs (HCPCS code E1031, E1037, E1038, E1039) • Warning devices, such as horns and backup signals • Wheelchair accessory, tray & half-lap tray (HCPCS code E0950) • Wheelchair lifts (e.g., Wheel-O-Vator, trunk loader) -- devices to assist in lifting wheelchair up stairways, into car trunks, or in vans (see CPB 0459 - Seat Lifts and Patient Lifts) • Wheelchair rack for automobile (auto carrier) -- car attachment to carry wheelchair • Wheelchair tie downs (transit options) • Miscellaneous items needed to adapt to the outside environment for convenience, work, leisure or recreational activities including, but not limited to:

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	- accessory holder: flag, cup, speech generating device - auto carriers - baskets, backpacks, bags, seat pouches used to transport personal belongings - firearm/weapon holder/support - gloves - lifts for car trunk, stairways, seat lifts and individual lifts - lowered seat elevator attachments for powered or motorized wheelchairs - ramps - snow tires for wheelchairs - support or mounting frames for cellular phone & tablets

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In 2000, almost 1.7 million people in the United States used wheelchairs due to a disability. Of these, 1.5 million people used a manual wheelchair (Kaye et al., 2000). Manual wheelchairs require extensive use of individuals' upper limbs for mobility, transfer and other daily functional activities. This repetitive weight-bearing use of the arms and shoulders may cause upper-extremity problems, and reports of shoulder pain are common. In a recent survey of individuals with thoracic spinal cord injuries, 40% of respondents reported current shoulder pain associated with wheelchair use (Alm et al. 2008).

One way to address shoulder pain in manual wheelchair users is with stretching and strengthening exercises. Several small trials have tested specific exercise programs and found statistically significant reduction in shoulder pain (Nawoczenski et al., 2006; Curtis et al., 1999).

Another option, for individuals who want to continue using manual wheelchairs, is to reduce the force put on the upper extremities by modifying the wheelchair. One modification is the addition of battery-powered wheels that can be fitted to standard manual wheelchairs. These wheels add a motorized boost, or "torque multiplier" allowing the user to go further with the same amount of force. A disadvantage of the battery-powered wheels is that the currently available products are heavy. For example, the Alber E-Motion weighs 53 pounds, excluding the wheelchair (Frankmobility.com). Newer, lighter products are being developed. The Quickie Xtend power assist product weighs 38 pounds (Quickie-wheelchairs.com). Another potential disadvantage of power-assisted wheels is that the batteries need to be recharged, sometimes frequently, which can be disruptive to daily activities.

A different modification to the manual wheelchair is to use the 2-gear wheelchair drive produced by MagicWheels, Inc. (Seattle, WA). The wheelchair drive adapts to most standard wheelchairs and does not include batteries or motors. By sliding a switch, the user can change from a conventional 1:1 gear ratio to a 2:1 ratio. The added weight is lighter than the battery-powered assist products. Depending on options, the additional weight per pair of wheels varies from 8.2-10.5 pounds. The gear shifting is designed to reduce upper body stress and assist the user to navigate ramps, hills and uneven terrain. Newer models include an automatic hill holding feature preventing the wheelchair from sliding backwards between pulls while going uphill, and a downhill assisted braking feature. MagicWheels was founded in 1996 by several partners. The University of Washington, where initial product development research took place, owns stock in MagicWheels as part of a patent licensing agreement.

Evidence and Source Documents

Wheelchair, 2-Gear (aka MAGICWHEELS® 2-Gear Wheelchair Drive)

Medical Technology Assessment Committee (MTAC)

Wheelchair, 2-Gear (aka MAGICWHEELS® 2-Gear Wheelchair Drive)

BACKGROUND

In 2000, almost 1.7 million people in the United States used wheelchairs due to a disability. Of these, 1.5 million people used a manual wheelchair (Kaye et al., 2000). Manual wheelchairs require extensive use of individuals' upper limbs for mobility, transfer and other daily functional activities. This repetitive weight-bearing use of the arms and shoulders may cause upper-extremity problems, and reports of shoulder pain are common. In a recent survey of individuals with thoracic spinal cord injuries, 40% of respondents reported current shoulder pain associated with

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wheelchair use (Alm et al. 2008). One way to address shoulder pain in manual wheelchair users is with stretching and strengthening exercises. Several small trials have tested specific exercise programs and found statistically significant reduction in shoulder pain (Nawoczenski et al., 2006; Curtis et al., 1999). Another option, for individuals who want to continue using manual wheelchairs, is to reduce the force put on the upper extremities by modifying the wheelchair. One modification is the addition of battery powered wheels that can be fitted to standard manual wheelchairs. These wheels add a motorized boost, or "torque multiplier" allowing the user to go further with the same amount of force. A disadvantage of the battery-powered wheels is that the currently available products are heavy. For example, the Alber E-Motion weighs 53 pounds, excluding the wheelchair (Frankmobility.com). Newer, lighter products are being developed. The Quickie Xtend power assist product weighs 38 pounds (Quickie-wheelchairs.com). Another potential disadvantage of power-assisted wheels is that the batteries need to be recharged, sometimes frequently, which can be disruptive to daily activities. A different modification to the manual wheelchair is to use the 2-gear wheelchair drive produced by MagicWheels, Inc. (Seattle, WA). The wheelchair drive adapts to most standard wheelchairs and does not include batteries or motors. By sliding a switch, the user can change from a conventional 1:1 gear ratio to a 2:1 ratio. The added weight is lighter than the battery-powered assist products. Depending on options, the additional weight per pair of wheels varies from 8.2-10.5 pounds. The gear shifting is designed to reduce upper body stress and assist the user to navigate ramps, hills and uneven terrain. Newer models include an automatic hill holding feature preventing the wheelchair from sliding backwards between pulls while going uphill, and a downhill assisted braking feature. MagicWheels was founded in 1996 by several partners. The University of Washington, where initial product development research took place, owns stock in MagicWheels as part of a patent licensing agreement. The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations. Mechanical wheelchairs and wheelchair components are Class 1 devices according to the FDA. Class 1 devices are subject to general controls such as product listing and labeling requirements but are exempt from the pre-market approval process including safety and effectiveness evaluation.

12/01/2008: MTAC REVIEW
Wheelchair, 2-Gear (aka MAGICWHEELS® 2-Gear Wheelchair Drive)
Evidence Conclusion: There is insufficient evidence to draw conclusions about the impact of the MagicWheels 2-gear wheelchair on functional ability and shoulder and arm pain. There was only one published empirical study on the MagicWheels wheelchair product. The study (Finley et al., 2007) was a small interrupted time series. 17 individuals started the study, and 12 completed the 5-month intervention phase. The study found improvement in shoulder pain, but not overall functional ability, or performance on an incline test when patients used MagicWheels. Shoulder pain decreased when MagicWheels was introduced and increased again after a return to standard wheels. Findings are subject to bias such as the Hawthorne effect (see evidence table for study details).
Articles: The PubMed search yielded 8 articles. Seven of these were on different related clinical topics, with the words "magic" and "wheels" included in the abstract or other part of the citation. No additional articles were identified via the "related articles" function in PubMed. There was only one published empirical article on the MagicWheels wheelchair, and this study was critically appraised: Finley MA, Rodgers MM. Effect of 2-speed geared manual wheelchair propulsion on shoulder pain and function. Arch Phys Med Rehabil 2007; 88: 1622-1627. See Evidence Table.

The use of 2-gear wheelchairs does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
Manual Wheelchairs	
K0001	Standard wheelchair
K0002	Standard hemi (low seat) wheelchair
K0003	Lightweight wheelchair
K0004	High strength, lightweight wheelchair
K0005	Ultralightweight wheelchair
K0006	Heavy-duty wheelchair
K0007	Extra heavy-duty wheelchair

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K0008	Custom manual wheelchair/base
K0009	Other manual wheelchair/base
E1050	Fully-reclining wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1060	Fully-reclining wheelchair, detachable arms, desk or full-length, swing-away detachable elevating legrests
E1070	Fully-reclining wheelchair, detachable arms (desk or full-length) swing-away detachable footrest
E1083	Hemi-wheelchair, fixed full-length arms, swing-away detachable elevating legrest
E1084	Hemi-wheelchair, detachable arms desk or full-length arms, swing-away detachable elevating legrests
E1085	Hemi-wheelchair, fixed full-length arms, swing-away detachable footrests
E1086	Hemi-wheelchair, detachable arms, desk or full-length, swing-away detachable footrests
E1087	High strength lightweight wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1088	High strength lightweight wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1089	High-strength lightweight wheelchair, fixed-length arms, swing-away detachable footrest
E1090	High-strength lightweight wheelchair, detachable arms, desk or full-length, swing-away detachable footrests
E1092	Wide heavy-duty wheelchair, detachable arms (desk or full-length), swing-away detachable elevating legrests
E1093	Wide heavy-duty wheelchair, detachable arms, desk or full-length arms, swing-away detachable footrests
E1100	Semi-reclining wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1110	Semi-reclining wheelchair, detachable arms (desk or full-length) elevating legrest
E1130	Standard wheelchair, fixed full-length arms, fixed or swing-away detachable footrests
E1140	Wheelchair, detachable arms, desk or full-length, swing-away detachable footrests
E1150	Wheelchair, detachable arms, desk or full-length swing-away detachable elevating legrests
E1160	Wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1161	Manual adult size wheelchair, includes tilt in space
E1170	Amputee wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1171	Amputee wheelchair, fixed full-length arms, without footrests or legrest
E1172	Amputee wheelchair, detachable arms (desk or full-length) without footrests or legrest
E1180	Amputee wheelchair, detachable arms (desk or full-length) swing-away detachable footrests
E1190	Amputee wheelchair, detachable arms (desk or full-length) swing-away detachable elevating legrests
E1195	Heavy-duty wheelchair, fixed full-length arms, swing-away detachable elevating legrests
E1200	Amputee wheelchair, fixed full-length arms, swing-away detachable footrest
E1220	Wheelchair; specially sized or constructed, (indicate brand name, model number, if any) and justification
E1221	Wheelchair with fixed arm, footrests
E1222	Wheelchair with fixed arm, elevating legrests
E1223	Wheelchair with detachable arms, footrests
E1224	Wheelchair with detachable arms, elevating legrests
E1229	Wheelchair, pediatric size, not otherwise specified
E1231	Wheelchair, pediatric size, tilt-in-space, rigid, adjustable, with seating system
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable, with seating system
E1233	Wheelchair, pediatric size, tilt-in-space, rigid, adjustable, without seating system
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable, without seating system
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system
E1240	Lightweight wheelchair, detachable arms, (desk or full-length) swing-away detachable, elevating legrest
E1250	Lightweight wheelchair, fixed full-length arms, swing-away detachable footrest
E1260	Lightweight wheelchair, detachable arms (desk or full-length) swing-away detachable footrest
E1270	Lightweight wheelchair, fixed full-length arms, swing-away detachable elevating legrests

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E1280	Heavy-duty wheelchair, detachable arms (desk or full-length) elevating legrests
E1285	Heavy-duty wheelchair, fixed full-length arms, swing-away detachable footrest
E1290	Heavy-duty wheelchair, detachable arms (desk or full-length) swing-away detachable footrest
E1295	Heavy-duty wheelchair, fixed full-length arms, elevating legrest
Power Wheelchairs	
E1239	Power wheelchair, pediatric size, not otherwise specified
K0010	Standard-weight frame motorized/power wheelchair
K0011	Standard-weight frame motorized/power wheelchair with programmable control parameters for speed adjustment, tremor dampening, acceleration control and braking
K0012	Lightweight portable motorized/power wheelchair
K0813	Power wheelchair, group 1 standard, portable, sling/solid seat and back, patient weight capacity up to and including 300 pounds
K0814	Power wheelchair, group 1 standard, portable, captain's chair, patient weight capacity up to and including 300 pounds
K0815	Power wheelchair, group 1 standard, sling/solid seat and back, patient weight capacity up to and including 300 pounds
K0816	Power wheelchair, group 1 standard, captain's chair, patient weight capacity up to and including 300 pounds
K0820	Power wheelchair, group 2 standard, portable, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0821	Power wheelchair, group 2 standard, portable, captain's chair, patient weight capacity up to and including 300 pounds
K0822	Power wheelchair, group 2 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0823	Power wheelchair, group 2 standard, captain's chair, patient weight capacity up to and including 300 pounds
K0824	Power wheelchair, group 2 heavy-duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0825	Power wheelchair, group 2 heavy-duty, captain's chair, patient weight capacity 301 to 450 pounds
K0826	Power wheelchair, group 2 very heavy-duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0827	Power wheelchair, group 2 very heavy-duty, captain's chair, patient weight capacity 451 to 600 pounds
K0828	Power wheelchair, group 2 extra heavy-duty, sling/solid seat/back, patient weight capacity 601 pounds or more
K0829	Power wheelchair, group 2 extra heavy-duty, captain's chair, patient weight 601 pounds or more
K0830	Power wheelchair, group 2 standard, seat elevator, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0831	Power wheelchair, group 2 standard, seat elevator, captain's chair, patient weight capacity up to and including 300 pound
K0835	Power wheelchair, group 2 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0836	Power wheelchair, group 2 standard, single power option, captain's chair, patient weight capacity up to and including 300 pounds
K0837	Power wheelchair, group 2 heavy-duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0838	Power wheelchair, group 2 heavy-duty, single power option, captain's chair, patient weight capacity 301 to 450 pounds
K0839	Power wheelchair, group 2 very heavy-duty, single power option sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0840	Power wheelchair, group 2 extra heavy-duty, single power option, sling/solid seat/back, patient weight capacity 601 pounds or more
K0841	Power wheelchair, group 2 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0842	Power wheelchair, group 2 standard, multiple power option, captain's chair, patient weight capacity up to and including 300 pounds
K0843	Power wheelchair, group 2 heavy-duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds

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K0848	Power wheelchair, group 3 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0849	Power wheelchair, group 3 standard, captain's chair, patient weight capacity up to and including 300 pounds
K0850	Power wheelchair, group 3 heavy-duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0851	Power wheelchair, group 3 heavy-duty, captain's chair, patient weight capacity 301 to 450 pounds
K0852	Power wheelchair, group 3 very heavy-duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0853	Power wheelchair, group 3 very heavy-duty, captain's chair, patient weight capacity 451 to 600 pounds
K0854	Power wheelchair, group 3 extra heavy-duty, sling/solid seat/back, patient weight capacity 601 pounds or more
K0855	Power wheelchair, group 3 extra heavy-duty, captain's chair, patient weight capacity 601 pounds or more
K0856	Power wheelchair, group 3 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0857	Power wheelchair, group 3 standard, single power option, captain's chair, patient weight capacity up to and including 300 pounds
K0858	Power wheelchair, group 3 heavy-duty, single power option, sling/solid seat/back, patient weight 301 to 450 pounds
K0859	Power wheelchair, group 3 heavy-duty, single power option, captain's chair, patient weight capacity 301 to 450 pounds
K0860	Power wheelchair, group 3 very heavy-duty, single power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0861	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0862	Power wheelchair, group 3 heavy-duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0863	Power wheelchair, group 3 very heavy-duty, multiple power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0864	Power wheelchair, group 3 extra heavy-duty, multiple power option, sling/solid seat/back, patient weight capacity 601 pounds or more
K0868	Power wheelchair, group 4 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0869	Power wheelchair, group 4 standard, captain's chair, patient weight capacity up to and including 300 pounds
K0870	Power wheelchair, group 4 heavy-duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0871	Power wheelchair, group 4 very heavy-duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0877	Power wheelchair, group 4 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0878	Power wheelchair, group 4 standard, single power option, captain's chair, patient weight capacity up to and including 300 pounds
K0879	Power wheelchair, group 4 heavy-duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0880	Power wheelchair, group 4 very heavy-duty, single power option, sling/solid seat/back, patient weight 451 to 600 pounds
K0884	Power wheelchair, group 4 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0885	Power wheelchair, group 4 standard, multiple power option, captain's chair, patient weight capacity up to and including 300 pounds
K0886	Power wheelchair, group 4 heavy-duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0890	Power wheelchair, group 5 pediatric, single power option, sling/solid seat/back, patient weight capacity up to and including 125 pounds
K0891	Power wheelchair, group 5 pediatric, multiple power option, sling/solid seat/back, patient weight

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	capacity up to and including 125 pounds
K0898	Power wheelchair, not otherwise classified
K0899	Power mobility device, not coded by DME PDAC or does not meet criteria
Power Scooters	
E1230	Power operated vehicle (three- or four-wheel nonhighway), specify brand name and model number
K0800	Power operated vehicle, group 1 standard, patient weight capacity up to and including 300 pounds
K0801	Power operated vehicle, group 1 heavy-duty, patient weight capacity 301 to 450 pounds
K0802	Power operated vehicle, group 1 very heavy-duty, patient weight capacity 451 to 600 pounds
K0806	Power operated vehicle, group 2 standard, patient weight capacity up to and including 300 pounds
K0807	Power operated vehicle, group 2 heavy-duty, patient weight capacity 301 to 450 pounds
K0808	Power operated vehicle, group 2 very heavy-duty, patient weight capacity 451 to 600 pounds
K0812	Power operated vehicle, not otherwise classified
Associated Parts and Supplies	
E0950	Wheelchair accessory, tray, each
E0951	Heel loop/holder, any type, with or without ankle strap, each
E0952	Toe loop/holder, any type, each
E0955	Wheelchair accessory, headrest, cushioned, any type, including fixed mounting hardware, each
E0956	Wheelchair accessory, lateral trunk or hip support, any type, including fixed mounting hardware, each
E0957	Wheelchair accessory, medial thigh support, any type, including fixed mounting hardware, each
E0958	Manual wheelchair accessory, one-arm drive attachment, each
E0959	Manual wheelchair accessory, adapter for amputee, each
E0960	Wheelchair accessory, shoulder harness/straps or chest strap, including any type mounting hardware
E0961	Manual wheelchair accessory, wheel lock brake extension (handle), each
E0967	Manual wheelchair accessory, hand rim with projections, any type, replacement only, each
E0968	Commode seat, wheelchair
E0969	Narrowing device, wheelchair
E0970	No. 2 footplates, except for elevating legrest
E0971	Manual wheelchair accessory, antitipping device, each
E0973	Wheelchair accessory, adjustable height, detachable armrest, complete assembly, each
E0974	Manual wheelchair accessory, antirollback device, each
E0978	Wheelchair accessory, positioning belt/safety belt/pelvic strap, each
E0980	Safety vest, wheelchair
E0981	Wheelchair accessory, seat upholstery, replacement only, each
E0982	Wheelchair accessory, back upholstery, replacement only, each
E0983	Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, joystick control
E0984	Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, tiller control
E0985	Wheelchair accessory, seat lift mechanism
E0986	Manual wheelchair accessory, push-rim activated power assist system
E0988	Manual wheelchair accessory, lever-activated, wheel drive, pair
E0990	Wheelchair accessory, elevating legrest, complete assembly, each
E0992	Manual wheelchair accessory, solid seat insert
E0994	Armrest, each
E0995	Wheelchair accessory, calf rest/pad, replacement only, each
E1002	Wheelchair accessory, power seating system, tilt only
E1003	Wheelchair accessory, power seating system, recline only, without shear reduction
E1004	Wheelchair accessory, power seating system, recline only, with mechanical shear reduction
E1005	Wheelchair accessory, power seating system, recline only, with power shear reduction
E1006	Wheelchair accessory, power seating system, combination tilt and recline, without shear reduction
E1007	Wheelchair accessory, power seating system, combination tilt and recline, with mechanical shear reduction
E1008	Wheelchair accessory, power seating system, combination tilt and recline, with power shear reduction
E1009	Wheelchair accessory, addition to power seating system, mechanically linked leg elevation system,

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	including pushrod and legrest, each
E1010	Wheelchair accessory, addition to power seating system, power leg elevation system, including legrest, pair
E1011	
E1012	Wheelchair accessory, addition to power seating system, center mount power elevating leg rest/platform, complete system, any type, each
E1014	Reclining back, addition to pediatric size wheelchair
E1015	Shock absorber for manual wheelchair, each
E1016	Shock absorber for power wheelchair, each
E1017	Heavy-duty shock absorber for heavy-duty or extra heavy-duty manual wheelchair, each
E1018	Heavy-duty shock absorber for heavy-duty or extra heavy-duty power wheelchair, each
E1020	Residual limb support system for wheelchair, any type
E1028	Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory
E1225	Wheelchair accessory, manual semi-reclining back, (recline greater than 15 degrees, but less than 80 degrees), each
E1226	Wheelchair accessory, manual fully reclining back, (recline greater than 80 degrees), each
E1227	Special height arms for wheelchair
E1228	Special back height for wheelchair
E1296	Special wheelchair seat height from floor
E1297	Special wheelchair seat depth, by upholstery
E1298	Special wheelchair seat depth and/or width, by construction
E1399	Durable medical equipment, miscellaneous
E2201	Manual wheelchair accessory, nonstandard seat frame, width greater than or equal to 20 in and less than 24 in
E2202	Manual wheelchair accessory, nonstandard seat frame width, 24-27 in
E2203	Manual wheelchair accessory, nonstandard seat frame depth, 20 to less than 22 in
E2204	Manual wheelchair accessory, nonstandard seat frame depth, 22 to 25 in
E2205	Manual wheelchair accessory, handrim without projections (includes ergonomic or contoured), any type, replacement only, each
E2206	Manual wheelchair accessory, wheel lock assembly, complete, replacement only, each
E2207	Wheelchair accessory, crutch and cane holder, each
E2208	Wheelchair accessory, cylinder tank carrier, each
E2209	Accessory, arm trough, with or without hand support, each
E2210	Wheelchair accessory, bearings, any type, replacement only, each
E2211	Manual wheelchair accessory, pneumatic propulsion tire, any size, each
E2212	Manual wheelchair accessory, tube for pneumatic propulsion tire, any size, each
E2213	Manual wheelchair accessory, insert for pneumatic propulsion tire (removable), any type, any size, each
E2214	Manual wheelchair accessory, pneumatic caster tire, any size, each
E2215	Manual wheelchair accessory, tube for pneumatic caster tire, any size, each
E2216	Manual wheelchair accessory, foam filled propulsion tire, any size, each
E2217	Manual wheelchair accessory, foam filled caster tire, any size, each
E2218	Manual wheelchair accessory, foam propulsion tire, any size, each
E2219	Manual wheelchair accessory, foam caster tire, any size, each
E2220	Manual wheelchair accessory, solid (rubber/plastic) propulsion tire, any size, replacement only, each
E2221	Manual wheelchair accessory, solid (rubber/plastic) caster tire (removable), any size, replacement only, each
E2222	Manual wheelchair accessory, solid (rubber/plastic) caster tire with integrated wheel, any size, replacement only, each
E2224	Manual wheelchair accessory, propulsion wheel excludes tire, any size, replacement only, each
E2225	Manual wheelchair accessory, caster wheel excludes tire, any size, replacement only, each
E2226	Manual wheelchair accessory, caster fork, any size, replacement only, each
E2227	Manual wheelchair accessory, gear reduction drive wheel, each
E2228	Manual wheelchair accessory, wheel braking system and lock, complete, each
E2230	Manual wheelchair accessory, manual standing system

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E2231	Manual wheelchair accessory, solid seat support base (replaces sling seat), includes any type mounting hardware
E2300	Wheelchair accessory, power seat elevation system, any type
E2301	Wheelchair accessory, power standing system, any type
E2310	Power wheelchair accessory, electronic connection between wheelchair controller and one power seating system motor, including all related electronics, indicator feature, mechanical function selection switch, and fixed mounting hardware
E2311	Power wheelchair accessory, electronic connection between wheelchair controller and 2 or more power seating system motors, including all related electronics, indicator feature, mechanical function selection switch, and fixed mounting hardware
E2331	Power wheelchair accessory, attendant control, proportional, including all related electronics and fixed mounting hardware
E2340	Power wheelchair accessory, nonstandard seat frame width, 20-23 in
E2341	Power wheelchair accessory, nonstandard seat frame width, 24-27 in
E2342	Power wheelchair accessory, nonstandard seat frame depth, 20 or 21 in
E2343	Power wheelchair accessory, nonstandard seat frame depth, 22-25 in
E2351	Power wheelchair accessory, electronic interface to operate speech generating device using power wheelchair control interface
E2398	Wheelchair accessory, dynamic positioning hardware for back
K0013	Custom motorized/power wheelchair base
K0014	Other motorized/power wheelchair base
K0015	Detachable, nonadjustable height armrest, each
K0017	Detachable, adjustable height armrest, base, replacement only, each
K0018	Detachable, adjustable height armrest, upper portion, replacement only, each
K0019	Arm pad, replacement only, each
K0020	Fixed, adjustable height armrest, pair
K0037	High mount flip-up footrest, each
K0038	Leg strap, each
K0039	Leg strap, H style, each
K0040	Adjustable angle footplate, each
K0041	Large size footplate, each
K0042	Standard size footplate, replacement only, each
K0043	Footrest, lower extension tube, replacement only, each
K0044	Footrest, upper hanger bracket, replacement only, each
K0045	Footrest, complete assembly, replacement only, each
K0046	Elevating legrest, lower extension tube, replacement only, each
K0047	Elevating legrest, upper hanger bracket, replacement only, each
K0050	Ratchet assembly, replacement only
K0051	Cam release assembly, footrest or legrest, replacement only, each
K0052	Swingaway, detachable footrests, replacement only, each
K0053	Elevating footrests, articulating (telescoping), each
K0056	Seat height less than 17 in or equal to or greater than 21 in for a high-strength, lightweight, or ultralightweight wheelchair
K0065	Spoke protectors, each
K0069	Rear wheel assembly, complete, with solid tire, spokes or molded, replacement only, each
K0070	Rear wheel assembly, complete, with pneumatic tire, spokes or molded, replacement only, each
K0071	Front caster assembly, complete, with pneumatic tire, replacement only, each
K0072	Front caster assembly, complete, with semipneumatic tire, replacement only, each
K0073	Caster pin lock, each
K0077	Front caster assembly, complete, with solid tire, replacement only, each
K0098	Drive belt for power wheelchair, replacement only
K0105	IV hanger, each
K0108	Wheelchair component or accessory, not otherwise specified
K0195	Elevating legrests, pair (for use with capped rental wheelchair base)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
03/1985	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC] ,12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	09/29/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/19/2015	The background statement was edited to state that WCs are for use in the home
08/04/2015	Manual Wheelchair: Added grade levels for severe dependent edema and removed “poor endurance” language
07/02/2016	Added addendum to exclusion list
08/01/2017	MPC approved to adopt indication for any requests for power wheelchair or power scooter must be submitted by a physiatrist who has examined the patient and done a thorough evaluation.
05/01/2018	MPC approved criteria for Power Assist Device
08/27/2019	Clarified qualifications of provider consulting for power assist device.
12/03/2019	MPC approved to adopt criteria for Specialized Wheelchairs: lightweight, ultra-lightweight and high-strength lightweight wheelchairs
05/05/2020	MPC approved to adopt updates to the power wheelchair supporting documentation requirements; clarifying language added for ultra-lightweight wheelchair and power assist device
06/23/2020	Added HCPC code E2398
06/10/2021	Added statement “This should most commonly be a physiatrist.” to criteria #3 related to evaluation for ultra-light wheelchairs.
09/29/2021	Moved criteria for manual lightweight, high-strength lightweight and ultra-lightweight wheelchairs into the MCG KP-0354 Manual Wheelchair criteria.

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Clinical Review Criteria
Whole Body Computed Tomography Scan

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Computed Tomography (220.1).
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or consulting specialist.
-

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Background

Computed tomography (CT) is a diagnostic procedure that uses x-rays to obtain cross-sectional images of the body. The images are based on the absorption of x-rays by different body tissues. Many CT systems allow imaging of multiple slices simultaneously so larger volumes of anatomy can be imaged in less time. Whole-body screening is a non-tailored, non-specific CT scan. It has recently been promoted as a general screening test to healthy individuals who have no symptoms or suspicion of disease. The purpose of screening is to prevent or delay, by means of early detection, the development of advanced disease and its adverse side effects. (From Kaiser Technology Assessment material.)

Currently some medical imaging facilities are promoting a new use of computed tomography (CT), also called computerized axial tomography (CAT) scanning. This use is referred to as whole-body CT scanning or whole-body CT screening, and it is marketed as a preventive or proactive health care measure to healthy individuals who have no symptoms or suspicion of disease. **At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death.** Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause. (From the FDA consumer Web site.)

Medical Technology Assessment Committee (MTAC)

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Whole Body Computed Tomography

07/14/2004: MTAC REVIEW

Evidence Conclusion: (Kaiser conclusions) No studies have been published that evaluate the efficacy of whole body CT screening of asymptomatic individuals.

Articles: (From Kaiser materials) Medline was searched through January 2004 with the search terms "whole body computed tomography" and "disease screening" - with variations. Screening of articles: (From Kaiser materials) No published studies were identified. Additional references: INTC Agenda packet, April 19, 2004. Included materials from Kaiser, Southern California and Hayes, Inc.

The use of whole body computed tomography scanning in the general screening of healthy individuals does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

HCPC Codes	Description
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
07/14/2004	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 04/04/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC]	07/29/2004

[MPC] Medical Policy Committee

Revision History	Description

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Date Sent: 6/28/23
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

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Clinical Review Criteria
Wound Care Treatments

- Electrical Stimulation and Electromagnetic Therapy
- Low Frequency, Noncontact, Nonthermal Ultrasound Wound Therapy
- Maggot Debridement Therapy (MDT)
- Noncontact Normothermic Wound Therapy
- OASIS Wound Dressing
- Tissue Engineered Skin Substitutes

A Separate Criteria Document Exists for the Following:
Negative Pressure Wound Therapy Pumps (NPWT)
Platelet Rich Plasma

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Manual, Chapter 1, Part 4, Section 270
National Coverage Determinations (NCD)	• Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1) • Non-Contact Normothermic Wound Therapy (NNWT) (270.2)* **This service is not covered per Medicare criteria* • Treatment of Decubitus Ulcers (270.4) • Porcine Skin and Gradient Pressure Dressings (270.5) • Infrared Therapy Devices (270.6)* **This service is not covered per Medicare criteria*
Local Coverage Determinations (LCD)	• Wound and Ulcer Care (L38904) • Surgical Dressings (L33831)
Local Coverage Article	• Billing and Coding: Wound and Ulcer Care (A58567) • Surgical Dressings – (A54563) • Billing and Coding: Wound Care and Debridement - Provided by a Therapist, Physician, NPP, or as Incident-to Services (A53046) • Use of Amniotic Membrane Derived Skin Substitutes (A56156) **RETIRED**
Kaiser Permanente Medical Policy – Skin Substitutes	Due to the absence of an NCD or LCD, Kaiser Permanente has chosen to use their own Clinical Review Criteria for Skin Substitutes for medical necessity determinations when these products are used in the outpatient hospital or office setting. Refer to the Non-Medicare Skin Substitutes criteria below.

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MLN Matters Article	January 2020 Update of the Ambulatory Surgical Center (ASC) Payment System **Section 4: Skin Substitutes (pp. 5-8)** ▪ **In the Ambulatory Surgery Care Setting** - Medicare considers skin substitutes for wound care to be dressings applied in the Ambulatory Surgery Center (ASC). These are not separately billable and do not need to go for Medical Review. ▪ **In the outpatient hospital or clinic setting** - Medicare considers skin substitutes billable. Refer to the Non-Medicare Skin Substitutes criteria below for medical necessity determinations.

For Non-Medicare Members

Treatment	Criteria Used
Noncontact Normothermic Wound Therapy • Warm-Up Wound Therapy	MCG* A-0351 This service is not medically necessary per MCG* For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist
Electrical Stimulation and Electromagnetic Therapy	MCG* A-0242 This service is not medically necessary per MCG* For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist
Low Frequency, Noncontact, Non-Thermal Ultrasound Wound Therapy	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Maggot Debridement Therapy (MDT)	No medical necessity review required for this service.

Skin Substitutes
Tissue-engineered skin substitute may be indicated for **ONE or more of the following**: 1. Diabetic foot ulcers, as indicated by **ALL of the following**: ▪ Treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70) ▪ Receiving conventional wound care and optimal glycemic management to continue during treatment ▪ Diabetes mellitus (type 1 or type 2) ▪ Other causes of neuropathy may be approved on a case by case bases by a medical director ▪ Full-thickness foot ulcer with location on plantar, medial, or lateral area, and no exposure of tendon, muscle, capsule, or bone (Full thickness ulcer extends thru dermis and epidermal layers. Subcutaneous fat may be visible, but bone, tendon or muscle are not exposed.) ▪ No allergy to bovine products ▪ No response to four weeks of consistent conventional therapy, including **ALL of the following**: o No weight-bearing (off loading, so there is no pressure on the wound) o Optimal glycemic management o Dressing that promote moist wound healing

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Skin Substitutes

- o Serial debridement as clinically indicated
- No wound infection defined as less than or equal to 3+ growth on semi-quantitative wound culture
- No slough or eschar in the wound bed

Only the following products are approved for treatment of diabetic ulcers
Biological skin substitutes: Use Integra/Musculoskeletal Transplant Foundation (MTF)
Synthetic skin substitutes: Use Integra/Smith & Nephew

Integra Biological products: AmnioExcell amniotic allograph, AmnioMatrix amniotic allograft, AmnioExcell plus placental allograph
MTF Biological products: AlloPatch Pliable Allograft Dermal Matrix, AmnioBand Membrane Allograft Placental Matrix, AmnioBand Particulate Allograft Placental Matrix, AmnioBand Viable Allograft Placental Matrix
Smith and Nephew Synthetic products: Oasis Ultra tri-layer Matrix, Oasis Wound Matrix Fenestrated
Integra Synthetic products: Integra Wound Matrix, PriMatrix, PriMatrix Fenestrated, PriMatrix Meshed, PriMatrix Ag, Integra Meshed Dermal Regeneration, Integra Meshed Bilayer Wound Matrix

2. Venous insufficiency ulcers, as indicated by **ALL of the following**:
   - Treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70)
   - Receiving concurrent conventional wound care for a minimum of four weeks, to include compression of extremity (e.g. compression stocking, ace bandage, lymphedema pump – if meets criteria) Receiving concurrent optimal glycemic management, if patient is also diabetic
   - Full-thickness ulcer due to venous insufficiency
   - No allergy to bovine products, porcine and/or ovine products
   - No response to conventional therapy, including ALL of the following:
     - o Dressing that promote moist wound healing
     - o Serial debridement as clinically indicated
   - No wound infection defined as less than or equal to 3+ growth on semi-quantitative wound culture
   - Compression
   - No slough or eschar in the wound bed

Only the following products are approved for treatment of venous insufficiency ulcers
Biological skin substitutes: Use Integra/Musculoskeletal Transplant Foundation (MTF)
Synthetic skin substitutes: Use Integra/Smith & Nephew

Integra Biological products: AmnioExcell amniotic allograph, AmnioMatrix amniotic allograft, AmnioExcell plus placental allograph
MTF Biological products: AlloPatch Pliable Allograft Dermal Matrix, AmnioBand Membrane Allograft Placental Matrix, AmnioBand Particulate Allograft Placental Matrix, AmnioBand Viable Allograft Placental Matrix
Smith and Nephew Synthetic products: Oasis Ultra tri-layer Matrix, Oasis Wound Matrix Fenestrated
Integra Synthetic products: Integra Wound Matrix, PriMatrix, PriMatrix Fenestrated, PriMatrix Meshed, PriMatrix Ag, Integra Meshed Dermal Regeneration, Integra Meshed Bilayer Wound Matrix

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

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Background

Chronic wounds, wounds with long healing time, and wounds with frequent recurrence are a major health problem. They are a problem for the patient who suffers from them, the clinician who treats them, and the health care system that is overburdened by their cost. It is estimated that chronic wounds affect approximately 2% of the American

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population at an estimated cost of US $20 billion per year. Many factors can impede wound healing, including chronic disease, venous insufficiency, arterial insufficiency, neuropathy, nutritional deficiencies and local features such as pressure, edema, and infection (Fonder, 2008, Rizzi 2010).

No single regimen is universally accepted as the best modality for treating chronic wounds. They are managed through conventional wound care procedures performed by primary care providers, community nurses, pharmacists, and others. In the early 2000s, the concept of wound bed preparation has been proposed as a means of providing a structured and systemic approach to the management of chronic wounds. It is believed to accelerate endogenous healing and/or facilitate the effectiveness of other therapeutic measures. Wound bed preparation involves ongoing wound debridement, management of exudates, and resolution of bacterial imbalance (Schulz 2003, Ramundo 2008).

Wound debridement is defined as the removal of devitalized or contaminated tissue as well as foreign material from the wound bed until healthy tissue is exposed. Efficient debridement reduces the necrotic burden, achieves healthy granulation tissue, and reduces wound contamination and tissue destruction. This can be performed by different enzymatic, autolytic, sharp/surgical, biological, and mechanical techniques. Each has its own advantages and limitations, and the methods that are most efficient at removal of debris, may at the same time be the most detrimental to fragile new growth (Schulz 2003, Beitz, 2005, Ramundo 2008).

Tissue-engineered skin substitutes (i.e., human skin equivalents [HSE]), also referred to as artificial skin, are bioengineered skin products and may be either acellular or cellular. Acellular (i.e., cadaveric human dermis with cellular material removed) products contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. The construction of the matrix allows easy access by host cells during the healing process. Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within a matrix may be allogeneic (i.e., obtained from another individual) or autologous (i.e., obtained from the same individual). Some products are derived from other species (e.g., bovine, porcine) and are referred to as a xenograft. Skin substitutes are generally comprised of epidermal cells, dermal cells or may be composites (i.e., a combination of dermal and epidermal). The substitutes can be used as either temporary or permanent wound coverings. Grafting techniques utilized to apply skin substitutes include autografting (i.e., tissue transplanted from one part of the body to another), allografting (i.e., transplant from one individual to another of the same species), and xenografting (i.e., a graft from one species to another unlike species). Skin substitutes have been proposed for the treatment of multiple conditions including breast reconstruction and chronic wounds nonresponsive to standard therapy.

During breast reconstruction, acellular dermal skin substitutes (i.e., AlloDerm, AlloMax) are primarily used in the setting of tissue expander and breast implant reconstruction. Patients should be in overall good health and have no underlying condition that would restrict blood flow or interfere with the normal healing process (e.g., uncontrolled diabetes, hypertension, previous surgery). These matrixes may be indicated when there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required, as may be the case in a very thin patient; if there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or if there is a need to re-establish the inframammary fold and lateral mammary fold landmarks. When used in appropriate candidates, these skin substitutes are proposed to improve control over placement of the inframammary fold and final breast contour, enhance use of available mastectomy skin, reduce the number of expander fills necessary, reduce time to complete expansion and eventual implant exchange, potential improved management of a threatened implant, reduce the need for explanation and the potential for reduction in the incidence of capsular contracture. However, there are ongoing concerns regarding the increased risk of seroma and infection, a higher risk of an implant having to be removed, and tissue flap death.

Evidence and Source Documents

Bilaminate Skin Substitutes
Electrical Stimulation and Electromagnetic Therapy
Low Frequency, Noncontact, Nonthermal Ultrasound Wound Therapy Maggot
Debridement Therapy (MDT)
Medihoney Dressing for Wound Management OASIS
Wound Dressing
Warm-Up Wound Therapy

Medical Technology Assessment Committee

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Bilaminate Skin Substitutes

BACKGROUND

Venous ulcers are a chronic recurring condition associated with long-standing venous hypertension of the lower extremities. They occur in approximately 1-3 patients per thousand in the general population with the incidence rising to 20 per thousand in individuals over 80 years old. The chronicity of care required to treat this condition involves significant time and resources and often treatment is unsuccessful in producing complete venous ulcer healing. Typical treatments include frequent dressing changes, compression bandages, antibiotic and antiseptic use, and mechanical debridement. One proposed treatment of chronic venous ulcers involves covering the ulcer with a natural bilayer skin substitute that is hypothesized to protect the wound and promote healing.

08/11/1999: MTAC REVIEW

Bilaminate Skin Substitutes

Evidence Conclusion: The best, published article reporting original data on the effect of using Apligraf on non-healing venous ulcers is a randomized controlled trial of 309 patients recruited from 5 wound treatment centers. The results of this randomized controlled trial indicate that venous ulcers resolve more quickly when treated with compression and human skin equivalent than when treated with compression alone. The results also suggest that patients treated with compression/human skin equivalent are more likely to have complete healing of a venous ulcer than those who are treated only with compression. The bias introduced by the failure to perform an intention-to-treat analysis could explain some of the differences between treatment groups. The results cannot be generalized to patients with conditions that are associated with poor wound healing or to patients with large venous ulcers. Additionally, the probability of ulcer recurrence after 12 months for patients treated with compression/human skin equivalent relative to that of patients treated only with compression remains unknown. This study has not defined the risk of clinically relevant immunologic rejection of human skin equivalent for patients with venous ulcers.

Articles: Falanga, V et al, *Arch. Dermatol*. 1998;134:292-300 See Evidence Table.

The use of Apligraf human skin equivalent for the treatment of non-healing venous ulcers has been approved by the FDA and therefore meets GHC criteria 1. There is sufficient scientific evidence that Apligraf is medically effective and therefore *Kaiser Permanente Medical Technology Assessment Criteria*.

Electrical Stimulation and Electromagnetic Therapy

BACKGROUND

Chronic wounds have been traditionally known as wounds that take prolonged time to heal, do not heal completely, or recur frequently. There is no agreed upon definition for chronic wounds; Lazarus et al (1994) defined them as wounds of at least 8 weeks in duration that have failed to proceed through an orderly and timely process that produces anatomic and functional integrity. Troxler et al (2006) defined them as wounds that fail to heal with ‘standard therapy’ in an orderly and timely manner. More recently Fonder and colleagues (2008) defined chronic skin wounds as break in the skin of long duration (>6 weeks), or frequent recurrence. Generally, the process of normal healing takes few days to 2 weeks and involves three phases that may overlap in time: 1. inflammatory phase, 2. proliferative phase, and 3. remodeling phase. If any of these phases is compromised, healing will be delayed. Chronic wounds are predominantly due to chronic venous insufficiency, atherosclerosis, pressure sores, or peripheral neuropathy. Chronic ulceration can affect any anatomic region of the body, but the majority is seen in the lower limbs. Pressure sores also known as pressure ulcers are the most common of all chronic wounds, and venous ulcers account for the majority of leg ulcers (70-85%). Diabetic foot ulcers and ischemic ulcers contribute to a significant proportion of the rest (Eaglestein 1997, Simon 2004, Jones 2007, Fonder 2008). Management of chronic wounds has challenged health care providers for generations, and various strategies have been used to accelerate the healing process. Standard care includes debridement of necrotic or infected tissue, maintenance of a moist wound environment, control of infection, wound dressing, nutritional support, and treatment of concurrent conditions that may delay healing. Adjuncts to wound care include several established or emerging therapies. These include compression therapy, pressure relieving beds or cushions, hyperbaric oxygen therapy, topical negative pressure devices, growth factors, skin substitutes, and topical or systemic medications. Selection of therapy is based on the individual patient’s clinical condition, and type and cause of wound. A whole range of other adjunctive treatment modalities, such as laser, ultrasound, and electricity have also been applied to chronic wounds (Cullum 2000, de Araujo 2003, Fonder 2008). Electrical stimulation (ES) or electrotherapy for wound healing is defined as the application of electrical current from electrodes placed directly within a wound or on skin in a close proximity to it. ES has been a topic for research for decades and is often used by physical therapists to promote healing. There are four basic treatment regimens for ES therapy: low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternating current (AC), and transcutaneous

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electrical nerve stimulation (TENS). Electromagnetic therapy is a related therapy but is distinct from other forms of electrotherapy in that it uses an electromagnet to generate the electric current. It has a field effect not a direct effect or a form of irradiation. It covers a wide range of wavelengths including radio-waves and X-rays. Short wave diathermy (SWD) is a non-ionizing radiation present in the radio-waves portion of the electromagnetic spectrum. The frequency of the short- wavelength radio-waves ranges from 10 to 100 MHz. The radiofrequency wave band of 27.12 MHz is used for therapeutic effect in continuous SWD. Electromagnetic therapy can also be delivered in short bursts of energies called Pulsed Short-Wave Diathermy or PSWD (gardener 1999, Ojingwa 2002, Stiller 1992, Olyaee 2006, Callaghan 2008). In vitro and animal studies have showed that electrical stimulation can increase the DNA and collagen synthesis, direct epithelial, fibroblast, and endothelial cell migration into wound sites, inhibit growth of some wound pathogens, and increase tensile strength of wound scar (Bassett 1974, Gordon 2007). Several devices have been used off-label to deliver ES or electromagnetic therapy to cutaneous wounds. The FDA approved electric stimulators as Class III devices for deep brain and bone stimulation and cleared them as class II devices for muscle stimulation. Electromagnetic devices were also FDA cleared for the treatment of selected medical conditions including relief of pain, muscle contracture, joint contractures, and others. None of the ES or electromagnetic devices has been cleared by the FDA, to date, for the treatment of wounds. The objective of this review is to determine whether electric stimulation and /or electromagnetic therapies are effective adjunctive treatments for chronic skin wounds. The technology has not been previously reviewed by MTAC for this indication.

04/09/2008: MTAC REVIEW
Electrical Stimulation and Electromagnetic Therapy
Evidence Conclusion: There is limited evidence on the effect of electric stimulation (ES) or electromagnetic (EM) therapy on the healing of chronic wounds. The body of evidence on ES therapy mainly consists of small randomized and nonrandomized controlled trials that used the therapy off-label to treat chronic wounds, as well as a meta-analysis that pooled the results of 15 randomized and nonrandomized studies. The literature on EM therapy was more limited. There were very few small trials that also used the therapy off- label. Due to this limited number of studies, the authors of the Cochrane reviews were unable pool the results in a meta-analysis. Although a number of the published RCTs were randomized, controlled, blinded, and had clinical outcomes, all had their limitations: they were too small, with short follow-up durations, and with no standardized dose, frequency, or duration for the electric stimulation (ES) or electromagnetic (EM) therapy. Moreover, several studies used the change in ulcer size rather than incidence of /or time to complete healing as their outcome. No adjustments were made for potential confounding factors, and analyses were not based on intention to treat. The results of these trials suggest that electrotherapy might be associated with improved healing, but the evidence is insufficient to draw any conclusions on the benefits of therapy on complete healing or health outcomes. Gardener and colleagues' (1999) pooled the results of nine small RCTs to quantify the effect of ES on chronic wound healing.
They showed a healing rate of 22% per week among patients treated with ES therapy compared to 9% healing rate per week among the controls. There were several differences among the studies included in the patients' characteristics, types of wounds, and devices used to deliver the ES therapy, as well as dose, frequency and duration of therapy. The two Cochrane reviews on EM therapy (Ravaghi 2006, and Manesh 2006) on venous leg ulcers, and pressure ulcers respectively, could not pool the results due to the limited number of included trials. In conclusion, there is insufficient evidence to determine whether the use of ES or EM therapy as adjunctive treatments would lead to healing of chronic wounds or improve the patients' health outcomes.
Articles: The literature search revealed over 90 articles. Several were reviews or non-related to the current report. There was a meta-analysis of randomized and non-randomized controlled studies on ES therapy for chronic wounds, and two small RCTs that were not included in the meta-analysis. There were also two Cochrane reviews on electromagnetic therapy for treating pressure ulcers and venous leg ulcers. The reviews however did not pool the results in meta-analyses due to the limited number of studies. A review by TEC of Blue Cross Blue Shield on electric stimulation and electromagnetic therapy for chronic skin ulcers (2005), and an ECRI report (1996) on electrical stimulation for the treatment of chronic wounds were also identified by the search. The meta-analysis and the two more recent RCTs on ES, as well as the two Cochrane reviews on electromagnetic therapy were critically appraised.
Gardener SE, Frantz R, Schmidt FL. Effect of electrical stimulation on chronic wound healing: a meta-analysis. Wound Rep Reg 1999; 7:495-503. See Evidence Table. Ravaghi H, Flemming K, Cullum NA, et al. Electromagnetic therapy for treating venous leg ulcers. (Review). Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.:CD002933. DOI:10.1002/14651858. CD002933.pub3. See Evidence Table. Manesh O, Flemming K, Cullum NA, et al. Electromagnetic therapy for treating pressure ulcers. (Review). Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.:CD002930. DOI:10.1002/14651858. CD002930.pub3. See Evidence Table. Peters EJ, Lavery LA, Armstrong DG, et al. Electrical stimulation as an adjunct to heal diabetic foot ulcers: a randomized clinical trial. Arch Phys Med Rehabil. 2001;82:721-725, See Evidence Table. Houghton PE, Kinacaid CB, Lovell M, et al. Effect of electrical stimulation on chronic leg ulcer size and appearance. Phys Ther 2003;83:17-28 See Evidence Table.

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The use of Electrical stimulation and electromagnetic therapy in the treatment of chronic skin wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Low Frequency, Noncontact, Nonthermal Ultrasound Wound Therapy

BACKGROUND

Chronic wounds, wounds with long healing time, and wounds with frequent recurrence are a major health problem. They are a problem for the patient who suffers from them, the clinician who treats them, and the health care system that is overburdened by their cost. It is estimated that chronic wounds affect approximately 2% of the American population at an estimated cost of US $20 billion per year. Many factors can impede wound healing, including chronic disease, venous insufficiency, arterial insufficiency, neuropathy, nutritional deficiencies and local features such as pressure, edema, and infection (Fonder, 2008, Rizzi 2010). No single regimen is universally accepted as the best modality for treating chronic wounds. They are managed through conventional wound care procedures performed by primary care providers, community nurses, pharmacists, and others. In the early 2000s, the concept of wound bed preparation has been proposed as a means of providing a structured and systemic approach to the management of chronic wounds. It is believed to accelerate endogenous healing and/or facilitate the effectiveness of other therapeutic measures. Wound bed preparation involves ongoing wound debridement, management of exudates, and resolution of bacterial imbalance (Schulz 2003, Ramundo 2008). Wound debridement is defined as the removal of devitalized or contaminated tissue as well as foreign material from the wound bed until healthy tissue is exposed. Efficient debridement reduces the necrotic burden, achieves healthy granulation tissue, and reduces wound contamination and tissue destruction. This can be performed by different enzymatic, autolytic, sharp/surgical, biological, and mechanical techniques. Each has its own advantages and limitations, and the methods that are most efficient at removal of debris, may at the same time be the most detrimental to fragile new growth (Schulz 2003, Beitz, 2005, Ramundo 2008). Noncontact, low frequency ultrasound therapy was recently introduced as a modality for promoting wound healing through wound cleansing and maintenance debridement. The therapy is thought to produce a number of biophysical effects that are associated with wound healing. These include increased protein and collagen synthesis, angiogenesis, production of growth hormone by macrophages, endothelial production of nitric oxide synthesis; and leukocyte adhesion. One of the main mechanisms of action for ultrasound therapy, as shown by in vitro studies, is achieved through the process of cavitation. This involves the production and vibration of micron-sized bubbles within the coupling medium and fluids in the tissues. As the bubbles collect and condense, they are compressed before moving to the next area. This movement and compression can potentially cause changes in the cellular activities of the tissues subjected to the ultrasound. Acoustic streaming is another mechanism by which ultrasound generates biologic activity producing a unidirectional movement of fluid along and around cell membranes. A more recent hypothesis known as the frequency resonance theory uses the above concepts at the protein and genetic level and result in a broad range of cellular effects that promote healing. Ultrasound energy is also believed to have a direct bactericidal action caused by the cavitation effects produced by the ultrasound waves (Ennis 2005 Ramundo 2008). The sound waves generated by the therapeutic ultrasound devices have lower frequencies than those generated by diagnostic devices (25-40 kHz vs. 200,000-400,000 kHz respectively). Ultrasound MIST therapy devices use saline to couple the ultrasound energy to tissue within the wound bed. This is accomplished by the noncontact non-thermal application of a fine oxygenated fluid (sterile saline) stream spray to the wound bed through which the ultrasound energy is transmitted from the applicator tip to the wound tissue. This noncontact ultrasound is believed to provide cellular stimulation, increase blood flow, and reduce bioburden with much less pain or thermal effect than other direct contact devices. It is usually applied three times a week for a duration dependent on the wound dimensions. The therapy should be performed in a closed environment area to avoid spread of microbes, and the clinician delivering the therapy should wear protective gear (Ramundo 2008, FDA webpage). Ultrasound MIST therapy (Celleration, Inc, Eden Prairie, MN), was cleared by the FDA in 2004 to promote healing of wounds through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria. Its use is contraindicated for malignant wounds, radiation wounds, for tissue previously treated with radiation, and for patients with bleeding disorders, or thrombophlebitis.

02/01/2010: MTAC REVIEW

Low Frequency, Noncontact, Nonthermal Ultrasound Wound Therapy

Evidence Conclusion: The literature search revealed two published RCTs on the low frequency noncontact ultrasound therapy for the treatment of wounds. The two trials were funded by the manufacturer. In one trial, Ennis and colleagues, 2005, compared the ultrasound therapy to a sham device for the treatment of patients with diabetic foot ulcers. Patients in the two treatment groups also received wound conventional therapy. The trial was randomized and controlled and had clinically important outcome. However, it had several methodological flaws which limit generalization of its results. The study had a very low completion rate (41%) due to dropouts or violations of the protocol, and the ulcers in the sham treatment group were significantly lager in size and with a

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longer duration than those in the investigational group, which are potential sources of bias and confounding. The results show significant difference in the wound closure favoring the ultrasound therapy group when the analysis included only those who completed the trials, but no significant differences were observed when the analysis was based on intention to treat. Kavros and colleagues, 2007, compared the effects of the ultrasound therapy plus standard wound care to standard wound care alone in 70 patients with non-healing ischemic lower-extremity wounds. The trial was also randomized and controlled, but was not blinded, and the outcomes were mainly based on measurements which are subject to potential error, and observational bias. Moreover, the authors did not discuss if there were any dropouts, rate of compliance, or adverse events associated with the intervention. Overall, the results of the trial show that patients managed with MIST therapy in addition to standard treatment, achieved a significantly higher >50% wound closure rate in 12 weeks than those managed with standard therapy alone. A secondary analysis of the trial showed that patients with critical limb ischemia with baseline TcPO2 <20 with dependency were significantly less likely to achieve >50% healing by week 12, using standard treatment with or without MIST therapy. In conclusion, the published literature does not provide sufficient evidence to determine that non-thermal, noncontact, low frequency ultrasound therapy "Mist therapy "is safe to use, or that it has similar or better outcomes than those achieved by other debridement methods or standard wound care management procedures.
Articles: The literature search yielded two RCTs, on the low frequency ultrasound therapy using the MIST therapy system for the treatment of chronic wounds, one non-randomized retrospective comparative study and prospective case series. The two RCTs were critically appraised. Ennis WJ, Formann P, Mozen N, et al. Ultrasound therapy for recalcitrant diabetic foot ulcers: Results of a randomized, double-blind, controlled, multicenter study. Ostomy Wound Management.2005;51:24-39. See Evidence Table. Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, low-frequency ultrasound The Mayo Clinic experience, 2004-2006. Adv skin Wound Care 2007; 20:221-226. See EvidenceTable.

The use of Low frequency, noncontact, nonthermal ultrasound therapy for the treatment of wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Maggot Debridement Therapy (MDT)

BACKGROUND

Chronic wounds, wounds with long healing time or frequent recurrence, are major health care and quality of life burdens. Approximately 1-2% of individuals in the United States are likely to be affected by leg ulceration at some time in their life. Many factors can impede wound healing, including chronic disease, vascular insufficiency, nutritional deficiencies and local features such as infection, pressure and edema (Fonder et al., 2008). Preparation of the wound bed is an important component of optimal healing. Proper preparation includes debridement of nonviable tissue, management of inflammation and infection, and establishment of proper moisture balance. Wound debridement serves several purposes. It removes necrotic tissue which can present physical barriers to healing, decreases the potential for infection, enhances the ability to assess wound depth, and helps to remove bacteria that may prevent healing (Beitz, 2005). Debridement methods include hydrogels, enzymatic agents, dextranomer polysaccharide beads or paste, adhesive zinc oxide tape, and sharp debridement. A systematic review of studies on different debridement methods concluded that there was insufficient evidence to recommend one method of debridement over another (Bradley et al., 1999). Maggot debridement therapy (MDT) is another method for wound debridement. Maggot or larval therapy has been used in some form for centuries, including treating battle wounds in Napoleon's army in the 1550s. Dr. William Baer, often called the founder of modern maggot therapy, observed the effects of maggots on the wounds of soldiers during World War I and he later refined the technique to use sterile maggots under controlled conditions. MDT increased in popularity after WWI and, by the 1930s, was widely used in the U.S. and Europe. Its use decreased after the advent of antibiotics in the 1940s. As of the late 1990s there has been resurgence in interest due to antibiotic resistance, particularly methicillin-resistant Staphylococcus aureus (MRSA) and the lack of other reliably effective methods (Gupta, 2008). Modern MDT involves the use of specially bred larvae, most commonly of the green-bottle fly Lucilia sericata species. Larvae 1-2 mm long larvae hatch from eggs in 12-24 hours and, when they feed on necrotic tissue in the moist environment of wounds, they mature in 4-5 days, at which time they measure about 10mm. Larvae need to be sterile to prevent contamination and should be used within 8 hours of hatching or stored in refrigerator at 8-10o C to slow their metabolism. They require an optimal body temperature, moist environment and adequate oxygen supply. The general procedure is to introduce larvae to the wound at a density of 5-8 per cm2 and cover with a containment dressing that allows oxygen to pass through. Dressings are generally changed once a day to avoid build-up of secretions, and the larvae are changed every 2-3 days. Wounds commonly require 2-6 treatment cycles for complete debridement (Gupta et al., 2008; Chan et al., 2007; FDA materials). The exact mechanisms by which maggots debride wounds are not fully understood. It is generally believed that there is a combination of: 1) Mechanical action: probing from the maggots' pair of mandibles/hooks may facilitate debridement; 2) Enzymatic action: Three proteolytic enzymes have been identified in maggot
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excretions/secretions (ES) that can degrade extracellular matrix components, including laminin and fibronectin. The ES also have antibacterial substances which appear to have an inhibitory effect on Gram-positive and Gram-negative bacteria including MRSA. Maggots may also secrete cytokines which aid in wound healing; 3) Digestion: Maggots appear to ingest bacteria and kill them in their alimentary tract (Chan et al., 2007). There are no reports that MDT is associated with major adverse effects or complications. Minor discomfort has been reported, and excessive pressure on the wound may kill some of the maggots, resulting in uneven healing. There is also the issue of social acceptance of larval therapy, the widely-cited "yuck" factor, for patients and providers. In 2004, FDA cleared Medical Maggots (Monarch Labs, Irvine, CA) for commercial production as a Class II medical device. The approved indication is debridement of non-healing necrotic skin and soft tissue wounds.

04/06/2009: MTAC REVIEW
Maggot Debridement Therapy (MDT)
Evidence Conclusion: There is fair evidence from one RCT that wound debridement is significantly faster with maggot debridement therapy than hydrogel, but that there is no significant difference in time to complete wound healing (Dumville et al., 2009). In the RCT, median time to healing was 236 days in the larvae therapy groups and 245 in the hydrogel group. Time to debridement was 14 days in the group receiving loose larvae, 28 days in the bagged larvae group and 72 days in the hydrogel group. The efficacy of maggot therapy for debridement is supported by the results of a retrospective cohort study, and several case series. The RCT found significantly higher reports of ulcer-related pain in the larvae therapy groups in the 24 hours before removal of the first treatment compared to hydrogel and did not report on pain during subsequent treatments. There is insufficient evidence on the efficacy of maggot therapy for MRSA eradication compared to standard wound care approaches. The number of MRSA-positive wounds in the RCT was too small to draw conclusions about eradication.
Articles: The search yielded two RCTs, one of which had a sample size of 12 patients and was excluded from further review. There was also one non-randomized comparative study and several case series. The larger RCT, cohort study and the three largest case series (n>50) were critically appraised. Citations are as follows: Dumville JC, Worthy G, Bland JM et al. Larval therapy for leg ulcers (VenUS II): randomized controlled trial. BMJ 2009; 338; online first. See Evidence Table. Sherman RA. Maggot versus conservative debridement therapy for the treatment of pressure ulcers. Wound Rep Reg 2002; 10: 208-214. See Evidence Table. Steenvoorde P, Jacob CE, Van Doorn L, Oskam J. Maggot debridement therapy of infected ulcers: patient and wound factors influencing outcome- a study on 101 patients with 117 wounds. Ann R Coll Surg Engl 2007; 89: 596-602. See Evidence Table. Wolff H, Hansson C. Larval therapy- an effective method of ulcer debridement. Clin Exper Dermatol 2003; 134-137. See Evidence Table. Courtenay M, Church JCT, Ryan TJ. Larva therapy in wound management. J Royal Soc Med 2000; 93: 72-73. See Evidence Table.

The use of maggot debridement therapy for the treatment of chronic and infected wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Medihoney Dressing for Wound Management
BACKGROUND
Honey has been used in wound care for thousands of years. The ancient Egyptians, Greeks, Romans, Chinese, and other early cultures used it as a remedy for wounds either alone or in combination with other ingredients. Its healing benefits were passed from generation to generation, and honey is still traditionally used in many parts of the world. Recently there has been a resurgent interest by the medical profession in using topical honey for wound treatment, mainly due to the increasing number of bacterial strains developing resistance to antibiotics. It is only in the last few decades that researchers started to investigate honey's mechanism of action in wound healing (Molan 2008, Lay-flurrie 2008). Honey is a viscous supersaturated sugar solution derived from nectar gathered and modified by the honeybee. It contains approximately 30% glucose, 40% fructose, 5% sucrose, 20% water and many other substances as amino acids, vitamins, minerals, and enzymes. In-vitro and animal studies indicate that honey has several therapeutic potentials. Its high osmolarity due to the sugar content causes bacterial cell wall shrinkage and inhibition of growth. Many bacteria grow and multiply in a neutral pH environment (6.5-7.0) and cannot thrive in the acidic pH of honey which ranges from 3.2 to 4.2. Researchers have reported that it in addition to its antibacterial properties, honey enhances tissue growth by drawing fluid from the underlying circulation providing both a moist environment and topical nutrition to the tissues. They also found that honey leads to cytokine release, promote autolytic debridement, deodorize malodorous wounds, and stimulates anti-inflammatory activity that reduces pain, edema, and exudate, and minimizes scarring (Molan 1999, Sato 2000, White 2005, Bell 2007). There are many different types of honey but the Manuka honey, a monofloral honey derived from the leptospermum tree species known as tea trees in Australia and New Zealand, has received particular interest for wound healing. Some researchers claim that it has a broad-spectrum antibacterial activity and is exceptionally effective for several bacterial species that commonly infect surgical wounds as Staphylococcus aureus and

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Pseudomonas aeruginosa (Lusby 2002, Visavadia 2008). Therapeutic honey is typically raw and does not undergo heat treatment like culinary honey. It is sterilized by gamma irradiation which destroys any bacterial spores while retaining its biologic activities. Honey dressings are available in various commercial preparations such as honey gel ointment, honey-impregnated tulle dressings, honey impregnated calcium alginate dressings, and honey-based sheet hydrogel dressings (Molan 1999, Lusby 2002 Visavadia 2008, Eddy 2008, Lay-flurrie 2008). Derma Sciences Medihoney Dressing with Active Manuka Honey received FDA approval for providing a moist environment conducive to wound healing. These are tulle dressings comprised of 95% Active Manuka Honey and 5% calcium alginate, and are offered in several sizes including 0.5, 1, and 1.5 ounces. According to the FDA, Medihoney dressings are indicated for the management of light to moderately exuding wounds as: diabetic foot ulcers, venous or arterial leg ulcers, partial or full thickness pressure ulcers/sores, first and second partial thickness burns, and traumatic and surgical wounds. Honey dressings should be avoided in patients with a known history of allergy to either honey or bee venom. It was also reported (Lay-flurrie 2008) that patients with diabetes should have their blood sugar monitored as they may be at higher risk of hyperglycemia due to the sugar content of honey.

12/01/2008: MTAC REVIEW
Medihoney Dressing for Wound Management

Evidence Conclusion: To date, there are no published high-quality studies to support the use honey in wound dressings. Jull and colleagues performed a systematic review (Cochrane review) of 19 randomized and quasi-randomized trials to determine the efficacy of honey on the healing of acute and chronic wounds. The meta-analysis had generally valid methodology. However, its strength is only as good as the trials it includes, and the majority was of low methodological quality. Moreover, 11 of the 19 studies were conducted by one and the same author in a single center. There was significant clinical and statistical heterogeneity between the studies which did not enable pooling of the results in the meta-analysis. Overall, the results of subgroup meta-analyses only showed a significant benefit of honey dressings (2 trials, n=992) in reducing time to complete healing of mild to moderate partial thickness burns vs. conventional dressings. The Jull et al's RCT, 2008 compared the effect of Manuka honey dressings to usual care for the treatment of venous ulcers. It was randomized, controlled and multicenter, and analysis was based on intention to treat. However, the trial was open-label, and a range of dressings were used in the control group, which are potential sources of bias. Its results showed no statistically significant differences between the honey dressing and the usual care in rate or time to complete healing. On the other hand, honey dressings were associated with significantly higher rates of overall adverse events, ulcer pain (NNH=7), and ulcer deterioration (NNH=10). Gethin and colleagues' trial compared Manuka honey to hydrogel dressings used for the treatment of venous ulcers. The trial was unblinded, small, and did not recruit the predetermined number of patients required to provide sufficient statistical power. The results of the trial showed no statistically significant differences between the Manuka honey and hydrogel therapy in desloughing the wound (percent of wound area covered by slough), or rate of slough removal in venous ulcers at 4 weeks. There was however, a higher rate of ulcer healing in the Manuka honey group (44%) vs. the hydrogel group (33%) with a risk ratio of 1.38, and NNT =9 in 12 weeks. The authors did not discuss how they defined wound healing. Conclusion: There is insufficient good quality evidence to determine whether the use of Medihoney dressings would improve the rate of healing in acute wounds as burns and traumatic wounds. There is insufficient evidence to determine whether the use of Medihoney improves the rate of healing in chronic wounds including venous ulcers, arterial ulcers, diabetic ulcers, and pressure ulcers.

Articles: The search revealed over 120 articles on the use of honey for wound care. The number of published articles dropped to just over 20 articles when the search was limited to Manuka or Medihoney. Many were review articles or opinion pieces on the benefits of honey in wound management. There was a Cochrane review on honey as a topical treatment of wounds, and a number of RCTs on the use of honey in the treatment of acute wounds due to burns. The majority of the latter trials were conducted in one center, and by one and the same author. The literature on the use of honey for chronic ulcers was limited. There were three RCTs on honey dressings for venous ulcers, two of which were conducted by the same investigators (Gethin and colleagues 2008) among the same group of patients but reported different outcomes. No randomized controlled trials on the use of honey in diabetic foot ulcers, ischemic, or pressure ulcers were identified. There were only very small non-randomized trials, case series and case reports. The Cochrane review and the three trials on the use of honey for venous ulcers were critically appraised: Jull AB, Rodgers A, Walker N. Honey as a topical treatment for wounds Cochrane Database of Systematic Reviews 2008, Isssue4. Art No.: CD005083.DOI10.1002/14651858.CD005083pub2: 16:1085-1100. See Evidence Table. Jull A, Walker N, Parag V, et al. Randomized clinical trial of honey- impregnated dressings for venous leg ulcers. Br J Surg 2008; 85:175-182 See Evidence Table. Gethin G, Cowman S. Manuka honey vs. hydrogel –a prospective, open label, multicenter, randomized controlled trial to compare desloughing efficacy and healing outcomes in venous ulcers. J Clin Nurs 2008; August 23 See Evidence Table. Gethin G, Cowman S. Bacteriological changes in sloughing venous leg ulcers treated with Manuka honey or hydrogel: an RCT. J wound

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Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

Care 2008;17:241-247 See Evidence Table.

The use of Medihoney dressing in the treatment of wound management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

OASIS Wound Dressing

BACKGROUND

OASIS® Wound Matrix (Cook Biotech, Inc.) is a biosynthetic skin substitute that is derived from porcine small intestine submucosa. This material is approximately 0.15 mm thick and consists primarily of a collagen-based extracellular matrix. However, unlike other purified collagen wound care products, biologically important components of the extracellular matrix such as glycosaminoglycans, proteoglycans, fibronectin, basic fibroblast growth factor, and transformind growth factor β are retained in the small intestine submucosa (Barber 2008, Chern 2009, Limová 2010). OASIS® Wound Matrix has a shelf life of 24 months and is FDA approved for use in patients with various partial- and full-thickness wounds such trauma wounds, ulcers, tunneled/undetermined wounds, draining wounds, and surgical wounds. It is not approved for use in patients with third-degree burn or with known allergies to porcine materials. According to the manufacturer's Web site, side-effects of OASIS Wound Matrix include: infection, chronic inflammation, allergic reaction, excessive redness, pain, swelling, and blistering. Additionally, the initial application of the wound dressing may be associated with transient, mild, localized inflammation (Cook Biotech, Inc 2011).

10/11/2000: MTAC REVIEW
OASIS Wound Dressing
Evidence Conclusion: Given the fact that there are no peer-reviewed articles on this topic, there is insufficient (no) evidence to determine the efficacy of this type of the Oasis Cook® wound care dressing.
Articles: Articles were selected based on study type. There were no peer-reviewed articles, so no articles were reviewed. Informational materials on the company's Web site (www.cookgroup.com) were reviewed, but no evidence tables were created.

The use of OASIS Wound Dressing in the treatment of non-healing partial thickness dermal wound does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/20/2011: MTAC REVIEW
OASIS Wound Dressing
Evidence Conclusion: *OASIS® versus usual care* - The first RCT included 50 subjects and compared the efficacy and tolerability of OASIS® Wound Matrix versus petrolatum-impregnated gauze in patients with difficult to heal mixed arterial/venous or venous leg ulcers. Results from this study suggest that patients treated with OASIS® have faster healing times, were more likely to experience complete wound closure, and required fewer dressing changes compared to usual care. Additionally, after 8 weeks patients treated with OASIS® had significantly more granulation tissue compared to usual care. No adverse events were observed in either treatment group. Results from this study should be interpreted with caution as it had several methodological limitations (Romanelli 2010). *OASIS® versus Hyaloskin®* - The second RCT included 54 subjects and compared the effectiveness of OASIS® Wound Matrix versus Hyaloskin® for the treatment of mixed arterial/venous leg ulcers. Results from this study suggest that patients treated with OASIS® Wound Matrix were more likely to experience wound closure compared to patients treated with Hyaloskin®. Additionally, patients treated with OASIS® Wound Matrix reported greater comfort, less pain, and required fewer dressing changes. No adverse events were observed in either treatment group. Results from this study should be interpreted with caution as it had several methodological limitations (Romanelli 2007). *OASIS® plus compression therapy versus compression therapy alone* - The third RCT included 120 subjects and compared the effectiveness of OASIS® Wound Matrix plus compression versus compression therapy alone for the treatment of chronic leg ulcers. The primary outcome was complete wound closure. Results from this study suggest that subjects who received OASIS® Wound Matrix plus compression therapy were significantly more likely to experience complete wound closure compared to standard care plus compression therapy. There was no significant difference in adverse events between the two groups. The most frequently occurring complications were allergic reaction or intolerance to secondary dressing and wound infection. Results from this study should be interpreted with caution as it had several methodological limitations (Mostow 2005). *Conclusion:* Evidence from three RCTs suggest that OASIS® Wound Matrix may be a safe and effective treatment for leg ulcers; however, results from these studies should be interpreted with caution as all of the trials had methodological limitations. For example, two of the trials were funded by the manufacturers of OASIS® Wound Matrix. Only one study performed an intent-to-treat analysis and assessed power and none of the studies provided confidence intervals.

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Articles: The literature search revealed several RCTs that evaluated the safety and efficacy of OASIS® Wound Matrix for the treatment of various partial- and full-thickness wounds. Three recent RCTs were selected for review. Two of these studies were performed by the same investigator. Another trial was excluded because it did not have sufficient power (Niezgoda 2005). The following studies were critically appraised:
Romanelli M, Dini V, and Bertone M. Randomized comparison of OASIS® Wound Matrix versus moist wound dressing in the treatment of difficult-to-heal wounds of mixed arterial/venous etiology. *Adv Skin Wound Care 2010;* 23:34-38. See Evidence Table. Romanelli M, Dini V, Bertone M, et al. OASIS® Wound Matrix versus Hyaloskin® in the treatment of difficult-to-heal wounds of mixed arterial/venous aetiology. *Int Wound J 2007;* 4:3-7. See Evidence Table. Mostow EN, Hataway D, Dalsing M, et al. Effectiveness of an extracellular matrix graft (OASIS® Wound Matrix) in the treatment of chronic leg ulcers. *J Vasc Surg 2005;* 41:837-843. See Evidence Table.

The use of OASIS Wound Dressing in the treatment of non-healing partial thickness dermal wound does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Warm-Up Wound Therapy

BACKGROUND
Noncontact normothermic wound therapy (The Warm-up therapy system) is used for the treatment of partial- and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, surgical wounds, and arterial wounds. Noncontact normothermic wound therapy is intended to speed the healing of wounds and venous ulcers by warming the wound and thereby increasing blood flow and allowing sufficient moisture in the wound to help cells grow and divide. The Warm-up therapy system consists of the following components: a noncontact wound cover, a temperature control unit with an AC adapter and a warming card. The non-contact wound cover is placed over the wound; the cover is raised so it does not touch the wound. It is designed to maintain warmth and humidity and to absorb exudate. There is space to insert the warming card into the wound cover. The temperature control unit, which is portable, controls the temperature of the warming card. The manufacturer recommends three warming sessions per day, heating the wound to 38°C (Augustine Medical Web site). Anodyne Therapy is another treatment for increasing the rate of wound healing; it is also used to treat patients with peripheral neuropathy. Treatment consists of monochromatic near-infrared photo energy (MIRE). The recommended course of treatment is 12 sessions of MIRE. For patients with peripheral neuropathy, the intention is to increase local circulation and restore sensation. MIRE has been shown to increase nitric oxide (NO) in the blood and plasma of normal adults (Horwitz, 1999). An elevation in NO may be beneficial for wound healing and increased circulation.

10/08/2003: MTAC REVIEW
Warm-Up Wound Therapy
Evidence Conclusion: *Noncontact Normothermic Therapy (Warm-up wound therapy)* - Combining the evidence from the current and previous MTAC reviews, four randomized controlled trials comparing Warm-up wound therapy to standard care were critically appraised (McCulloch and Kloth in the current review, Warwick and Price from the 2002 review). All of the studies were subject to selection bias due to the limited sample sizes (the treatment groups are likely to be dissimilar on characteristics that may affect outcome). The Price study had the strongest methodology and did not find a statistically significant difference in healing rates in an intention to treat analysis; the study may have been underpowered. The other three RCTs found statistically significant improvement in healing according to one or more outcome variables, but were subject to biases including improper randomization, lack of intention to treat analysis, potential data manipulation and funding by the manufacturer.
Articles: *Noncontact Normothermic Therapy* - The search yielded 8 articles. There were four new RCTs, sample sizes were n=16, n=20, n=36 and n=40. The two RCTs with the larger sample sizes were critically appraised: McCulloch J, Knight A. Noncontact normothermic wound therapy and offloading in the treatment of neuropathic foot ulcers in patients with diabetes. *Ostomy/Wound Management* 2002; 48: 38-44. See Evidence Table. Kloth LC, Berman JE, Nett M et al. A randomized controlled clinical trial to evaluate the effects of noncontact normothermic wound therapy on chronic full-thickness pressure ulcers. *Adv SkinWound Care* 2002; 15: 270-276. See Evidence Table.

The use of Warm-up Wound Therapy in the treatment of partial and full-thickness wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/10/2002: MTAC REVIEW
Warm-Up Wound Therapy
Evidence Conclusion: Two relatively small RCTs evaluating the efficacy of noncontact normothermic wound therapy (Warm-up® Therapy System) for accelerating the healing rate of pressure ulcers were reviewed. The

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Price study, which had the stronger methodology, found no significant differences in healing rates in an intention to treat analysis. Patients receiving Warm-up wound therapy took an average of 5 fewer days for their wound to be reduced to 25% of original size. This difference was not have been statistically significant, but the study may have been under-powered. Whitney found a statistically significant improvement in the linear rate of healing using Warm-up wound therapy. However, the Whitney study had substantial threats to validity (e.g. no power analysis, substantial dropout; no intention to treat analysis). The absolute difference in healing was 0.008 cm/day. The clinical significance of this difference in healing rates needs to be considered. The two RCTs reviewed had pressure ulcers as the outcome; no conclusions can be drawn about the effectiveness of this treatment for other types of wounds.

Articles: The search yielded 6 articles on this treatment, all of which were empirical and had small sample sizes (most had sample sizes of 20 or less). There were three RCTs with clinical outcomes. One had n=13 and was not reviewed. The other two RCTs (n=40 and n=58) were critically appraised: Whitney JD, Salvadalena G, Higa L, Mich M. Treatment of pressure ulcers with noncontact normothermic wound therapy: healing and warming effects. J WOCN 2001; 28:244-52. See Evidence Table. Price P, Bale S, Crook H, Harding KGH. The effect of a radiant heat dressing on pressure ulcers. J Wound Care 2000; 9:201-205. See Evidence Table.

The use of Warm-up Wound Therapy in the treatment of partial and full-thickness wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Skin Substitutes - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
Q4102	Oasis wound matrix, per sq. cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq. cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq. cm
Q4108	Integra matrix, per sq. cm
Q4110	PriMatrix, per sq. cm
Q4124	OASIS ultra tri-layer wound matrix, per sq. cm
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq. cm
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq. cm
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4151	AmnioBand or Guardian, per sq. cm
Q4168	AmnioBand, 1 mg
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per square centimeter
A4100	Skin substitute, fda cleared as a device, not otherwise specified
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind, per square centimeter
Q4256	Mlg-complete, per square centimeter
Q4257	Relese, per square centimeter
Q4258	Enverse, per square centimeter

Skin Substitutes - Considered not medically necessary:
**There are many products available - this list is not all-inclusive.*

HCPC Codes	Description
A2014	Omeza Collagen Matrix, per 100 mg
A2015	Phoenix Wound Matrix, per sq cm
A2016	PermeaDerm B, per sq cm
A2017	PermeaDerm Glove, each
A2018	PermeaDerm C, per sq cm
C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq. cm

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C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq. cm
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq. cm
C9364	Porcine implant, Permacol, per sq. cm
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq. cm
Q4103	Oasis burn matrix, per sq. cm
Q4106	Dermagraft, per sq. cm
Q4107	GRAFTJACKET, per sq. cm
Q4111	GammaGraft, per sq. cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq. cm
Q4116	AlloDerm, per sq. cm
Q4117	HYALOMATRIX, per sq. cm
Q4118	MatriStem micromatrix, 1 mg
Q4121	TheraSkin, per sq. cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq. cm
Q4123	AlloSkin RT, per sq. cm
Q4125	ArthroFlex, per sq. cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntegoPly, per sq. cm
Q4127	Talymed, per sq. cm
Q4130	Strattice TM, per sq. cm
Q4132	Grafix Core and GrafixPL Core, per sq. cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq. cm
Q4134	HMatrix, per sq. cm
Q4135	Mediskin, per sq. cm
Q4136	E-Z Derm, per sq. cm
Q4138	BioDFence DryFlex, per sq. cm
Q4140	BioDFence, per sq. cm
Q4141	AlloSkin AC, per sq. cm
Q4142	XCM biologic tissue matrix, per sq. cm
Q4143	Repriza, per sq. cm
Q4145	EpiFix, injectable, 1 mg
Q4146	Tensix, per sq. cm
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq. cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq. cm
Q4149	Excellagen, 0.1 cc
Q4150	AlloWrap DS or dry, per sq. cm
Q4152	DermaPure, per sq. cm
Q4153	Dermavest and Plurivest, per sq. cm
Q4154	Biovance, per sq. cm
Q4155	Neox Flo or Clarix Flo 1 mg
Q4156	Neox 100 or Clarix 100, per sq. cm
Q4157	Revitalon, per sq. cm
Q4158	Kerecis Omega3, per sq. cm
Q4159	Affinity, per sq. cm
Q4160	Nushield, per sq. cm
Q4161	bio-ConneKt wound matrix, per sq. cm
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	WoundEx, BioSkin, per sq. cm
Q4164	Helicoll, per sq. cm
Q4165	Keramatrix or Kerasorb, per sq. cm
Q4166	Cytal, per sq. cm
Q4167	Truskin, per sq. cm

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Q4169	Artacent wound, per sq. cm
Q4170	Cygnus, per sq. cm
Q4171	Interfyl, 1 mg
Q4173	PalinGen or PalinGen XPlus, per sq. cm
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4175	Miroderm, per sq. cm
Q4176	NeoPatch, per sq. cm
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	FlowerAmnioPatch, per sq. cm
Q4179	FlowerDerm, per sq. cm
Q4180	Revita, per sq. cm
Q4181	Amnio Wound, per sq. cm
Q4182	Transcyte, per sq. cm
Q4183	Surgigraft, per sq cm
Q4184	Cellesta, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4186	Epifix, per sq. cm
Q4187	Epicord, per sq cm
Q4188	AmnioArmor, per sq cm
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4200	SkinTE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5g/cc), 1cc
Q4203	Derma-Gide, per sq cm
Q4204	XWRAP, per sq cm
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	AlloGen, per cc
Q4213	Ascent, 0.5 mg
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218	SurgiCORD, per sq cm

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Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227	AmnioCoreTM, per sq cm
Q4229	Cogenex Amniotic Membrane, per sq cm
Q4230	Cogenex Flowable Amnion, per 0.5 cc
Q4231	Corplex P, per cc
Q4232	Corplex, per sq cm
Q4233	SurFactor or NuDyn, per 0.5 cc
Q4234	XCellerate, per sq cm
Q4235	AMNIOREPAIR or AltiPly, per sq cm
Q4237	Cryo-Cord, per sq cm
Q4238	Derm-Maxx, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4240	CoreCyte, for topical use only, per 0.5 cc
Q4241	PolyCyte, for topical use only, per 0.5 cc
Q4242	AmnioCyte Plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	AmnioText, per cc
Q4246	CoreText or ProText, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249	AMNIPLY, for topical use only, per sq cm
Q4250	AmnioAmp-MP, per sq cm
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4253	Zenith Amniotic Membrane, per sq cm
Q4254	Novafix DL, per sq cm
Q4255	REGUaRD, for topical use only, per sq cm
Q4259	Celera Dual Layer or Celera Dual Membrane, per sq cm
Q4260	Signature APatch, per sq cm
Q4261	TAG, per sq cm
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2003	bio-ConneKt Wound Matrix, per sq cm
A2004	XCelliStem, per sq cm
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm

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Q4199	Cygnus matrix, per sq cm

Normothermic Wound Therapy – Considered not medically necessary:

HCPC Codes	Description
A6000	Noncontact wound-warming wound cover for use with the noncontact wound-warming device and warming card
E0231	Noncontact wound-warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover
E0232	Warming card for use with the noncontact wound-warming device and noncontact wound-warming wound cover

Low Frequency, Noncontact, Non-Thermal Ultrasound Wound Therapy -
Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare – Considered not medically necessary

CPT Codes	Description
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day

Electrical Stimulation and Electromagnetic Therapy – Considered not medically necessary:

HCPC Codes	Description
E0761	Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
G0281	Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses
G0329	Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
11/25/2002	03/02/2010P[MDCRPC], 01/04/2011P[MDCRPC],11/01/2011P[MDCRPC], 09/04/2012[MDCRPC], 07/02/2013P[MDCRPC], 05/06/2014P[MPC], 12/02/2014P[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/18/2023

[MPC] Medical Policy Committee

Revision History	Description
07/29/2015	Added Medicare language for skin substitutes

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Revision History	Description
10/06/2015	Added new products to indications and non-coverage
08/02/2016	Added new products to the exclusion/non-coverage list
05/02/2017	MPC approved to utilize KP criteria for Skin-Engineered substitutes for Medicare members
01/23/2018	Added the 2018 new HCPC codes Q4176-82
09/27/2018	Added C9360, C9361, C9363, C9364
09/30/2019	Revised skin substitute criteria to meet state mandate requirements
11/05/2019	MPC approved to adopt the revisions to skin substitutes criteria, effective 04/01/2020: specifically updating the list of approved products for diabetic ulcers and venous insufficiency ulcers as directed by the Kaiser Permanente National Surgical Core Group (SCG) and the National Product Council (NPC) as listed in the criteria above
04/07/2020	Added the LCA for Amniotic Derived Skin Substitutes and updated the link to the MLN Matters article on ASC payment for skin substitutes
04/28/2020	Added code Q4195
04/05/2021	Added codes to the “Skin Substitutes - Considered not medically necessary” section
04/06/2021	Removed platelet rich plasma codes as there is a separate criteria page for that service.
04/05/2022	Updated applicable codes. Added LCD/LCA for Wound and Ulcer Care
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
03/03/2023	Updated applicable new codes released 10/01/2022 to the “Skin Substitutes- considered not medically necessary” section including HCPC codes A2014, A2015, A2016, A2017, A2018.
03/06/2023	Updated applicable new codes released 07/01/2022 to the “Skin Substitutes- considered not medically necessary” section including HCPC codes Q4259, Q4260, Q4261.
04/18/2023	Updated Medicare Billing and Coding article link A58567 and A53046

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KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Spinal Decompression Device

- Coflex
- Vertiflex Superion

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13)
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Spinal Distraction Devices (A-0494) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

MCG*are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedic surgeon, orthopedics, chiro, physiatrist, neurosurgeon)
- Most recent back/spine imaging

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Lumbar spinal stenosis refers to the narrowing of the spinal canal resulting in compression of the spinal cord. The decrease in size of the spinal canal is believed to be due to a combination of degenerative processes including bulging of the intervertebral disc, hypertrophy of the ligamentum flavum, facet joint hypertrophy with bone spurring and spondylolisthesis. Symptoms include pain and numbness in the lower back, legs and buttocks after lumbar extension and walking. Symptoms are generally relieved by flexion of the lower back or sitting. Spinal stenosis is the most prevalent diagnosis for spinal surgery; it affects approximately 0.5% of Americans older than 50 (Batt & Carlson, 2006; CTAF technology assessment).

Functional loss associated with lumbar spinal stenosis is typically slow and thus an initial course of non-surgical

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therapy is recommended. Conservative management is particularly indicated for patients with mild to moderate symptoms. Initial recommended therapies are activity modification (e.g. avoiding aggravating activities) and use of oral medications such as NSAIDS and salicylates. Other medications that have been found to be helpful for some patients are oral corticosteroids, tricyclic antidepressants and salmon calcitonin. Epidural steroid injections are another commonly used another conservative treatment. These can reduce the radicular pain associated with acute exacerbations of neurogenic claudication (leg or buttock pain). In addition to the various types of pain relief or pain reduction discussed above, physical therapy can be helpful, especially flexion-based exercises. Surgical treatment, specifically decompression surgery, may be appropriate for selected patients. Patients whose function is limited (e.g. limitations in walking and activities of daily living) are potential surgical candidates. Intractable pain, especially neurogenic claudication, not responding to non-surgical therapies, is another reason for considering surgery. Laminectomy is considered the “gold standard” for decompression in patients with lumbar spinal stenosis (Yuan et al., 2005).

The X-Stop Interspinous Process Decompression System (St. Francis Medical Technologies, Alameda, CA) is proposed as a minimally invasive alternative to surgical treatment of lumbar spinal stenosis in patients with a moderate level of symptoms. Patients with severe symptoms are not eligible to receive this device and may be candidates for laminectomy. X-Stop consists of an oval titanium implant that fits between the adjacent spinous processes at the level of spinal stenosis and a wing assembly that prevents the implant from moving from side-to-side. The spinal processes are thin projections from back of spinal bones to which muscles and ligaments are attached. X-Stop is designed to remain permanently in place without attaching to the bones and ligaments in the back. The device is intended to slightly flex the affected area and to prevent extension to avoid nerve root impingement (manufacturers’ materials; FDA materials; CTAF technology assessment).

The device is usually implanted under local anesthesia with fluoroscopy guidance. The procedure involves making a 4-5 cm midline incision over the spinous processes of the affected levels. An attempt is made to keep the supraspinous and interspinous ligaments intact. The implant size is determined (it is available in 5 sizes) and an appropriately sized implant is inserted. After fastening the wing assembly, the incision is closed (manufacturers’ materials; FDA materials; CTAF technology assessment).

X-Stop was approved by the FDA in November 2005. As specified in the FDA premarket application (PMA) approval letter, X-Stop:

- Is indicated for patients age 50 and older with neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis;
- Is indicated for patients with moderately impaired physical function who experience relief in flexion from leg, buttock and/or groin pain, with or without back pain, and have undergone at least 6 months of non-operative treatment;
- May be implanted at 1 or 2 lumbar levels in patients for whom surgery is indicated (no more than 2 levels).
- Is not currently indicated for patients with mildly impaired physical function.

As part of the approval agreement, the manufacturer agreed to conduct a study on the long-term safety and effectiveness of X-Stop.

Prior to FDA approval, the FDA’s Orthopedic and Rehabilitation Devices Advisory Panel recommended disapproval in August, 2004. A majority of committee members felt that the pivotal clinical trial (discussed below in evidence summary) had substantial threats to validity. After the panel decision, the company submitted additional data to the FDA and defended their study methodology including the use of a relatively new self-report instrument as the primary outcome.

Medical Technology Assessment Committee (MTAC)

X-stop Interspinous Process Decompression System

02/05/2007: MTAC REVIEW

Evidence Conclusion: There is one published RCT that evaluated the safety and effectiveness of the X-Stop system. This was the pivotal clinical trial presented to the FDA. The investigators, who included the device inventors, reported that patients who received the X-Stop had significantly better clinical outcomes than patients receiving non-operative treatment. The study had numerous threats to validity including a lack of blinding, use of subjective outcomes, an inappropriate comparison group and possibly inadequate randomization, and thus provides insufficient evidence for concluding that X-Stop is safe and effective. In addition, there is no comparative pain or functional outcome data beyond two years.

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Articles: The safety and efficacy of the X-Stop system compared to standard treatment for patients with the FDA approved indication for device use. The ideal study would be a randomized, double-blind controlled trial comparing the X-Stop system to the best-accepted alternative treatment or a sham intervention.
The search yielded one unblinded RCT that compared X-Stop with conservative management. There were no double-blind trials or trials comparing X-Stop to a sham intervention. Five publications were identified based on the single RCT. The two articles that reported primary clinical outcomes were critically appraised. Zucherman et al. (2004) reported 1 year outcomes and Zucherman et al., 2005 reported 2 year outcomes. Other publications using RCT data include a case series analysis on a sub-set of treated patients (Kondrashov 2006), another sub-analysis on patients with lumbar degenerative spondylolisthesis (Anderson et al., 2006) and an in-depth look at the quality of life outcomes that were reported in the main outcome papers (Hsu et al., 2006). The secondary publications from the RCT and small case series identified in the search were not reviewed. *The articles that were critically appraised (in a single evidence table) were:* Zucherman JF et al. A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X-Stop interspinous implant: 1-year results. Eur Spine J 2004; 12:22-31. Zucherman JF et al. A multicenter, prospective, randomized trial evaluating the X-Stop interspinous process decompression system for the treatment of neurogenic intermittent claudication: 2-year follow-up results. Spine 2005; 30: 1351-1358. See Evidence Table.

The use of X-stop Interspinous Process Decompression System in the treatment of lumbar spinal stenosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
C1821	Interspinous process distraction device (implantable)
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
03/21/2007	02/05/2007, 05/21/2007 MDCRPC, 04/29/2008 MDCRPC, 02/9/2009 MDCRPC, 12/18/2009 MDCRPC, 09/07/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013MDCRPC, 01/07/2014 MPC, 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/07/2023MPC	02/02/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
04/12/2019	Added Coflex to Medicare Covered Criteria

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02/02/2021	Added Vertiflex Superion product to criteria; removed products that are no longer in the market (DIAM, Wallis, X-Stop) from criteria. Added NCD (150.13) Percutaneous image-guided lumbar decompression for lumbar spinal stenosis for Medicare Members.

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