MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR ROUTINE FOOT CARE

Routine Foot Care, regardless of the provider rendering the service, involves: 1) the cutting or removal of corns and calluses; 2) the clipping, trimming, or debridement of nails; 3) shaving, paring, cutting or removal of keratoma, tyloma, and heloma; and 4) non-definitive, simple palliative treatments like shaving or paring of plantar warts which do not require thermal or chemical cautery and curettage; 5) other hygienic and preventive maintenance care in the realm of self-care, such as cleaning and soaking the feet and the use of skin creams to maintain skin tone of both ambulatory and bedridden patients, and 6) any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

Except when the below criteria are met, routine foot care is excluded from coverage, usually performed by the beneficiary him/herself, or by a caregiver.

DEFINITIONS

Peripheral vascular disease (PVD): any abnormal condition affecting the blood vessels outside of the heart and lymphatic vessels, characterized by signs and symptoms such as numbness, pain, pallor, elevated blood pressure and impaired peripheral pulsations. Examples of PVD include arteriosclerosis and atherosclerosis.

CRITERIA

Qualifying conditions include:

A. Diagnosis and/or treatment is a necessary and integral part of otherwise covered services (e.g. diagnosis and/or treatment of foot ulcers, wounds or infection).

B. Treatment of warts on foot.

C. **The presence of systemic conditions (see list) such as metabolic, neurologic, or peripheral vascular disease and these systemic conditions have resulted in peripheral complications that increase the danger for infection and injury if a non-professional provides the foot care services.

Evidence of the following clinical finding is required to be documented in the medical record:

1) the Class A finding OR
2) two Class B findings OR
3) one Class B finding in addition to two Class C findings):

Class A Finding

- Non-Traumatic amputation of foot or integral skeletal portion thereof or,
Class B Findings

- Absent posterior tibial pulse,
- Three advanced trophic changes such as: hair growth (decrease or absence of), nail changes (thickening), pigmentary changes (discoloration), skin texture (thin, shiny), skin color (rubor or redness),
- Absent dorsalis pedis pulse,

Class C Findings

- Claudication (cramping or pain in leg muscles, related to peripheral vascular disease),
- Temperature changes (e.g. cold feet),
- Edema
- Paresthesias (abnormal spontaneous sensations in the feet),
- Burning

D. Mycotic nails:
   1. In the presence of systemic conditions as noted above in #3.
   2. In the absence of systemic conditions:
      a. Ambulatory patient must have a marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of infected toenail plate.
      b. Non-ambulatory patient suffers from pain or secondary infection resulting from the thickening and dystrophy of infected toenail plate.

E. Diabetic sensory neuropathy with documented loss of protective (LOP) sensation to the feet.

**The diagnoses listed below represent systemic conditions that may result in the need for routine foot care (this list is not exhaustive):

Amyotrophic Lateral Sclerosis (ALS)
Arteriosclerosis obliterans (ASO, arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)
Arteritis of the feet
Buerger’s disease (thromboangiitis obliterans)
Chronic indurated cellulitis
Chronic thrombophlebitis
Chronic venous insufficiency
Peripheral vascular disease
Raynaud’s disease
Diabetes mellitus
Intractable edema secondary to a specific disease (e.g. congestive heart failure, kidney disease, hypothyroidism)
Lymphedema secondary to a specific disease (e.g. Milroy’s disease, malignancy)
Peripheral neuropathies involving the feet:
   - Associated with malnutrition and vitamin deficiency
   o Malnutrition (general, pellagra)

These criteria do not imply or guarantee approval. Please check 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. NOV 19
Alcoholism
- Malabsorption (celiac disease, tropical sprue)
- Pernicious anemia
- Associated with carcinoma
- Associated with diabetes mellitus
- Associated with drugs and toxins
- Associated with multiple sclerosis
- Associated with uremia (chronic kidney disease)
- Associated with traumatic injury
- Associated with leprosy or neurosyphilis
- Associated with hereditary disorders
- Associated with hereditary sensory radicular neuropathy
- Associated with angiookeratoma corporis diffusum (Fabry’s)
- Associated with amyloid neuropathy

SPECIAL GROUP CONSIDERATIONS

Individual and Commercial group (including Feds and PEBB): See member’s summary of benefits for specific coverage information. Procedures and/or services may be excluded by coverage under the member’s medical plan. When covered, medical necessity must be established.

Medicare: No special considerations

Oregon Medicaid: Check Linefinder/Prioritized List

Washington Medicaid: No special considerations

REFERENCES

CLINICAL
1. CMS/NCD for Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (70.2.1)
2. CMS/LCD for Routine Foot Care: L33636 (there is no LCD for OR/WA nor an NCD for Routine Foot Care)

BEAM Policy
https://sites.sp.kp.org/teams/nwreg/NWHP/MABACARE/bp/beampolicy/Pages/BeamPolicyIndex.aspx

These criteria do not imply or guarantee approval. Please check 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. NOV 19
MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SKILLED NURSING FACILITY CARE FOR COMMERCIAL, MEDICAID, AND MEDICARE BUSINESS—see Special Group Considerations for Medicare

Washington Medicaid specific information

DEFINITIONS

Definitions of Skilled Nursing Facility

1. An institution or distinct part of an institution that is primarily engaged in providing skilled nursing care and related services for the rehabilitation of injured, disabled or sick persons, and meets the requirements for participation in # 1819 of the Social Security Act and in regulations 42CFR part 483.

2. For Medicare purposes, the term SNF does not include any institutions that are primarily for the care of mental disease or tuberculosis.

Definition of Benefit for Skilled Services

1. Post-hospital extended care services furnished to inpatients of a skilled nursing facility are covered under the Part A hospital insurance program, commercial plans, and under Oregon and Washington Medicaid benefits.

2. Patients with hospital insurance coverage are entitled to have payment made on their behalf for the reasonable cost of covered extended care services furnished by a skilled nursing facility, or by a hospital with which the facility has a transfer agreement.

3. Part A covers up to 100 days of skilled nursing facility services per each benefit period. Oregon Medicaid Health Plan (OHP) covers up to 20 days of skilled nursing services per each benefit period. Commercial plans have various benefits periods. A benefit period begins with the first day of a Medicare covered inpatient skilled nursing stay, and ends with the close of a period of 60 consecutive days during which the member was neither an inpatient of a hospital or a SNF. As long as the beneficiary continues to be entitled to Part A, or OHP, there is no limit on the number of benefit period(s) he/she may have. There is no limit to the amount of skilled benefit days for Washington Medicaid members as long as they meet medically necessary criteria.

4. Beginning the benefit period: A benefit period begins upon admission to a qualified SNF for skilled care, even though payment for the services cannot be made because the prior hospitalization or transfer requirement has not been met.

5. See Waiver of a Three Day Stay Admission Criteria below for details on the waiver of a three-day qualifying stay.

These criteria do not imply or guarantee approval. Please check 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.
6. Prolonging a benefit period: Beneficiaries who continue to require skilled care after exhausting their 100 days of covered Part A coverage until the close of a period of 60 consecutive days during which the beneficiary was neither an inpatient of a hospital or a SNF at a skilled level of care.

**Covered Skilled Services**

1. Skilled nursing care.
2. Bed and board.
3. Physical Therapy (PT), Occupational Therapy (OT), Speech Therapy (ST).
4. Respiratory services (RT).
5. Medical/Social Services
6. Drugs and biologicals. (See below)
7. Medical services of interns and residents (see regulations for details).
8. Other health services necessary to the health of patients as are generally provided by SNFs (e.g., labs, x-ray, routine personal hygiene items and services).
9. Medical equipment, both standard and complex.
10. Medically necessary ambulance services.

**Covered Drugs and Biologicals**

1. During a covered skilled stay, prescribed drugs and biologicals that are ordinarily furnished by the facility are covered. Three requirements for coverage are:
   a. Must represent a cost to the institution, AND
   b. Must be included in the US Pharmacopoeia, the National Formulary, or the US Homeopathic Pharmacopoeia; or, except for those unfavorably evaluated, in AMA Drug Evaluations Accepted, AND
   c. Must be reasonable and necessary.

2. Drugs not included in the compendia are nevertheless covered if such a drug:
   a. Was furnished during the patient’s prior hospitalization, AND
   b. Was approved by the hospital’s drug therapeutic committee, AND
   c. Is required for the continued treatment in the SNF.

3. Drugs used outside the facility:
   a. If the drug or biological is deemed medically necessary to permit the patient’s departure from the facility, and a supply is required until he/she can obtain a continuous supply, the drugs or biologicals would be covered as an extended care service of the SNF.

**CRITERIA**

Extenuating circumstances around pre-authorization and admission notification is based on the Best Practice Recommendations (BPR) put forth by the Washington Healthcare Forum operated by OneHealthPort, but are applicable to all lines of business in Oregon and Washington. Please see associated Regional UM Policy: UR Policy 70: Extenuating Circumstances Policy at [http://internal.or.kp.org/utilization/](http://internal.or.kp.org/utilization/).

These criteria do not imply or guarantee approval. Please check 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. NOV 19
Pre-Admission Qualifying Criteria (Medicare Part A and Commercial)

A. Entitlement to Part A Medicare or Commercial Kaiser Permanente Health Plan coverage.
B. SNF day(s) available.
C. Care is reasonable and necessary.
D. The need for skilled services is certified/re-certified by a physician (MD), nurse practitioner (NP) or Clinical Nurse Specialist (CNS) (see Timing of Certifications and Re-certifications for frequency).
E. Prior hospitalization: Part A - The patient must have been an inpatient of a hospital for a medically necessary stay of at least three consecutive days. (See Waiver of a Three Day Stay Admission Criteria regarding waiver of this and associated requirements).
F. In addition, the patient must have been either:
   a. transferred to a participating SNF within 30 days after discharge from the hospital (the day of discharge is not counted); or
   b. if period of more than 30 days has elapsed, and the patient’s condition makes it medically inappropriate to begin and achieve a course of treatment within 30 days after hospital discharge AND it is medically predictable at the time of hospital discharge that such care will be required within a pre-determinable time period.
G. The care is related to prior hospitalization (NOTE: “related to” means the condition requiring skilled care was treated during the hospitalization). Or
H. The patient has been evaluated by a physician within the last 7 days in a clinic, emergency room, or in Home Health and skilled care is required to prevent hospitalization.
I. Skilled services (nursing or rehabilitation) must be needed and provided on a “daily basis” i.e., on essentially a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the daily basis requirement when services are needed and received on at least 5 days per week.

Waiver of Three Day Stay Admission Criteria (Medicare Part A)

A. A number of Kaiser Foundation Health Plans have elected to waive the 3-day qualifying stay requirement allowing patients to be directly admitted to a SNF when medically appropriate
B. This waiver means that a SNF stay not preceded by a qualifying stay for the 1876 Cost member must be billed to KFHP not Medicare.
C. Medicare Advantage member admissions are always billed to KFHP.
D. If the Kaiser Permanente (KP) SNF benefit waives the qualifying stay, the 30-day transfer rule and the requirement for the SNF care to be related to the preceding hospital care is also waived.

Pre-Admission Qualifying Criteria (Washington Medicaid)

A. Entitlement with Medicaid managed care organization (MCO).
B. Washington Medicaid covers costs when the patient is not covered by Medicare, another primary insurance, or third party insurance. Medicaid is the payor of last resort.
C. All members are required to have a Preadmission Screening and Resident Review Level I screening (PASRR). This screening looks for indicators of an intellectual disability or a serious mental illness.
D. Care is reasonable and necessary. Covered when the Plan determines that nursing facility care is more appropriate that acute hospital care.
E. The need for skilled services is certified/re-certified by a physician (MD), nurse practitioner (NP) or Clinical Nurse Specialist (CNS) (see Timing of Certifications and Re-certifications for frequency).
F. Skilled services (nursing or rehabilitation) must be needed and provided on a “daily basis” i.e., on essentially a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the daily basis requirement when services are needed and received on at least 5 days per week.

These criteria do not imply or guarantee approval. Please check 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.
G. Services are not covered by DSHS Aging and Long Term Supports Administration.
H. Services are not covered if it is determined to not be medically necessary for rehabilitation.
I. The Plan shall coordinate with the Skilled Nursing facility to provide prescription medications, durable medical equipment, therapies, intravenous medications, and any other medically necessary service or product.

Pre-Admission Qualifying Criteria (Oregon Medicaid)

A. The post hospital extended care benefit must be authorized by pre-admission screening for individuals not enrolled in managed care.
B. SNF days available.
C. Must be receiving Oregon Health Plan benefits and not Medicare eligible.
D. Have a medically necessary, qualifying hospital stay, not including a hold bed, observation bed, or emergency room bed. The stay must consist of three or more consecutive days, not counting the day of discharge.
E. Transfer to a nursing facility within 30 days of discharge from the hospital.
F. Need skilled nursing or rehabilitation services on a daily basis meeting Medicare skilled criteria that may be provided only in a nursing facility.
G. All members are required to have a Preadmission Screening and Resident Review Level I screening (PASRR). This screening looks for indicators of an intellectual disability or a serious mental illness.

Criteria for Skilled Care under Medicare Part A, Commercial and Oregon and Washington Medicaid

A. Skilled means:
   1. The patient requires skilled nursing or skilled rehabilitation services (PT, OT, ST). The patient meets medical necessity criteria.
   2. These services require the skills of technical or professional personnel and are furnished directly by, or under the supervision of such personnel.
   3. These services are required on a daily basis (skilled nursing 7 days per week; skilled therapies at least 5 days per week).
   4. As a practical matter, considering economy and efficiency, the daily skilled services can only be provided on an inpatient basis in a SNF.
B. Specific categories of skilled services are:
   1. Direct care.
   3. Observation and assessment of a patient’s condition.
   4. Teaching and training services.

OTHER CLINICAL REQUIREMENTS

Physician Services in SNF

A. A physician must approve, in writing, a recommendation that an individual be admitted to a facility.
B. Each resident must remain under the care of the physician.
C. Visits: Physician must:
   1. Review the total program of care at each visit.
   2. Write, sign and date progress notes at each visit.
   3. Sign and date all orders.
4. Frequency: Beneficiary must be seen once every 30 days for the first 90 days after admission and at least once every 60 days thereafter. The visits must be timely which means the visit occurs no later than 10 days after the required visit date.

D. The physician must make the initial visit. Thereafter he/she may elect to alternate between personal visits and visits by a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) as permitted by State Law.

E. Physician must be available for emergency care.

F. Physician must certify and/or re-certify to the skilled level of care (also see Physician Delegation below).

**Physician Delegation of Tasks in SNF**

All required physician visits must be made by the physician personally except at the option of the State, the physician may delegate these tasks/visits to a NP, CNS, or PA who is not an employee of the facility, but who is working in collaboration/association with the physician, and is acting within their scope of practice.

Note: A Physician Assistant is not permitted to sign certifications/re-certifications.

**Discharge Planning**

1. The resident must have a discharge summary that includes a post-discharge plan of care that is developed with the participation of the resident and his/her family, and that will assist the resident to adjust to his or her new living environment.

2. DME may be delivered to a facility that does not qualify as the patient’s home, up to 2 days prior to discharge for the purposes of fitting or training. However, suppliers may only bill from date of discharge.

**OTHER ADMINISTRATIVE REQUIREMENTS**

**Certification General Requirements**

A. A physician must approve in writing a recommendation that an individual be admitted to a facility.

B. Each resident must remain under the care of a physician.

C. Certification: A physician must certify in writing that:
   1. The beneficiary needs daily skilled nursing or rehabilitation services which can only be provided in a SNF on an inpatient basis for either the condition for which he/she received inpatient hospital services, or for a condition which arose after transfer while in the SNF for treatment of a condition for which he/she received inpatient hospital services, OR
   2. The individual has been correctly assigned to one of the RUGs designated as representing the required level of care (Part A).

**Re-Certification General Requirements**

A. Re-certification: The physician must recertify to:
   1. The reasons for the continued need for post-hospital SNF care.
   2. The estimated time the individual will need to remain in the SNF.
   3. Plan for home care, if any.
   4. If appropriate, that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he/she had received inpatient hospital services.

B. There is no requirement for a specific procedure or form as long as the approach permits verification that the certification and re-certification requirement is met. They may be entered in forms, notes, or other records that a physician normally signs in caring for the patient, or on a separate form.

These criteria do not imply or guarantee approval. Please check 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.
Certification and Re-certification:

A. The attending physician or a physician on the staff who has knowledge of the case signs certifications and re-certifications.

B. The physician may delegate certification/re-certification to a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but is working in collaboration with the physician.

Note: Per regulation, Physician Assistants may not sign certifications/re-certifications.

Timing of Certifications and Re-certifications

A. Certification: First certification must be made at the time of admission or as soon thereafter as is reasonable and practical.

B. Re-certifications: No later than the 14th day of post-hospital SNF care. Subsequent recertification must be made at intervals not exceeding 30 days.

Change From Skilled to Custodial Level or Exhausted Benefit

A. Beneficiaries who are in a skilled Medicare Part A covered SNF stay, whose physician determines that they no longer require skilled care must be notified in writing via a Medicare Notice of Non-Coverage (NOMNC) prior to discharge to the non-skilled level (Form CMS 10123-NOMNC).

B. Beneficiaries who exhaust their Medicare Part A 100-day benefit and continue to require skilled care are not considered custodial, and must receive a Medicare Notice of Denial of Medical Coverage (CMS-10003-NDMCP).

C. Beneficiaries who are in a skilled commercial covered SNF stay, whose physician determines that they no longer require skilled care and the beneficiary disagrees, or who have exhausted their benefit must be notified in writing via a Concurrent Care Claim Denial Notice.

D. Beneficiaries who are in a Washington Medicaid skilled covered SNF stay, whose physician determines that they no longer meet medical necessity criteria for skilled care, must be notified in writing via a Notice of Denial of Services (Notice 16-2429) if the patient does not agree with the discharge.

E. Beneficiaries who are in an Oregon Medicaid skilled covered SNF stay, whose physician determines that they no longer require skilled care or have exhausted their 20-day benefit, must be notified in writing via a Notice of Action.

Minimum Data Set (MDS)/Resident Assessment (Part A)

A. The Balanced Budget Act (BBA) of 1997 established the Prospective Payment System (PPS) for SNFs. Under the PPS, SNFs are paid a per diem rate by Medicare based on a case-mix using a resident classification system that accounts for the relative resource utilization of different patient types. This classification system, called Resource Utilization Group-III (RUG), assigns beneficiaries to one of 44 RUG groups using assessment data from the Minimum Data Set (MDS).

B. The SNF is required to complete a MDS according to Medicare assessment schedule if they are billing Medicare directly. If the SNF is billing Kaiser Foundation Health Plan, Inc., the first MDS is not due until the 14th day of SNF stay.

Billing Rules (Medicare Part A)

A. Care must be ordered and directed by a physician, AND

B. The care must be furnished for a condition for which the beneficiary received inpatient hospital care, or which arose while receiving inpatient hospital care (see Waiver of Three Day Stay).
C. Under the Prospective Payment System, when the SNF bills Medicare directly, the clinical criteria for covered skilled care must include documentation per the Minimum Data Set assessment (see aspect S1.0 on MDS) and assignment to a payable RUG category.

D. Patients assigned to one of the top 26 RUG categories are PRESUMED to be receiving daily skilled services.

E. Services which are not included in the SNF PPS and for which separate Part B payment must be made:
   1. Cardiac catheterization
   2. CT (computerized tomography)
   3. MRI (magnetic resonance imaging)
   4. Ambulatory surgery
   5. Emergency services
   6. Radiation therapy
   7. Angioplasty
   8. Lymphedema and venous insufficiency
   9. Physician services

F. Medicare Advantage Contract billing requirements:
   1. SNFs bill KFHP
   2. Payment based on contract terms
   3. MDS not required until the 14th day

G. #1876 Cost Contract billing requirements:
   1. SNFs bill Medicare directly
   2. SNFs must abide by Medicare PPS and consolidated billing rules, i.e., MDS assessment schedule and RUG assignment.

Contracts (Medicare Part A and Commercial) KFHP must use a Medicare-certified provider. The SNF must have an active state license.

(Oregon and Washington Medicaid) KFHP must use a Medicaid-certified provider.

SPECIAL GROUP CONSIDERATIONS, WHEN GROUP HAS A SNF BENEFIT
Commercial, FEDs, Oregon Medicaid: None;

Medicare: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary’s lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary’s medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary’s maintenance care needs can be addressed safely and effectively through the use of nonskilled personnel.

Washington Medicaid: Skilled Nursing care is covered for members that meet Milliman Care Guidelines (MCG) for skilled nursing care instead of Medicare criteria. There is no limit to the number of days in a benefit period. The coverage of skilled care will continue as long as the care is medically necessary.

REFERENCES

NCQA
NCQA Standards and Guidelines are updated annually and available by contacting Quality Resource Management at 503-813-3819.

WASHINGTON
RCW 284-43-410 & RCW 483.43.520: Requirement to maintain a documented utilization review program description and written utilization review criteria.

OREGON
OAR 411-070-0033: Post Hospital Extended Care Benefit
ORS 743.804: Requirements to provide criteria and information about utilization management
ORS 743.806: Utilization review requirements for medical services contracts to which insurer not party
ORS 743.807: Utilization review requirements for insurers offering health benefit plans
ORS 743.837: Prior authorization requirements

MEDICARE
Criteria are based on Medicare Standards: SNF Manual CMS Publication 12, Chapter 2, Sections 214 - 214.5.
Medicare Benefit Policy Manual, Chapter 8, Coverage of SNF Services (Rev. 10/13/16).
Note: Kaiser Foundation Health Plan (KFHP) of the Northwest does not require a 3-day hospital stay prior to admission to a Skilled Nursing Facility (SNF).

These criteria do not imply or guarantee approval. Please check 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. NOV 19
MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR HOME HEALTH ADMISSION

CRITERIA-See Special Group Considerations for Medicare-specific information

A. Patients must require skilled and intermittent care which can be safely provided in the home setting with reasonable expectation of clinical improvement or the need for these services are required to maintain the maximum practicable level of function.

Skilled care includes care services such as physical and occupational therapy, speech language therapy, medical and social services. “Skilled care” is care that must be provided by a Registered Nurse (RN), licensed physical or occupational therapist or speech and language pathologist, which is primarily rehabilitative in nature.

“Intermittent care” in general is not performed on a daily basis. In some cases, where daily care is required, it may be provided only for a period of short duration (weeks versus months).

B. Patient is homebound.

For purposes of the statute, an individual shall be considered “confined to the home” (homebound) if the following two criteria are met:

1. Criteria One: The patient must either:
   a. Because of illness or injury - need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence.

   OR

   b. Have a condition such that leaving his or her home is medically contraindicated.

If the patient meets Criteria-One conditions, then the patient must ALSO meet two additional requirements defined below:

2. Criteria Two:
   a. There must exist a normal inability to leave home;

   AND

   b. Leaving home must require a considerable and taxing effort.
If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

- Attendance at adult day centers to receive medical care;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited to furnish adult day-care services in a State, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration.

For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. It is expected that in most instances, absences from the home that occur will be for the purpose of receiving health care treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

OTHER REQUIREMENTS

Decisions for accepting patients for care by the Home Health Department are based on medical, nursing, therapy, and social information provided by the physician responsible for the patient's care and is determined after assessing the member's unique medical condition. Decisions are made by institutional personnel and staff of the Home Health Program.

Considerations Prior to Acceptance of patient for Home Health Services

- There are adequate and suitable department personnel and resources to provide the services required by the patient.
- Attitudes of patient and his family toward his care at home.
- There is a benefit to the patient's health to receive care at home as distinguished from care in a hospital, long-term care facility, or medical office setting.
- There is a reasonable expectation that patient's medical, nursing, therapy and social needs can be met adequately and safely in his residence, including the availability of a plan to meet medical emergencies.
- There are adequate physical facilities and equipment in the patient's residence for safe care.
- There is an assessment whether there is the availability of family or other caregiver in the home, with the ability and willingness to participate in the care and if it is required to assure the patient's safety and adequacy of care.
- There is an assessment of the degree of patient and family awareness of their rights and responsibilities.
• How recently the patient has had contact with the ordering physician.

• Assurance that services can be effectively coordinated through liaison with other organizations and individuals also providing care to the patient.

• Acceptance of any patient by Home Health is at the discretion of Continuing Care Services (CCS), which exists to provide home health services to members of the Kaiser Foundation Health Plan. Medical necessity denials are made by a MD or DO.

CONTRAINDICATIONS

None

SPECIAL GROUP CONSIDERATIONS

See individual member’s summary of benefits for specific coverage information. Procedures and/or services may be excluded under certain service agreements and/or employer group and individual contracts. In all instances, medical necessity must be established for the procedure to be a covered health benefit.

Commercial: None

Medicare: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary’s lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary’s medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary’s maintenance care needs can be addressed safely and effectively through the use of nonskilled personnel.

Washington Medicaid: not applicable

Oregon Medicaid: not applicable

REFERENCES

NCQA

NCQA Standards and Guidelines are updated annually and available by contacting Quality Resource Management at 503-813-3819.

CLINICAL


Northwest Region Utilization Review

UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial, OEBB and PEBB

Department: Surgery
Section: KPNW Region
Applies to: Bariatric Surgery
Review Responsibility: Dr. Andre Leger & Dr. Nathan Bronson, Bariatric Surgery; Terri Graven, RN
Number: UR 10.A
Effective: 3/2000
Reviewed and/or revised: 12/01, 6/02, 2/03, 12/04, 3/05, 3/06, 05/07, 10/07, 01/08, 10/08, 7/09, 11/09, 10/10, 7/11, 7/12, 7/14, 7/15, 8/18, 7/19
Revised 7/11; 7/13; 7/16; 7/17

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR THE BARIATRIC SURGERY PREPARATION PROGRAM (NOTE: admission into the Program, also known as the Severe Obesity Program, is required prior to consideration of bariatric surgery) FOR COMMERCIAL LINES OF BUSINESS

CRITERIA

Patients will be eligible to participate in the preparation process and may be a candidate for bariatric surgery if:

1. Body Mass Index (BMI) is >35 Kg/m2 with one or more serious co-morbid conditions in the following categories:
   a. Sleep apnea requiring treatment with Continuous Positive Airway Pressure (CPAP) or inability to use CPAP with an Apnea/Hypopnea Index (AHI) >15 on sleep study or inability to use CPAP with an AHI >5 and documentation of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, hypertension, ischemic heart disease, or history of stroke;
   b. Congestive heart failure (CHF) or cardiomyopathy with a NW Permanente Cardiologist recommendation for bariatric surgery;
   c. Obesity hypoventilation and PCO2 >45 and a NW Permanente Pulmonologist recommendation for bariatric surgery;
   d. Diabetes mellitus requiring medical therapy that includes insulin or an insulin sensitizing oral agent (e.g., metformin or pioglitazone) or documented intolerance to insulin or insulin sensitizing oral agents or >15 pound weight gain within 2 years of starting insulin therapy or endocrinologist recommendation for bariatric surgery;
   e. Severe hypertriglyceridemia (>1000 mg/dl) requiring medical therapy, which includes fibrate drugs and therapeutic doses of omega-3 fatty acid (6 grams daily), or a NW Permanente Endocrinologist recommendation for bariatric surgery;
   f. Hypertension with blood pressure >140/90 (130/80 in the presence of diabetes or renal disease) documented on two consecutive visits requiring the use of antihypertensive medications, including a diuretic, unless contraindicated;
   g. Extremity edema with ulceration documented by a NW Permanente Primary Care Provider;
   h. Gastroesophageal reflux requiring prolonged medical management documented by a NW Permanente Physician;
   i. Stress incontinence related to obesity and a NW Permanente Urologist or uro-gynecologist recommendation for bariatric surgery;
   j. Pseudotumor cerebri documented by a NW Permanente Neurologist.

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2. BMI is >40 Kg/m² with no co-morbid condition;

AND

3. Be ≥18 years old and general health adequate to tolerate surgery;

AND,

4. Have documentation in the medical record or referral that the member has been previously unsuccessful with medical treatment for obesity. The general expectation is bariatric surgery will not be done until a prior effort to lose weight is made as an adult. Programs attempted prior to adult years do not qualify.

Practitioner documentation in the medical record of one of the following must occur:

a. Minimum of 6 month participation (does not need to be continuous or uninterrupted for 6 months) in a recognized commercial behavioral weight management program. For example, 4 months with Weight Watchers and 2 months with Jenny Craig would meet criteria. The treatment program must include hypocaloric diet changes, nutrition education, physical activity, and behavior change strategies. Acceptable programs include but are not limited to: Weight Watchers or similar behavioral-based programs such as Medifast, Nutrisystem, and/or Jenny Craig. Non-commercial, book-based programs, such as Atkins and Dr. Phil, do not qualify.

b. Minimum of 6 month participation in a Physician, Nurse Practitioner, Physician Assistant, Registered Dietician, or Licensed Behavioral Therapist supervised weight loss program, with or without obesity pharmacotherapy.

c. Three or more primary care visits over a minimum of 6 months with weight management treatment and follow-up plan in the progress note.

d. Participation and completion of at least an 8 week Kaiser Permanente NW health education weight management program.

OTHER REQUIREMENTS

After the bariatric surgery referral, but prior to bariatric surgery, the member must sign and understand the document, "Severe Obesity Evaluation and Management Program Contract for Participation" and complete all program requirements. Surgical clearance must be received.

OTHER CONSIDERATIONS

1. Surgical risk determinations: Individuals with BMI >60 and/or age >60 years are at higher surgical risk. Decisions regarding the appropriateness of surgery will be made individually based on rehabilitation potential and the physician and surgeon’s judgment regarding surgical risk and likelihood of benefit.
2. Revisional bariatric surgery: Patients who have previously had bariatric surgery requesting re-operation for weight loss or severe reflux will be managed individually but will need to meet BMI and co-morbidity requirements. There is no evidence suggesting that performing more aggressive bariatric procedures is indicated for weight regain after procedures with both restrictive and malabsorptive components or impaired absorption of nutrients, such as roux-en-y gastric bypass.

3. Because the most common reason for surgical failure (weight regain) is inappropriate eating behaviors and lack of physical activity, patients will need to have their current behaviors carefully assessed and surgery will not be recommended unless current behaviors are conducive to post-operative success.

CONTRAINDICATIONS
1. Current pregnancy or desire for pregnancy in the next 18 months

2. Alcohol or substance abuse within the last year

3. Uncontrolled major psychiatric disorder. If you suspect the presence of uncontrolled depression, suicidal ideation, paranoid ideation, psychotic disorder, multiple personality disorder or active/untreated eating disorder i.e. bulimia, a NW Permanente Psychiatrist must be consulted pre-referral to ascertain control.

4. Endogenous reasons for obesity i.e. Cushing’s disease

5. Clinical cirrhosis or advanced liver disease is a contraindication to bariatric surgery due to excessive operative mortality. Patients with hepatitis C or chronic active hepatitis B, prior jejunoileal bypass, or chronically abnormal liver tests of any cause should be evaluated with further testing including transaminase levels, tests of hepatic synthetic function (albumin and PT/INR), CBC, and abdominal ultrasound with doppler. If significant abnormalities are found (i.e., ascites, hepatofugal blood flow, splenomegaly, thrombocytopenia, albumin < 3, coagulopathy despite vitamin K replacement, referral to gastroenterology is recommended for further evaluation prior to consideration of bariatric surgery. Although fatty infiltration of the liver and NASH (non-alcoholic steatohepatitis) are the most common causes of abnormal transaminase levels in severely obese patients, persistently abnormal liver tests should have serologic evaluation for chronic viral hepatitis as well as other causes of transaminase elevation.

6. Other conditions that the primary care provider, bariatric surgeon, KPNW consultant, or Severe Obesity Team members feel would raise the risk of surgery to unacceptable levels.

SPECIAL GROUP CONSIDERATIONS-
Commercial (UR10A): Applies to all commercial groups, including Federal, OEBB and PEBB members
Medicare: See UR 10B Medicare MNC for bariatric surgery
Washington Medicaid: Not covered
Oregon Medicaid: See UR 10C OHP MNC

NOTE
Patients requesting repeat bariatric procedures need to have their prior operative records obtained to define post-surgical anatomy. If this is not possible, an upper GI x-ray may be useful. If metabolic, renal, or hepatic complications are present from prior jejunoileal bypass, general surgery referral is
recommended regardless of the BMI status to discuss revision of this operation unless clinical cirrhosis or other conditions are present that would increase operative risk to unacceptable levels.

Patients with mechanical complications stemming from previous bariatric surgeries (i.e. vomiting, obstruction) should be referred to general surgery or gastroenterology for further evaluation.

Patients with intact post bariatric surgical anatomy from previous procedures with both malabsorbtive and restrictive components will not be offered revisional operative procedures (i.e. stomal narrowing, band over bypass or pouch reductions) because of inadequate weight loss or weight regain. Those whose operative anatomy have broken down (i.e. gastric-gastric fistulae) will be considered for revisions as indicated by risk/benefit ratios.

REFERENCES

CLINICAL
1. CMS NCD 100.1 Bariatric Surgery for Treatment of Morbid Obesity
MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BARIATRIC SURGERY PROGRAM MEDICARE LINE OF BUSINESS (FFS and Senior Advantage)

DEFINITIONS
A. Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GR): A variant of the biliopancreatic bypass. Instead of performing a distal gastrectomy, a "sleeve" gastrectomy is performed along the vertical axis of the stomach. The sleeve gastrectomy decreases the volume of the stomach and the parietal cell mass.

B. Roux-en-Y Gastric Bypass (RYGBP): A procedure which restricts the size of the stomach by stapling shut 90% of the lower stomach. The proximal intestinal anatomy is rearranged, thereby bypassing the duodenum.

C. Laparoscopic Adjustable Gastric Banding (AGB): A procedure which involves placing a gastric band around the outside of the stomach. The stomach is not entered.

D. Laparoscopic Sleeve Gastrectomy is an irreversible surgical removal of a large portion of the stomach along the greater curvature in which the stomach is reduced to about 25% of its original size.

MEDICAL NECESSITY CRITERIA
Patients will be eligible to participate in the preparation process and may qualify for bariatric surgery if:

<table>
<thead>
<tr>
<th>Bariatric surgery for Medicare beneficiaries is considered reasonable and necessary for those who:</th>
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<tr>
<td>A. Have a body-mass index (BMI) ≥ 35 kg/m², and</td>
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<tr>
<td>B. Have at least one co-morbidity related to obesity, and</td>
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<tr>
<td>C. Have documentation in the medical record or referral that the member has been previously unsuccessful with medical treatment for obesity (i.e., clearly demonstrating the failure of reasonable non-invasive/non-surgical treatments) with which the member has been compliant.</td>
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These treatments include but are not limited to:

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1. Participation and completion of at least an 8 week Kaiser Permanente NW (KPNW) health education weight management program,

2. Active participation within the 12 months prior to bariatric surgery in a weight-management program that is supervised by a physician or other health care professionals for a minimum of four consecutive months. The weight-management program must include monthly documentation of patient’s weight and BMI, current dietary regimen and physical activity (e.g. exercise program).

**NOTE:** Physician-supervised programs consisting exclusively of pharmacological management are not sufficient to meet this requirement

D. Have a diagnosis that appears on the Medicare list of co-morbid conditions supporting medical necessity for bariatric surgery procedures which includes but is not limited to diabetes, hypertension, cardiac and/or respiratory diseases. Co-morbid conditions, to qualify, must have other (nonsurgical) treatment options exhaustively considered and exercised. The co-morbidity may be controlled or uncontrolled. A controlled comorbidity will not make an individual ineligible for the bariatric surgery program if all other criteria are met.

Providers: see the following Medicare website for a complete list of ICD-10 codes associated with qualifying co-morbidity diagnoses for medically necessary bariatric surgery: https://med.noridianmedicare.com/documents/10546/7933826/Bariatric+Surgery+Coverage+LCD/33e2be08-1adc-42cb-b16c-d9076c11cf92

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**Bariatric surgery complications.**

Procedures that may be covered for treatment of complications are addressed in the EOC Medical Benefits Chart under ‘Services related to noncovered services or items.’

**OTHER REQUIREMENTS**

CMS no longer requires that covered bariatric surgery procedures be performed in facilities that are certified Centers of Excellence.

**CONTRAINDICATIONS**

a. Current pregnancy or desire for pregnancy in the next 18 months.
b. Alcohol or substance abuse within the last year.
c. Uncontrolled major psychiatric disorder. If the presence of uncontrolled depression, suicidal ideation, paranoid ideation, psychotic disorder, multiple personality disorder or active/untreated eating disorder i.e. bulimia is suspected, a NWP Psychiatrist must be consulted pre-referral to ascertain control.
d. Endogenous reasons for obesity i.e. Cushing’s disease.
e. Clinical cirrhosis or advanced liver disease is a contraindication to bariatric surgery due to excessive operative mortality. Patients with hepatitis C or chronic active hepatitis B, prior jejunal-ileal bypass, or chronically abnormal liver tests of any cause should be evaluated with further testing including transaminase levels, tests of hepatic synthetic function (albumin and PT/INR), CBC, and abdominal ultrasound with Doppler. If significant abnormalities are found (i.e., ascites, hepatofugal blood flow, splenomegaly, thrombocytopenia, albumin < 3, coagulopathy despite vitamin K replacement) referral to gastroenterology is recommended for further evaluation prior to consideration of
bariatric surgery. Although fatty infiltration of the liver and NASH (non-alcoholic steatohepatitis) are the most common causes of abnormal transaminase levels in severely obese patients, persistently abnormal liver tests should have serologic evaluation for chronic viral hepatitis as well as other causes of transaminase elevation.

f. Other conditions that the primary care provider, bariatric surgeon, KPNW consultant, or Severe Obesity Team members feel would raise the risk of surgery to unacceptable levels.

g. Procedures determined by CMS to be non-covered because evidence of “reasonable and necessary” is not adequate for coverage:
   1. Open adjustable gastric banding*
   2. Open sleeve gastrectomy;
   3. Open and laparoscopic vertical banded gastroplasty
   4. Intestinal bypass surgery; and,
   5. Gastric balloon for treatment of obesity

Summary: Medicare provides coverage for the laparoscopic gastric sleeve procedures, not the open gastric sleeve, for the conditions listed (diagnoses) that support medical necessity.

SPECIAL GROUP CONSIDERATIONS

Medicare requires patients pursuing bariatric surgery to participate in a thorough multidisciplinary evaluation within six months prior to surgery which includes ALL of the following:

a. an evaluation by a bariatric surgeon recommending surgical treatment, including a description of the proposed procedure(s),

b. a separate medical evaluation from a physician other than a surgeon and preferably the beneficiary’s primary care physician that includes both a recommendation for bariatric surgery as well as a medical clearance for the proposed bariatric surgery,

c. mental health and psychosocial clearance for bariatric surgery by a mental health provider including a statement regarding motivation and ability to follow post-surgical requirements,

d. a nutritional evaluation by a physician or registered dietician.

REFERENCES

CMS Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity
(CAG-00250R)

National Coverage Determination for BARIATRIC Surgery for Treatment of Morbid Obesity 100.1 effective 9/24/13 (National Coverage Determination Manual (NCDM))

Noridian:
https://med.noridianmedicare.com/documents/10546/7933826/Bariatric+Surgery+Coverage+LCD/33e2be08-1adc-42cb-b16c-d9076c11cf92

LCD: https://med.noridianmedicare.com/web/jfb/policies/ncd

*These criteria do not imply or guarantee approval. Please check 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. NOV 19
Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

Requests from KP clinicians for Cardiac Rehabilitation Programs and Intensive Cardiac Rehabilitation Programs are submitted through the HealthConnect referral process for non-Kaiser services. Select patients, per cardiology discretion, might be offered virtual cardiac rehab but can always opt for center-based rehab instead.

DEFINITIONS

Cardiac Rehabilitation is a coordinated sum of interventions required to ensure the best physical, psychological, and social conditions so that patients with chronic or post acute cardiovascular disease may, by their own efforts, preserve or resume optimal functioning in society and, through improved health behaviors, slow or reverse progression of disease. It is a complex, individualized program intended to modify cardiac risk factors through prescribed exercise, education, counseling, and behavioral intervention.

MEDICAL NECESSITY CRITERIA (APPLICABLE TO COMMERCIAL AND MEDICARE MEMBERS)

Members will have been diagnosed with ONE of the following cardiac diagnoses or had ONE of the following cardiac procedures:

- coronary artery bypass surgery
- stable, chronic heart failure with left ventricular ejection fraction of \(<45\) and New York Heart Association Class II to IV symptoms (including patients with a ventricular assist device) despite being on optimal heart failure therapy \(>6\) weeks. Stable patients are defined as those who have not had recent \(<6\) weeks) or planned \(<6\) months) major cardiovascular hospitalizations or procedures.

- acute myocardial infarction (MI) within the preceding 12 months
- current stable angina pectoris
- heart valve repair or replacement
- percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- heart or heart-lung transplant

OTHER REQUIREMENTS

Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Programs must include the following components:

- Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
- Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to patients’ individual needs;
- Psychosocial assessment;

These criteria do not imply or guarantee approval. Please check 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.
d. Outcomes assessment; and

An individualized treatment plan detailing how components are utilized for each patient.

OTHER REQUIREMENTS- APPLICABLE TO MEDICARE MEMBERS ONLY

Cardiac rehabilitation and intensive cardiac rehabilitation items and services must be furnished in a physician’s office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times during which items and services are being furnished under the program.

a. Unmonitored exercise programs are not considered to be medically indicated and are not authorized.

b. The program must be a graded exercise program, incorporating some educational components and monitored by a healthcare professional.

c. The facility meets the definition of a hospital outpatient department or a physician directed clinic i.e., a physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician.

d. The facility has available for immediate use the necessary cardio-pulmonary, emergency, diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.

e. The program is conducted in an area set aside for the exclusive use of the program while it is in session.

f. The program is staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary (heart) disease. Services of non-physician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted.

CONTRAINDICATIONS

NOTE: Coverage for cardiac rehabilitation can not be denied for a Medicare member based on the existence of a contraindicated condition. When medical necessity criteria and the facility/program requirements are met, coverage for Medicare members must be authorized. It is up to the prescribing practitioner to determine if a co-existing condition contraindicates the provision of cardiac rehabilitation.

Cardiac rehabilitation should not be used when the following conditions exist (for review of Commercial members only):

a. unstable angina defined as chest, neck, intrascapular or bilateral or unilateral arm discomfort felt to represent angina that occurs at rest or awakens a patient from sleep, or that is occurring on a more frequent basis than the patient’s baseline frequency.

b. uncontrolled hypertension:
   - resting systolic blood pressure >200 mm Hg
   - resting diastolic blood pressure >110 mm Hg

c. symptomatic aortic stenosis- severe aortic stenosis w chest pain (angina) or tightness with activity; feeling faint or dizzy or fainting with activity; symptoms of congestive heart failure.

d. acute systemic illness or fever

e. uncontrolled atrial arrhythmia defined as a ventricular response over 100 beats per minute at rest, within the last 30 days.

f. uncontrolled ventricular arrhythmia defined as 1) a ventricular rhythm associated with symptoms of chest pain, dizziness, light-headedness, presyncope, syncope or shortness of breath, within the last 60 days OR 2) a ventricular rhythm detected by an automatic implantable cardioverter-defibrillator (AICD) that required anti-tachycardia pacing (ATP) or AICD discharge, within the last 60 days.

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g. uncontrolled sinus tachycardia (>120 bpm)
h. uncompensated heart failure— a sudden worsening of the signs and symptoms of heart failure, which typically includes difficulty breathing (dyspnea), leg or feet swelling, and fatigue.
i. third degree atrioventricular block (without a functioning pacemaker)
j. active pericarditis or myocarditis
k. recent venous thromboembolism (DVT or PE) within the last 2 months

SPECIAL GROUP CONSIDERATIONS

OR/WA Medicaid: These criteria do not apply, refer to the specific criteria for these populations.

Medicare:
As specified at 42 CFR 410.49(f)(1), cardiac rehabilitation program sessions are limited to a maximum of two 1-hour sessions per day for up to 36 sessions over or up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor.

Intensive cardiac rehabilitation programs must be approved by Medicare. In order to be approved, a program must demonstrate through peer-reviewed published research that it has accomplished one or more of the following for its patients:

- Positively affected the progression of coronary heart disease;
- Reduced the need for coronary bypass surgery; and/or
- Reduced the need for percutaneous coronary interventions.

An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

- Low density lipoprotein;
- Triglycerides;
- Body mass index;
- Systolic blood pressure;
- Diastolic blood pressure; and
- The need for cholesterol, blood pressure, and diabetes medications.

CLINICAL

1. Pub 100-04, Medicare Claims Processing Manual; Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Programs Furnished On or After January 1, 2010.
2. MCG; Ambulatory Care- Cardiac Rehabilitation (contraindications)
3. Medicare Decision memo for Cardiac Rehabilitation (CR) Programs- Chronic Heart Failure (CAG-00437N), February 18, 2014.
4. LVEF threshold of ≤45% is based on the Heart Failure Reduced Ejection Fraction used by the American College of Cardiology and the American Heart Association.
DEFINITIONS

Pulmonary Rehabilitation is a multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and independence.

MEDICAL NECESSITY CRITERIA

A. Diagnosis of moderate to very severe chronic obstructive pulmonary disease (COPD), defined as GOLD classification II, III and IV, when referred by the physician treating the chronic respiratory disease; or,

B. Preoperative or postoperative for lung transplant or resection

C. Interstitial lung diseases (especially idiopathic pulmonary fibrosis)

D. Bronchiectasis

E. Pulmonary arterial hypertension

F. For other diagnoses for which pulmonary rehab may be indicated, the pulmonologist will provide evidence-based references supporting its approval.

OTHER REQUIREMENTS:

Pulmonary Rehabilitation Programs must include the following components:

a. Physician-prescribed exercise. Some aerobic exercise must be included in each pulmonary rehabilitation session (Respiratory Therapists who see patients under case management may order Pulmonary Rehab under the Pulmonology doctor-of-the-day);

b. Education or training closely and clearly related to the individual’s care and treatment which is tailored to the individual’s needs, including information on respiratory problem management and, if appropriate, brief smoking cessation counseling;

c. Psychosocial assessment;

d. Outcomes assessment; and

c. An individualized treatment plan detailing how components are utilized for each patient.
Pulmonary rehabilitation items and services must be furnished in a physician’s office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times during which items and services are being furnished under the program.

**CONTRAINDICATIONS** (THESE ARE NOT MEDICARE APPROVED, APPLY TO COMMERCIAL MEMBERS ONLY)

**NOTE:** Coverage for pulmonary rehabilitation cannot be denied for a Medicare member based on the existence of a contraindicated situation/condition. When medical necessity criteria and the facility/program requirements are met, coverage for Medicare members must be authorized. It is up to the prescribing practitioner to determine if a co-existing condition contraindicates the provision of pulmonary rehabilitation.

a. The patient has not quit smoking or will not participate in smoking cessation activities prior to or during the course of pulmonary rehabilitation services (including tobacco, marijuana and vaping);  
b. The patient is not physically able, motivated or willing to participate;  
c. There is no expectation of measurable improvement in a reasonable and predictable time frame;  
d. Presence of unstable cardiac disease;  
e. Presence of active pulmonary infection (excludes COPD exacerbation);  
f. Presence of unstable pulmonary hypertension.

**SPECIAL GROUP CONSIDERATIONS**

Medicare: As specified at 42 CFR 410.47(f), pulmonary rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if medically necessary. Contractors shall accept the inclusion of the KX modifier on the claim lines as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond the 36 sessions is medically necessary up to a total of 72 sessions for that beneficiary.

**CLINICAL REFERENCES:**

1. Pub 100-02 Medicare Benefit Policy; Pulmonary Rehabilitation Program Services Furnished On or After January 1, 2010.  
2. MCG; Ambulatory Care- Pulmonary Rehabilitation (contraindications) 22nd Edition.
MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR PRIVATE DUTY NURSING

PURPOSE

The purpose of these criteria is to define KFHPNW coverage of private duty nursing (PDN) for patients who require complex, long-term care for a condition of such severity and/or complexity that continuous skilled nursing care is required. Persons with medically intensive needs require more individual and continuous care than is available from an intermittent visiting nurse. PDN services are considered supportive to the care provided to the patient by family members or guardians and are decreased as the family/guardian or other caregiver becomes able to meet the patient’s needs or when the patient’s needs diminish. PDN services must be performed by a Registered Nurse or a Licensed Practical Nurse under the direction of a physician. The patient can still receive other home health services such as therapies. The goal is to avoid institutionalization and to maintain or improve the recipient’s function level in a home setting.

PDN consists of at least four, but no more than sixteen hours per day (see exceptions) of continuous skilled nursing services, restricted to the least costly, equally effective amount of care. The cost of PDN does not exceed the cost of institutionalized care.

These criteria were developed by the Washington Administrative Code and the Division of Developmental Disabilities, an organization within the Department of Social and Health Services of Washington.

Note that separate criteria exist for coverage of intermittent home health services.

CRITERIA

To be eligible for private duty nursing (PDN), the patient must meet 1 or 2, in addition to 3-9 below:

1) must be 18 years old or older and dependent upon technology every day with at least one of the following skilled care needs (based on WAC 388-106-1010):
   a) mechanical ventilation
   b) complex respiratory support, requiring at least two of the following treatment needs:
      (i) postural drainage and chest percussion;
      (ii) application of respiratory vests;
      (iii) nebulizer treatments with or without medications;
      (iv) intermittent positive pressure breathing;
      (v) O2 saturation measurement with treatment decisions dependent on the results; or

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(vi) tracheal suctioning.

c) intravenous/parenteral administration of multiple medications, and care is occurring on a continuing or frequent basis; or

d) intravenous administration of nutritional substances, and care is occurring on a continuing or frequent basis.

2) must be 17 years old or younger and dependent upon at least one of the following skilled care needs every day (based on WAC 182-551-3000):

   a) skilled assessments (e.g. respiratory assessment, patency of airway, vital signs, feeding assessment, seizure activity, hydration, level of consciousness, constant observation for comfort and pain management);

   b) administration of treatment related to technological dependence (e.g. ventilator, tracheotomy, BIPAP (bilevel positive airway pressure), IV (intravenous) administration of medications and fluids, feeding pumps, nasal stints, central lines);

   c) monitoring and maintaining parameters/machinery (e.g. oximetry, blood pressure, lab draws, end tidal CO2s, ventilator settings, humidification systems, fluid balance, etc);

   d) interventions (e.g. medications, suctioning, IVs, hyperalimentation, enteral feeds, ostomy care, tracheostomy care).

3) must otherwise require care in a hospital or meet nursing facility level of care; and

4) must have unmet skilled nursing needs that cannot be met in a less costly program or less restrictive environment; and

5) must have a complex medical need that requires four or more hours every day of continuous medically necessary skilled nursing care that can be safely provided outside a hospital or nursing facility; and

6) must have a caregiver who is authorized and able to supervise the care; and

7) must have a family member or other appropriate caregiver who is responsible for assuming a portion of the care; and

8) must be medically stable and appropriate for PDN services.

9) the cost of PDN does not exceed the cost of institutionalized care.

Exceptions to the 16-hour maximum per day:
The utilization reviewer may authorize additional hours for a maximum of 30 days if any of the following apply:

- The family or guardian is being trained in care and procedures;
- There is an acute episode that would otherwise require hospitalization and the treating physician determines that non-institutional care is still safe for the patient;
- The family or guardian caregiver is ill or temporarily unable to provide care;
- There is a family emergency; or
- The Agency or its designee determines it is medically necessary.

SPECIAL GROUP CONSIDERATIONS

Commercial plans, Medicare and FEHB all exclude coverage of private duty nursing and continuous nursing services in the home.

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REFERENCES

Molina Healthcare Provider Manual:
http://www.molinahealthcare.com/providers/nm/medicaid/manual/Pages/PrivateDutyNursing.aspx

Molina Benefits at a Glance:

WA Medicaid Managed Care Guidance (WA Apple Health):

WAC 388-106-1010 (Medicaid funded PDN for 18 years and older)
WAC 182-551-3000 (Medicaid funded PDN for 17 years and younger)

These criteria do not imply or guarantee approval. Please check 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. NOV 19
MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR FEMALE REDUCTION MAMMOPLASTY FOR COMMERCIAL LINES OF BUSINESS

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

Cosmetic Services (as defined under the Exclusions section of the Evidence of Coverage): Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

CRITERIA

Please cross reference UR 65 Transgender Surgery criteria for transgender individuals having F2M procedures.

Relevant history and physical findings must establish medical necessity, including all of the following:

1. The member must have two or more of the following conditions present for at least 6 months, with documented failed therapeutic measures i.e. weight loss strategies, supportive garments, and dermatologic measures:
   a. Upper back pain, from breast size
   b. Persistent breast pain (not relieved with hormonal adjustments or analgesics)
   c. Rash under breast (unresolved with dermatologic therapies)
   d. Painful bra strap grooves
   e. Shoulder pain from breast size
   f. Neck pain from breast size
   g. Arm pain from breast size

2. Breast size D cup bra size or above

3. Body Mass Index (BMI) less than or equal to 34

4. Predicted removal of the following:
   a. Minimum of 200 grams of breast tissue from the larger of the two breasts when BMI is less than 25;
   b. Minimum of 250 grams of breast tissue from the larger of the two breasts when BMI 25-30
   c. Minimum of 450 grams of breast tissue from the larger of the two breasts when BMI is greater than 30

5. Must have a normal mammogram within the past year in women 40 years or older.

These criteria do not imply or guarantee approval. Please check 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.
6. Members who smoke must be actively involved in a smoking cessation program and must be smoke-free for a minimum of 30 days prior to surgery.

CONTRAINDICATIONS

1. Active smoker with no plans to quit smoking.
2. Obesity is also a risk factor for poor surgical outcome. Members who are obese but otherwise meet the above medical necessity criteria will be assessed on a case by case basis.
3. Surgical contraindications will be surgeon determined.

SPECIAL GROUP CONSIDERATIONS

Policy applies to all Commercial groups

This policy does not apply to OR or WA Medicaid

This policy does not apply to Medicare, see UR 20.5 Breast Reduction (Female and Male)

If the reduction mammoplasty is to reduce the size of a normal breast, with breast reconstruction after cancer surgery and is governed by the WHCRA (Women’s Health and Cancer Rights Act), the reduction is covered and is not considered to be included in these breast reduction criteria.

CLINICAL

9. Medicare Coverage Database: LCD for Mammaplasty, Reduction (L15600)
11. Padubidri, Arvind N. MD; Yetman, Randall MD; Browne, Earl MD; Lucas, Armand MD; Papay, Frank MD; Larive, Brett MS; and Zins, James MD, (2001), Complications of Postmastectomy Breast Reconstruction in Smokers, Ex-smokers, and Nonsmokers. Plastic & Reconstructive Surgery, 107(2) 342-349

WHCRA (Women’s Health and Cancer Rights Act)

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR PANNICULECTOMY AND REMOVAL OF EXCESS/REDUNDANT SKIN

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

MEDICAL NECESSITY CRITERIA

DEFINITIONS

a. Panniculectomy: The excision of an apron of abdominal subcutaneous fat that lacks adequate supportive tissue in people who are or had been morbidly obese.


c. Cosmetic Services (as defined under the Exclusions section of the Evidence of Coverage): Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

CRITERIA FOR ABDOMINAL PANNICULECTOMY

Patient must meet all of the following:

1. The pannus hangs below the level of the mons and completely covers the mons on front view.
2. The pannus interferes with activities of daily living.
3. Patient’s weight has reached a stable plateau for at least 6 months, AND 1 or more of the following:
   - Adherence to multidisciplinary nonsurgical program of weight maintenance
   - One year or more has elapsed following bariatric surgery.(7)(8)

CRITERIA FOR REMOVAL OF EXCESS/REDUNDANT SKIN OR TISSUE (other than abdominal fat/panniculus)

Patient must have one or more of the following, with documented failed therapeutic measures and/or functional compromise as stated below:

1. Documented recurrent or chronic rashes, infections, cellulitis, or non-healing ulcers that do not respond to dermatologic management for a period of 3 months, per dermatology consultation, OR
2. Documented difficulty with ambulation/function and interference with Activities of Daily Living (ADLs), per physiatry consultation.

These criteria do not imply or guarantee approval. Please check 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.
OTHER REQUIREMENTS

Difficult surgical access, where the excess skin will interfere with surgery, requires referring physician to talk with the Plastic Surgeons prior to referral.

Relevant history and physical findings establishing medical necessity must be documented, including consultations and/or visits with dermatology and/or physiatry.

Panniculectomy or abdominoplasty, with or without diastasis recti repair, for the treatment of back pain is considered not medically necessary.

Cosmetic services (see definition above) are specifically excluded by the members’ benefit coverage. This exclusion does not apply to services that are covered under “Reconstructive Surgical Services” or services that are medically necessary.

CONTRAINDICATIONS

Active smoker (defined as someone who has not refrained from smoking for at least 30 days prior to surgery).

SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial and Federal groups, Medicare, WA Medicaid
Oregon Medicaid: subject to eligibility on OHP Linefinder

REFERENCES

NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

CLINICAL

8. Taber’s Cyclopedic Medical Dictionary” (Taber’s: F.A. Davis Company) 2004

These criteria do not imply or guarantee approval. Please check 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. NOV 19
MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SCAR REVISION

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

Cosmetic Services (as defined under the Exclusions section of the Evidence of Coverage): Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

MEDICAL NECESSITY CRITERIA

When a scar revision meets one of the criteria listed below it will be covered as a form of reconstructive surgery. (Determinations which are considered cosmetic services are not covered.)

1. To correct significant disfigurement resulting from an injury or from medically necessary surgery;
2. To treat congenital vascular lesions such as port wine stains on the face for members age 18 or younger;
3. To complete all stages of breast reconstruction following a mastectomy, including surgery to the unaffected breast to produce a symmetrical appearance, and treatment of physical complications including lymphedemas;
4. To correct a congenital defect, disease, or anomaly in order to produce significant improvement in physical function.

OTHER REQUIREMENTS

Cosmetic services (see definition above) are specifically excluded by the members' benefit coverage. This exclusion does not apply to services that are covered under “Reconstructive Surgical Services” or services that are medically necessary.

SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial and Federal groups, Medicare, WA Medicaid
Oregon Medicaid: subject to eligibility on OHP Linefinder

REFERENCES

NCQA

NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

These criteria do not imply or guarantee approval. Please check 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.

These criteria do not imply or guarantee approval. Please check 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.
MEDICAL NECESSITY CRITERIA FOR GYNECOMASTIA SURGERY

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

Definition of Cosmetic Services under the Exclusions section of the EOC (member’s contract) states: Cosmetic Services are those services intended primarily to change or maintain appearance and will not result in significant improvement in physical function.

CRITERIA

1. Endocrinology assessment completed by primary care, with consultation by endocrinology or pediatric endocrinology if appropriate.
2. Physical exam completed including breast and testicular exam.
3. Documentation indicating no offending medications, including anabolic steroids and/or illicit substances such as marijuana are contributing to the gynecomastia.\(^\text{12,17}\)
4. Documentation indicating no other medical conditions such as renal failure, cirrhosis, endocrine problems, testicular or other HCG (human chorionic gonadotropin) secreting cancer, or malnutrition and refeeding are contributing to the gynecomastia.\(^\text{1,17}\)
5. Failed conventional medical treatments including stopping offending medications/substances, treating reversible medical conditions, using pain medications or consideration of 6 to 12 week trial of tamoxifen in appropriate candidates.\(^\text{1,14}\)
6. Minimum age 15 or completed or nearly completed puberty.\(^\text{1,12}\)
7. Firm subareolar or glandular breast tissue > 4 cm in diameter, present x 2 yrs in adolescents and stable x 1 yr in adolescents and adults (>18 yrs)
8. BMI less than or equal to 34.\(^\text{5,15,18}\)
9. Nonsmoking at least 30 days.

These criteria do not imply or guarantee approval. Please check 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. NOV 19
CONTRAINDICATIONS

a. Illicit substance use/anabolic steroid abuse and/or any use of offending medications \textsuperscript{12,17}

b. Active smoker with no plans to quit smoking. To be referred for gynecomastia surgery, the member must be actively involved in a smoking cessation program AND must be smoke free for a minimum of 30 days prior to surgery \textsuperscript{3}

SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial and Federal groups, Medicare, WA Medicaid
Oregon Medicaid: subject to eligibility on OHP Linefinder

REFERENCES

NCQA
NCQA Standards and Guidelines, Utilization Management, updated annually and available by contacting Quality Resource Management at 503-813-3850.

CLINICAL INFORMATION

1. Gynecomastia (enlargement of the male breast) is usually benign. \textsuperscript{1}

2. Most cases of gynecomastia result from an imbalance between estrogenic (stimulatory) and androgenic (inhibitory) effects on the breast. \textsuperscript{1}

3. Occurrences may appear during puberty, followed by a decline in late teen years and among men ages 50-80. \textsuperscript{1}

4. Pseudogynecomastia (fatty breasts) is common in obese men and needs to be differentiated from true gynecomastia. In true gynecomastia there may be a button of firm subareolar tissue, or there may be a more diffuse collection of fibroglandular tissue. \textsuperscript{1}

5. Absolute estrogen excess which contributes to gynecomastia: Leydig cell tumors, estrogen-producing adrenal tumors, tumors producing chorionic gonadotropin. \textsuperscript{1}

6. Relative estrogen excess which contributes to gynecomastia: primary hypogonadism, Klinefelter syndrome, secondary hypogonadism, puberty, refeeding syndrome, renal failure and dialysis, cirrhosis of the liver, hyperthyroidism \textsuperscript{1}

7. Drugs which contribute to gynecomastia include, but are not limited to: histamine H\textsubscript{2}-receptor blockers, phenytoin, digoxin, spironolactone, nifedipine, reserpine and other cardiovascular drugs, diethylstilbestrol, testosterone antagonists, flutamide, leuprolide, finasteride, diazepam, tricyclic anti-depressants, phenothiazine, risperidone, haloperidol, alcohol, amphetamines, marijuana, heroin, methadone, anti-tuberculosis drugs, cytotoxic agents. \textsuperscript{2,12,17}

8. Herbal products that can cause gynecomastia include lavender oil or tea tree oil. \textsuperscript{2}

9. Lab screening should include: thyroid function, liver enzymes, serum creatinine, serum total testosterone, serum beta-hCG and may also include estradiol, LH, FSH, and prolactin, serum DHEA-S or urine 17-keto-steroids as directed by endocrinology or per practice resource algorithm. \textsuperscript{1}

10. Glandular tissue of more than 4 cm in diameter is unlikely to regress spontaneously. \textsuperscript{17}

11. Gynecomastia may cause considerable psychological distress, especially in adolescents who are struggling with issues relative to sexual identity and self-image. If neither reassurance nor medical treatment is successful, surgery should be considered. \textsuperscript{17}
12. Tamoxifen at 10 mg bid for 6 to 12 weeks has been shown to be helpful in several small studies in adolescents and adults. It is usually more effective early in the course of gynecomastia and is less likely to be helpful in long established gynecomastia. Although this is not an FDA approved indication, it is suggested as an option for adolescents and adults in UpToDate and other references if symptoms are significant and persistent. Testosterone is the appropriate treatment in hypogonadal men with gynecomastia. Tamoxifen should not be used in these patients. 2, 6, 12, 14, 16, 19

Evidence/Source Documentation
1. Bembo, Shirley A. MD; Carlson, Harold E. MD “Gynecomastia: Its features, and when and how to treat it” Cleveland Clinic Journal of Medicine, 71(6) (June 2004) pp 511-517
4. Columbo-Benkmann, Mario MD, PhD.; Buse, Benedikt, MD; Stern, Josef MD, Herfarth, Christian MD. “Indications for and Results of Surgical Therapy for Male Gynecomastia”
10. Lawrence, Sarah E MD; Faught, Arnold, MD, Vethamuthu Md; Lawson, MD “Beneficial Effects of Raloxifene and Tamoxifen in the Treatment of Pubertal Gynecomastia”
13. Macmillan, Douglas MD; Dixon, Michael MD. “Gynaecomastia: when is action required”


22. Wiesman, Irvin M, MD; Lehman, Jr. James A. MD; Parker, MD; Tantri, M. Devi Prasad MD; Wagner, Douglas S, MD; Pederson, John C. MD “Gynecomastia: An Outcome Analysis”, Annals of Plastic Surgery 53(2), (August 2004 )pp 97-101
## MEDICAL NECESSITY CRITERIA FOR MEDICARE PLASTIC SURGERY BREAST REDUCTION

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

### DEFINITIONS

- **Breast hypertrophy** - an increase in the volume and weight of breast tissue (one-sided hypertrophy may result in symptoms following mastectomy of the opposite breast).
- **Gynecomastia** - enlargement of breast tissue in males.
- **Macromastia** - abnormally large breasts.

Cosmetic Services, as defined in the Exclusions section of the EOC (member’s contract), are those services intended primarily to change or maintain appearance and will not result in significant improvement in physical function. Cosmetic surgery to reshape the breasts to improve appearance is not a Medicare benefit. Cosmetic signs and/or symptoms would include ptosis (drooping), poorly fitting clothing and beneficiary perception of unacceptable appearance.

### MEDICAL NECESSITY CRITERIA:

Medicare’s medical necessity criteria for reduction mammoplasty (breast surgery) are limited to circumstances in which:

- **A.** There are signs and/or symptoms resulting from the enlarged breasts (macromastia) that have not responded adequately to non-surgical interventions.
- **B.** To improve symmetry following cancer surgery on one breast.
- **C.** The signs and/or symptoms have been present for **at least** six months.
- **D.** Medical treatment and/or physical interventions have not adequately eased symptoms.
- **E.** Please refer to diagnoses section below – diagnoses requirements must be met.

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These criteria do not imply or guarantee approval. Please check 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. **NOV 19**
Diagnoses:

<table>
<thead>
<tr>
<th>Group I - Primary Diagnosis</th>
<th>Group I - Secondary Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertrophy of the breast - Gynecomastia, or</td>
<td>Mastodynia (breast pain), or</td>
</tr>
<tr>
<td>Hypertrophy of the breast - Not Otherwise Specified, or</td>
<td>Other specified erythematous (redness of the skin) conditions, or</td>
</tr>
<tr>
<td>Hypertrophy of the breast - Massive Pubertal</td>
<td>Pain in joint involving shoulder region, or</td>
</tr>
<tr>
<td></td>
<td>Cervicalgia (neck/cervical spine pain), or</td>
</tr>
<tr>
<td></td>
<td>Pain in thoracic spine, or</td>
</tr>
<tr>
<td></td>
<td>Rash and other non-specified skin eruption, or</td>
</tr>
<tr>
<td></td>
<td>Backache, unspecified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group II - Primary Diagnosis</th>
<th>Group II - Secondary Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant neoplasm of the nipple and areola of female breast (which includes) Malignant neoplasm of the breast (female) - unspecified site, or</td>
<td>After care following surgery for neoplasm</td>
</tr>
<tr>
<td>Personal history of malignant neoplasm of breast</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** There are No BMI (Body Mass Index) requirements.

**Medicare Documentation Requirements:** Medical documentation prior to referral must include all diagnostic/therapeutic measures attempted, objective member findings, and any response to treatments attempted.

**Additional Comments:** For Medicare purposes, a reasonable and necessary reduction mammoplasty could be indicated in the presence of significantly enlarged breasts and the presence of at least one of the following signs and/or symptoms:

A. Back pain from macromastia and unrelieved by ALL:
   1. Conservative analgesia
   2. Supportive measures (garment, etc.)
   3. Physical Therapy

B. Significant arthritic changes in the cervical or upper thoracic spine, optimally managed, with persistent symptoms and/or significant restriction of activity.

C. Intertriginous maceration (dermatitis in the folds of the skin) or infection of the inframammary skin (skin underneath the breasts) refractory to dermatologic measures.

D. Shoulder grooving with skin irritation by supporting garment (bra strap).

**Diagnostic/Therapeutic measures prior to referral:**

Non-surgical interventions preceding reduction mammoplasty should include as appropriate, but are not limited to, the following:

1. Determining the macromastia is not due to an active endocrine or metabolic process.

2. Determining the symptoms are refractory to appropriately fitted supporting garments, or following unilateral mastectomy, persistent with an appropriately fitted prosthesis or reconstruction therapy at the site of the absent breast.

3. Determining that dermatologic signs and/or symptoms are refractory to, or recurrent following, a completed course of medical management.
**Removal of breast implants**: For a patient who has had implant(s) placed for reconstructive or cosmetic purposes, Medicare considers treatment of any one or more of the following conditions to be medically necessary:

- A. Broken or failed implant
- B. Infection
- C. Implant extrusion
- D. Siliconoma (tissue response to silicone) or granuloma (tumor or growth in response to a foreign body)
- E. Interference with diagnosis of breast cancer
- F. Painful capsular contracture with disfigurement

**CONTRAINdications**

**REFERENCES:**
- CMS/Noridian Local Coverage Determination: Plastic Surgery, L37020
- CMS/Noridian Policy” Cosmetic vs Reconstructive

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MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BREAST RECONSTRUCTION SURGERY

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

Cosmetic Services: Services that are intended primarily to change or maintain appearance and will not result in significant improvement in physical function (as defined under the Exclusions section of the Evidence of Coverage, however, this exclusion does not apply to ‘Reconstructive Surgical Services’ or services that are medically necessary).

CRITERIA

Patients will be eligible for breast reconstructive surgery under these criteria only 1) after medically necessary mastectomy or lumpectomy related to breast cancer or 2) to correct significant disfigurement resulting from an injury or from medically necessary surgery.

- Reconstructive surgery of the affected side may include any or all of the following:
  - Tissue/muscle reconstruction (e.g., flaps);
  - Use of tissue expanders;
  - Implantation of FDA-approved internal breast prosthesis. Augmentation may be appropriate only when one of the following conditions is met:
    - Patient has undergone lumpectomy but NOT radiation therapy; OR
    - Patient has undergone mastectomy, with or without radiation therapy.
  - Areolar and nipple reconstruction;
  - Areolar and nipple tattooing;
  - Autologous fat grafting.
  - Liposuction
  - Mastopexy or reduction
  - Capsule revision (capsulotomy, capsulectomy, capsulorrhaphy)

- Reconstructive procedures may be performed on the contralateral (unaffected) side to restore the appearance of the breasts to the level of symmetry present prior to mastectomy or lumpectomy ONLY when mastectomy or lumpectomy has produced significant asymmetry.
  - The patient qualifies as having significant asymmetry when the following criteria are met:
    - There is an absence of breast tissue unilaterally where there is no ability to maintain a normal breast shape using non-surgical methods; AND
    - At least 250 g of tissue were removed OR there is a difference of at least 1 cup size.

These criteria do not imply or guarantee approval. Please check 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.
Reconstructive surgery of the contralateral (unaffected) side may include any of the following when the above criteria are met:

- Breast reduction by mammoplasty or mastopexy;
- Augmentation mammoplasty;
- Areolar and nipple reconstruction;
- Areolar and nipple tattooing;
- Capsulotomy;
- Capsulectomy;
- Breast implant removal and subsequent re-implantation when original implant was in the unaffected breast prior to disease in the affected breast.
- Liposuction
- Autologous fat grafting

- Reconstructive surgical revisions may be performed as deemed necessary by a physician board-certified in plastic surgery.
  - Revisions will not be covered when performed to correct changes in form or symmetry due to natural processes, such as aging or changes in weight.
  - Once the initial sequence of tattoo sessions has been completed, further touch-ups will be considered cosmetic (see Special Group Considerations).

SPECIAL GROUP CONSIDERATIONS

Medicare EOC- Cosmetic Surgery or Procedures are covered:

1) in cases of an accidental injury or for improvement of the functioning of a malformed body member, and
2) for all stages of reconstruction for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.

Medicare Manual- 120 states cosmetic surgery or expenses incurred in connection with such surgery is not covered. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (i.e., as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.

Tattooing is covered when performed in conjunction with breast reconstruction. Generally; the tattooing within six weeks after reconstruction is included in the global code 19350 and not separately reported. (Reconstruction code has a 90 day global period)

The touch up tattooing after one year is separately reportable and is covered indefinitely for Medicare members when associated with a covered breast reconstruction (Medicare does not have a NCD (National Coverage Determination) for tattooing to correct color defects of the skin nor does Noridian have a LCD (Local Coverage Determination)).

REFERENCES

WHCRA (Women’s Health and Cancer Rights Act):
http://breastreconstruction.org/breast_reconstruction_insurance_coverage.html
ORS 743A.110 Mastectomy-related Services
Oregon House Bill 3616 amending ORS 743A.110 defines "mastectomy" for purposes of statute requiring health benefit plan coverage.

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Medical necessity criteria and policy are applied only after member eligibility and benefit coverage are determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR COCHLEAR IMPLANT

DEFINITIONS

A. Cochlea: a spirally wound, tube-like structure that forms part of the inner ear and is essential for hearing. It is composed of a network of liquid filled tubing and tiny hairs. When sound is sent to the cochlea, it causes ripples in the liquid and the hairs to bend. This movement triggers electrical impulses which are transmitted to the auditory nerve.

B. Cochlear implant device: an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. The purpose is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired. A cochlear implant consists of two (2) main components:
   1. The implant package and electrode array (or receiver-stimulator) – this controls the flow of electrical pulses into the ear and is inserted into the shell-like structure in the inner ear known as the cochlea; and
   2. The external speech processor and headset – a coil is held in position against the skin by a magnet and the microphone is worn behind the ear; the body-worn speech processor can be worn in a pocket, in a belt pouch, or in a harness (the other option is an ear-level speech processor).

C. dB: decibel, unit for expressing loudness of sound

D. Hz: hertz, unit for expressing frequency of sound

E. The Lexical Neighborhood Test and the Multi-syllabic Lexical Neighborhood Test, designed for children who may be cochlear implant candidates, assess recognition of words and individual sounds. The results are used as a benchmark for children with hearing impairment.

F. Middle ear: the hollow portion of the ear behind the eardrum. The middle ear contains one or more ossicles, which amplify vibration of the eardrum into pressure waves in the fluid in the inner ear.
MEDICAL NECESSITY CRITERIA

A. Adults (age 18 or older) with:
   1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing aids.
      a. Limited benefit from binaural amplification: defined by test scores of <50% correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and <60% in the opposite ear (See Special Group Considerations below for Medicare criteria).
      b. Profound sensorineural hearing loss: for individuals older than 24 months, the pure tone average for both ears should equal or exceed 70dB at 500Hz, 1000Hz, and 2000Hz.
   2. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
   3. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.

B. Children (age 12 months through 17 years):
   1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from binaural amplification, defined by test scores of <50% correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and <60% in the opposite ear.
   2. For children age 12-24 months, profound sensorineural hearing loss: thresholds of 90dB or greater at 1000Hz.
   3. For children age 24 months to 17 years, pure tone average of 70dB or greater at 500Hz, 1000Hz, and 2000Hz.
   4. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six-month period.
      In older children, lack of aided benefit is defined as <30% correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child’s cognitive ability and linguistic skills.
   5. A three to six-month hearing aide trial is required for children without previous experience with hearing aides. Radiographic evidence of labyrinthine fibrosis that would lead to ossification will justify implantation without a trial of amplification.
   6. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.
   7. Freedom from lesions in the auditory nerve and acoustic areas of the central nervous system.

OTHER REQUIREMENTS or CONSIDERATIONS

Replacement of battery charger is not covered; replacement of batteries is covered for all members.
Replacement of a cochlear implant and/or its external components is considered medically necessary when the existing device cannot be repaired or when replacement is required because a change in the member’s condition makes the present unit non-functional and improvement is expected with a replacement unit. Must be performed in an ambulatory surgery center (ASC) or an inpatient or outpatient hospital facility.

CONTRAINDICATIONS

A. Agenesis of the 8th cranial nerve
B. Complete CN aplasia
C. Pathologies of the central auditory pathway

These criteria do not imply or guarantee approval. Please check 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. NOV 19
D. Michel deformity (complete labyrinthine aplasia/non-development) present
E. Known intolerance to materials used in the implant
F. Perforated tympanic membrane
G. Deafness attributed to central damage of the acoustic nerve or central auditory pathway
H. External or middle ear infection present

SPECIAL GROUP CONSIDERATIONS

Medicare: Cochlear implants for Medicare members with open-set sentence recognition tests of scores between 40% and 60% correct are covered if the device is implanted in an acceptable clinical trial or study. Otherwise, open-set sentence recognition tests of scores must be less than 40%.

Oregon Medicaid: See Prioritized List

REFERENCES

OREGON: Senate Bill 491 requires that bilateral cochlear implants be provided when medically necessary.

CLINICAL

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

Medicare: These criteria apply to all Commercial and Medicare members with a rehabilitation/habilitation benefit; also, see SPECIAL GROUP CONSIDERATIONS, MEDICARE for information added as a result of the Jimmo v. Sebelius Settlement Agreement.

FOR POLICY AND PROCESS, PLEASE SEE UR 43, UTILIZATION REVIEW PHYSICAL/OCcupATIONAL/SPEECH THERAPY POLICY AND PROCEDURES

PURPOSE: To provide guidelines for the medical necessity of member’s outpatient physical therapy, occupational therapy and speech therapy services.

DEFINITIONS
A. Acute: Sudden onset, or significant increase in symptoms which have been present for six months or less which require a course of treatment to improve or restore function. First treatment of symptoms outside the six months window may be considered when significant, sustainable improvement is still expected; and/or, the overall medical condition precluded the earlier initiation of therapy. Example:
  1. Medical acuity precluded start of therapy, such as a burn or post orthopedic event
  2. Throat cancer patients who receive radiation treatment may be seen 1 time every 1-2 months; however, it may not be until the 12-13 month point that the tissues of the throat have softened and the edema has gone down that full therapy can begin.
  3. Bell’s Palsy patient may not have full growth of the facial nerve into the affected muscle tissue until 10 to 12 months have elapsed.

B. Acute exacerbation: A significant increase (in frequency, duration, intensity, or irritability) of pain, or other signs or symptoms, resulting in a functional impairment related to an underlying condition, for which a course of therapy would result in measurable and sustainable improvement. Acute exacerbations can often be tied to a precipitating event such as participation in non-routine or extended activity, or, in pediatric patients, during progression to a new stage of development. Example: a child with dysfluency (stuttering disorder when s/he faces new social or communication challenges as a result of maturation or growth) as can occur in adolescence. Acute exacerbation is specified as 1.5 standard deviations from the previous standard test provided. If no standard testing was provided, for example due to severity of condition, the acute exacerbation will be identified and described by the evaluating/treating clinician.
C. Subacute or neurodevelopmental: Conditions present during an early childhood period of rapid developmental progress where significant sustainable improvement is anticipated with a course of targeted interventions. The nature of these disorders is such that most are amenable to intervention; they are not static or chronic.

D. Catastrophic: Significant functional impairment which limits the patient’s motor or sensory functions and activities of daily living. The identified conditions are an acute injury or neurological event such as, but not limited to acute CVA/stroke; a cognitive disorder as a result of an acute head injury; acute swallowing, breathing and feeding disorders; lymphedema, as a result of a catastrophic situation; post orthopedic surgery; crush injury; i.e., significant trauma to neurological or bony tissue, such as a spinal cord injury; extensive burns with contractures; functional receptive and expressive communication, thinking skills including abstract reasoning and problem solving; acute swallowing, breathing and or feeding disorders.

E. Chronic: Long duration, frequent recurrence over a long time, slow progression and/or greater than six months duration.

F. Maintenance Rehabilitation Therapy Services: Once the functional status has remained stable for a given condition, without expectation of additional functional improvement. Any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

G. Pediatric Neurodevelopmental Disorder: A congenital or acquired neurologically based condition in which a child does not reach developmental milestones at normative times, failing to master age-appropriate acquired skills such as self-care, gross and fine motor skills, coordination and motor planning skills, and communication skills (including speech, speech with augmentative and alternative communication device, language, sensory/motor skills, social communication, and normal swallowing and feeding abilities).

H. Plateau: Point at which the functional status has remained stable for a given condition, without expectation of additional functional improvement.

I. Sustainable: Able to be maintained. For purposes of PT, OT, and ST, progress toward goals can be maintained across visits and following discharge.

J. Acquisition of voice and communication skills for the transgender patient, consistent with their sexual identity. The American Speech and Hearing Association states: The speech-language pathologist provides voice and communication training. The SLP will look at a variety of aspects of communication including vocal pitch, intonation and resonance and nonverbal communication.

MEDICAL NECESSITY CRITERIA FOR PHYSICAL, OCCUPATIONAL and SPEECH THERAPY

When therapy services are referred by a KP practitioner, the PT/OT/ST department will evaluate and approve the requested services if:

1. the patient’s condition is acute, subacute-, neurodevelopmental, an acute exacerbation of a chronic condition or a function-limiting chronic condition,
2. the patient’s condition can be expected to show measurable, significant, sustainable functional improvement within a reasonable and generally predictable period of time as a result of the prescribed therapy,

3. the prescribed therapy services are of the complexity and nature to require that they be performed by a licensed PT, OT, or ST provider,

4. the therapy plan of care includes the patient’s diagnosis with planned treatment interventions; frequency and duration; measurable, time-specific, functional goals for therapy; and expected potential for achievement of goals.

Standardized assessment tests or outcome measures are to be used in the evaluation process. For members whose medical condition does not allow norm referenced testing or criterion referenced assessment, progress will be determined by other objective measures, formal observation, speech and language sampling and/or parent/caregiver report.

NOTE: If a referral is made to a PT/OT/ST provider outside of KP, or out of the plan service area, it must be authorized by the Regional Referral Center (for HMO members).

Continuation Criteria

Treatment progress must be clearly documented in an updated plan of care/current progress summary at the end of each authorization period and/or when additional visits are being requested. Progress Note Documentation must include the following:

1. Current and previous level of functioning, including:
   - Objective tests or measurements of physical function
   - A description of the member's current level of functioning or impairment

2. Identification of any health conditions which could impede the member’s ability to benefit from treatment.

3. Objective measures of the member’s functional progress relative to each treatment goal, and a comparison to the previous progress report

4. Summary of member’s response to therapy, with documentation of any issues which have limited progress

5. Documentation of member’s participation in treatment as well as member/caregiver participation or adherence with a home exercise program (HEP)

6. Brief prognosis statement with clearly established discharge criteria

7. An explanation of any significant changes to the member’s POC, and the clinical rationale for revising the POC

8. Recommended treatment techniques and/or modalities, their anticipated frequency and duration

Reevaluation Documentation for pediatric members: Retesting with norm-referenced or criterion-referenced standardized tools for re-evaluations is recommended annually for chronic or developmental conditions. Tests must be age appropriate for the child being tested and providers must use the same testing as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate ie due to change in client status or restricted age range of the testing tool, the provider should explain the reason for the change. If additional visits are being requested, documentation will need to support the medical necessity.

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Discharge Criteria

A member will be discharged from therapy when any of the following occurs:

- Member no longer demonstrates functional impairment or has achieved goals set forth in the POC or has returned to their prior level of function
- Member has adapted to impairment with assistive/adaptive equipment or devices
- Member has been receiving services over an extended period of time and it cannot be determined whether the progress is due to therapeutic intervention or natural development, services can be discontinued.
- Member is unable to participate in the plan of care due to medical, psychological, or social, complications
- Member (and/or family/caregiver) is non-compliant with Home Exercise Program and/or lacks participation in scheduled therapy appointments

Non-Covered Services

Physical, Occupational, and Speech Therapy services are not covered in the following circumstances:

- For maintenance therapy for chronic conditions except for members on a Washington group or Washington individual contract with a neuro-developmental condition. For these members, maintenance therapy is covered when, in the judgment of a KP practitioner, the condition would result in significant deterioration without such treatment. Neuro-developmental disorders include a broad spectrum of disabilities, delays in normal development and/or impairments in functional activity.
- For drills, techniques, and exercises after completion of medically necessary therapy. This includes sports-enhancement therapy. The patient is responsible for practicing independent community program, including learned drills, techniques, and exercises to preserve or enhance the present level of function and prevent regression of that function.
- For instruction of a secondary language. Included in this would be the acquisition of a secondary language including instruction of a new secondary grammar structure, vocabulary and accent.
- Self-correcting disorders (e.g. natural dysfluency or articulation errors that are self-correcting)
- Treatment that is investigational or unproven
- Support groups
- A member whose impairments/goals are related to skills that are routinely taught as part of a school curriculum will be deemed educationally, rather than medically necessary, and the member will be referred to the School/District to obtain services, regardless of IEP status
- Summer programs for therapy normally provided by school districts during the school year

There will be no PT/OT/ST visit limits applied when treatment is associated with a mental health diagnosis. Although these are most often Autism and/or Pervasive Developmental Disorder diagnoses, identified by the following diagnosis codes, this applies to all mental health diagnoses.

ICD-9 Codes

- 299.00 Autistic disorder, current or active state
- 299.80 Other specific pervasive developmental disorders, current or active state (Asperger’s disorder; Rhett’s disorder)
- 299.90 Unspecified pervasive developmental disorder, current or active state

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ICD-10 Codes

- F84.0  Autistic disorder
- F87.5  Asperger’s syndrome
- F84.8  Other pervasive developmental disorders
- F84.9  Pervasive developmental disorder, unspecified

AQUATIC THERAPY

Aquatic therapy is a type of physical therapy or occupational therapy intervention. Scope of services will be limited to development of an independent pool therapy program that the member (and caregiver, as indicated) can perform upon discharge from skilled services.

To be considered for authorization for aquatic based therapy, the member must have demonstrated an inability to tolerate exercise for rehabilitation under gravity-based weight bearing conditions (land-based therapy) according to the following criteria:

1. Failed trial of land based motor therapy*:
   - trial of at least 6 sessions within 3 consecutive months (excluding appointments with the seating specialist) WITH:
     - documented absence of progress towards motor goals as evidenced by therapist documentation on each session over the previous 3-month period
   AND/OR
     - documented inability to tolerate land based therapy as evidenced by subjective pain score or a FLACC scale score for pediatric clients of 6-10/10 on each of these sessions

* A licensed Physical Therapy or Occupational therapy provider may request an exception of the stated visit requirement for land-based motor therapy should they determine, during the course of such intervention, that further participation in land-based program would be detrimental to member’s rehabilitation process, and that aquatic therapy is clinically indicated. Such exceptions are subject to UM review.

2. Cleared in writing from the primary care physician to participate in aquatic based therapy (for consideration of complex medical issues including feeding tubes, tracheostomies, chronic ear and other infections, exposure to and transmission of communicable diseases, etc.)

3. Primary caregiver (parent) able to attend and participate in learning a home program of aquatic therapy from the aquatic physical therapist

Stipulations of approved referrals to aquatic therapy:

- Cannot receive concurrent land-based therapy (PT and OT) unless for DME seating and positioning for safe mobility and feeding.

SENSORY-PERCEPTUAL AND VISUAL PERCEPTUAL DEFICITS AFTER ACQUIRED BRAIN INJURY

Occupational therapy is covered for treatment to improve occupational performance related to visual perceptual impairments after an acquired brain injury such as TBI, CVA or Concussion. The OT focuses on activities of daily living and functional activities to improve or compensate for the neurological vision impairments. A member will be referred to OT to improve a visual perceptual or visual spatial diagnosis.

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SPEECH AND LANGUAGE DELAY

Intervention to improve speech, language, and communication skills (including but not necessarily limited to: individual speech therapy, group speech therapy, caregiver facilitated intervention programs, behavioral intervention programs) will be provided for children who fall below the 7th percentile (standard score of 78, 1.5 SD below the mean) on standard tests of speech and language development.

SPEECH/ARTICULATION DISORDER

Speech and language therapy will be provided when:
1. The member’s score is more than 1.5 standard deviations below the mean on a standardized test of articulation that is appropriately normed for the child’s age (below 7th percentile, standard score of 78 or below) AND
2. There is clinically significant impairment of speech intelligibility AND
3. A Kaiser Permanente Speech Language Pathologist has determined that the articulation deficits are not expected to improve with normal maturation.

RESPONSIBILITIES

A. Physician Reviewer
   1. Review to determine if condition meets PT/OT/ST medical necessity criteria.
   2. Notify PT/OT/ST designated Initial Evaluator of the determination, within regulatory timelines.

B. PT/OT/ST designated Initial Evaluator
   1. Monitor to ensure that all review processes, including physician review, will be completed and documented within the regulatory timelines, depending upon the clinical urgency of the request.
   2. Ensure that all required information is documented.
   3. Appoint members, if approved.
   4. Notify Member Relations of all denial determinations.

SPECIAL GROUP CONSIDERATIONS

Commercial: These criteria apply to all commercial groups with a PT/OT/ST benefit

NOTE: In response to the Washington Supreme court ruling in the O.S.T. v. Regence case, the OIC had instructed carriers to amend their 2015 filings to remove the age limits for neurodevelopmental therapies related to conditions found in DSM.

NOTE: Due to the legal, Federal and State guidance on the PPACA and Mental Health parity, therapies for the treatment of Autism Spectrum Disorder and Pervasive Developmental Disorders (PDD), such as Sensory Integration (SI), are considered an essential health benefit (EHB) and will no longer have any annual visit limits applied to therapy services.

Medicare: These criteria apply to all Medicare with a PT/OT/ST benefit; also, added as a result of the Jimmo v. Sebelius Settlement Agreement: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary’s lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary’s medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order

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to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary’s maintenance care needs can be addressed safely and effectively through the use of nonskilled personnel.

Washington Medicaid: Check WAC 182-545-200 (7)

Oregon Medicaid: Check LineFinder

CLINICAL

18. Functional Disorders: The American Speech Language Pathology Association (ASHA)’s position on medical necessity includes speech-language, swallowing, hearing, and voice DISORDERS tension (Lusis, 2006). ASHA further defines a voice disorder as “the abnormal production and/or absence of vocal quality, pitch, loudness, resonance, and/or duration, which is inappropriate for an individual’s age and/or sex”...Voice disorders that result from improper or inefficient use of the vocal mechanism when the

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physical structure is normal (e.g. vocal fatigue, muscle dysphonia or aphonia, diplophonia, ventricular phonation. (American Speech-Language Association, overview of voice disorders.)


MEDICAL NECESSITY CRITERIA FOR ACUPUNCTURE

DEFINITIONS
Acupuncture: A complementary/alternative system of medical theory, oriental diagnosis and treatment used to promote health and treat organic or functional disorders. Acupuncture treats specific acupuncture points or meridians.

Maintenance Treatment/Therapy: Once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

CRITERIA
A. Acupuncture is covered for nausea associated with pregnancy or chemo, overactive bladder with urge incontinence and for some chronic pain conditions. A condition is considered chronic if it has been present for ≥3 month (90 days).

B. Telephonic, email or face-to-face evaluation by the referring clinician is required prior to requesting a referral (this must be a KP clinician if the member has an HMO plan). A member request for referral without documented evaluation is generally not sufficient, however, an evaluation will not be required if:
   - The condition is an acute exacerbation or recurrence of the same condition which was evaluated recently (within the previous 12 months) or recurrently over many years by a Kaiser Permanente clinician; AND
   - The condition previously exhibited significant improvement after the acupuncture treatments; AND
   - The previous exam and information otherwise exhibits no contraindications, as outlined below in the Contraindications section.

For all qualifying diagnoses, there must be documentation in the medical record of the intensity of the symptoms for both the initial acupuncture referral and any extensions requested. An example of documenting the intensity of symptoms may be asking the patient to rate their worst pain and their current pain on a scale from 1 to 10. It is important to note that sometimes the intensity of symptoms will be modest but will significantly interfere with a particular activity of importance to the patient. Reviewers need to consider that those making the referral consider it implicit that the condition is of sufficient concern to warrant intervention.

C. Significant, sustainable and measurable improvement must be evident after the initial course of treatments. If objective improvements are documented, additional treatments may be clinically indicated. Services are not provided for on-going chronic conditions or maintenance therapy lacking improvement. In
the situation of chronic pain, when the patient’s condition is not expected to completely resolve, there must be an expectation of some functional or other improvement for therapy to be continued.

D. Approved Diagnoses:
   i. Nausea of pregnancy
   ii. Nausea associated with chemotherapy
   iii. Overactive bladder with urge incontinence
   iv. Migraine and tension headache (episodic or chronic, with symptom onset 3 or more months ago)
   v. Chronic pain syndromes, when due to
      1. Musculoskeletal pain, including myofascial neck pain
      2. Osteoarthritis
      3. Fibromyalgia
      4. TMJ disorder/pain (NOTE: TMJ services may be a benefit exclusion)
      5. Rotator cuff tendonitis
      6. Neuropathic pain

E. Patients actively participating in the KP Pain Clinic program may be considered for other diagnoses if:
   1. Patient has intractable chronic pain (lasting greater than 3 months); AND,
   2. The pain syndrome has been unresponsive to other reasonable traditional therapies or side effects or side effect/concerns have prevented the patient from using traditional therapies; AND,
   3. Patient has tried acupuncture therapy and there is documented evidence of efficacy (i.e., increased function; reduced utilization of services such as prescription drugs; and/or subjective reports of reduced pain).

CONTRAINDICATIONS
Medical contraindications include:
   1. Bleeding dyscrasia
   2. Acupuncture at sites of active infection
   3. Electro-acupuncture is contraindicated in patients with pacemakers

OTHER CONSIDERATIONS
**A maximum of 2 units of acupuncture will be authorized per visit.

Acupuncture is not covered for other conditions, including but not limited to tinnitus, epilepsy, psoriasis, smoking cessation, weight reduction or stroke. CMI (Care Management Institute) does not recommend acupuncture for the treatment of persistent asthma.

SPECIAL GROUP CONSIDERATIONS
Commercial: Covered for all Washington groups as a mandate; Oregon contracts vary, check CM.
Medicare: Acupuncture is not covered.
Washington Medicaid: Acupuncture is not covered.
Oregon Medicaid: Covered for certain conditions, check Linefinder

CLINICAL INFORMATION
3) Mosby: The Desktop Guide to Complementary and Alternative Medicine, online
4) The National Standard: Authority of Integrative Medicine, on-line 2006

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MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS

DEFINITIONS

Manual Manipulation: treatment by use of hands or with manual devices i.e. those that are hand-held with the thrust of the force of the device being controlled manually. (Medicare does not make separate payment for use of any device).

Subluxation: a partial or incomplete dislocation; displacement; or misalignment of a joint. It is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact. This may be demonstrated by x-ray or by physical examination.

Common examples of acceptable descriptive terms include:
- off-centered,
- malpositioning,
- spacing: abnormal, altered, decreased, increased,
- rotation,
- listhesis: antero, postero, retro, lateral, spondylo
- motion: limited, lost, restricted, flexion, extension, hyper/hypo mobility, aberrant

Acute Subluxation: a condition is considered acute when the patient is being treated for a new injury identified by an x-ray or physical examination. Result of chiropractic treatment is expected to be an improvement in, or arrest of progression, of the condition.

Chronic subluxation: a condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as in the case with an acute condition) but where continued therapy can be expected to result in some functional improvement. When the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

Exacerbation: an exacerbation is a temporary marked deterioration of the patient’s condition due to a flare-up of the condition being treated.

Recurrence: A return of symptoms of a previously treated condition that has been quiescent for 30 days or more. This may require reinstitution of therapy.

Maintenance Treatment/Therapy is a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. (Medicare covers only for manual manipulation of the spine to

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correct a subluxation. The subluxation needs to have resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. Chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not covered by Medicare. When chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

**CRITERIA**

There must be subluxation of the spine.

- Subluxation of the spine must have resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. The result of chiropractic manipulation is expected to be an improvement in, arrest or retardation of the patient’s condition and treatment must have a direct therapeutic relationship to the patient’s level of subluxation and diagnosed condition.

**Demonstrated by X-ray**

To demonstrate a subluxation with an x-ray the following applies:

a. X-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment (i.e., no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment).

b. In certain chronic subluxation cases (e.g., scoliosis) an older x-ray may be accepted if health record indicates condition has lasted longer than 12 months and there is a reasonable basis for concluding condition is permanent.

c. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

**Demonstrated by Physical Examination**

To demonstrate a subluxation based on physical examination, two of the four following criteria must be present, one of which must be a.) asymmetry/ misalignment or c.) range of motion abnormality:

a. Asymmetry/misalignment identified on a sectional or segmental level;

b. Pain/tenderness evaluated in terms of location, quality and intensity;

c. Range of motion abnormality (changes in active, passive and accessory joint movements resulting in an increase or decrease of sectional or segmental mobility);

d. Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia (connective tissue), muscle and ligament.

- Telephonic, video, email or face-to-face evaluation by the referring clinician is required prior to requesting a referral.

- If there is chronic subluxation of the spine, and the patient’s condition is not expected to completely resolve, there must be an expectation of some functional improvement for therapy to be continued. **When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is considered maintenance therapy and is not covered.**

- Symptoms must bear a direct relationship to the level of subluxation. The subluxation must be causal. A statement that there is “pain” is insufficient. The location of the pain must be...
described and whether particular vertebra listed is capable of producing pain in the area determined.

OTHER REQUIREMENTS FOR APPROVING SERVICE CONTINUATION

- The clinical condition must be evaluated by a chiropractic physician who will evaluate for appropriateness when/if asking for the continuation to determine that this condition is appropriate for manipulation modalities. Patient record should include the following and it should be provided with the request for the continuation:
  1. Symptoms causing patient to seek treatment
  2. Family history if relevant
  3. Past health history
  4. Mechanism of trauma
  5. Quality and character of symptoms/problem
  6. Onset, duration, intensity, frequency, location and radiation of symptoms
  7. Aggravating or relieving factors
  8. Prior interventions, treatments, medications, secondary complaints

- Chiropractic treatment may not be medically indicated for a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss the risks of such relative contraindications with the patient and record this in the chart. Such conditions include:
  1. Articular hypermobility and circumstances where the stability of the joint is uncertain;
  2. Severe demineralization of the bone
  3. Benign bone tumors of the spine
  4. Bleeding disorders and anticoagulant therapy (this does not include antiplatelet medications)
  5. Radiculopathy with progressive neurological signs

ABSOLUTE CONTRAINDICATIONS

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

- Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis
- Acute fractures and dislocations or healed fractures and dislocations with signs of instability
- Unstable os odontoideum
- Malignancies that involve the vertebral column
- Infections of bones or joints of the vertebral column
- Signs and symptoms of myelopathy or cauda equine syndrome
- For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
- A significant major artery aneurysm near the proposed manipulation.

SPECIAL GROUP CONSIDERATIONS: MEDICARE

Medicare does not pay for X-rays or any other diagnostic test ordered; taken; or interpreted by a chiropractor. 2013 Noridian published guidance for chiropractic that states, "Under the Medicare program chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is not payable." It goes on to say, "When further clinical improvement cannot reasonably be
expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time.

MEDICARE REFERENCES

- Medicare Benefit Policy Manual, Chapter 15, 30.5 and 240.1.1 re no coverage for x-rays and any other diagnostic test.
- 42 CFR 410.21 re manual subluxation
- Medicare Benefit Policy Manual, Chapter 15, 240.1.2 re criteria needed for manual manipulation for a subluxation
- Medicare Benefit Policy Manual, Chapter 15, 240.1.3 re maintenance

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MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

Manual Manipulation- treatment by use of hands or with manual devices i.e. those that are hand-held with the thrust of the force of the device being controlled manually.

Maintenance Treatment/Therapy- once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

Radiculopathy- disease of the spinal nerve root

Subluxation- a partial or incomplete dislocation.

CRITERIA FOR INITIAL REFERRAL

For a referral for a course of short-term treatment (2 months or less), all of the following must be met:

- Condition must be acute or subacute (<90 days) and/or related to a new injury and/or acute condition
- Musculoskeletal back or neck pain (cervical, thoracic or lumbar spine; not sacrum or sacroiliac joint)

NOTE: chiropractic care is fundamentally for non-radicular pain, however, radiculopathy is a relative, not absolute, contraindication to referral.

CRITERIA FOR A TREATMENT EXTENSION

For a treatment extension to be approved, there must be documentation of 1) subluxation of the spine, 2) a treatment plan must be provided which includes measurable goals for continued improvement, and 3) evidence of improvement. The subluxation may be demonstrated by x-ray or by physical examination.

To demonstrate a subluxation based on physical examination, two of the four criteria listed below must be present, one of which must be asymmetry/ misalignment or range of motion abnormality:

a. Pain/tenderness evaluated in terms of location, quality and intensity;
b. Asymmetry/misalignment identified on a sectional or segmental level;
c. Range of motion abnormality (changes in active, passive and accessory joint movements resulting in an increase or decrease of sectional or segmental mobility); and
d. Tissue, tone changes in the characteristics of adjacent or associated soft tissues, including skin, fascia (connective tissue), muscle and ligament.

OTHER REQUIREMENTS FOR REFERRAL

- Telephonic, email or face-to-face evaluation by the referring clinician is required prior to requesting a referral (this must be a KP clinician if the member has an HMO plan). A member request for referral without documented evaluation is generally not sufficient, however, an evaluation will not be required if:
  o The condition is an acute exacerbation or recurrence of the same condition which was evaluated recently (within the previous 12 months) or recurrently over many years by a clinician (this must be a KP clinician if the member has an HMO plan); AND,
  o The condition previously exhibited significant improvement after the chiropractic adjustment(s); AND,
  o The previous exam and information otherwise exhibits no contraindications, as outlined below in Contraindications section.
- Therapeutic measures prior to referral must be considered; i.e., standard medical management including medications, physical therapy, exercise programs, etc.
- The result of chiropractic manipulation is expected to be an improvement in, arrest or retardation of the patient’s condition and treatment must have a direct therapeutic relationship to the patient’s diagnosed condition.
- If there is a chronic spinal component, and the patient’s condition is not expected to completely resolve, there must be an expectation of some functional improvement for therapy to be continued. Once the functional status has remained stable for a given condition, without expectation of additional functional improvement, further manipulative treatment is considered maintenance therapy and is not covered.
- Chiropractic treatment may not be medically indicated for a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. Such conditions include:
  A. Radiculopathy
  B. Presence of osteoporosis
  C. Known herniated disk or prior spinal fusion
  D. Patient has not reached skeletal maturity
  E. Joint hypermobility and circumstances where the stability of the joint is uncertain
  F. Benign bone tumors of the spine
  G. Bleeding disorders and anticoagulant therapy (this does not include antiplatelet medications)

CONTRAINDICATIONS

1. Acute fractures and dislocations or healed fractures and dislocations with signs of instability
2. Unstable cervical vertebra
3. Infections of bones or joints of the vertebral column
4. Signs and symptoms of spinal cord disease, i.e. cauda equina syndrome

6. Neck pain with prior history of dizziness, unsteadiness and/or vertigo, unless vertebral basilar artery disease has been ruled out
7. History of malignancy, without diagnostic studies to rule out metastatic lesions.
8. Malignancies that involve the vertebral column

SPECIAL GROUP CONSIDERATIONS
This document does not apply to OR and WA Medicaid, which both have their own specific criteria for chiropractic care.

CLINICAL REFERENCES


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21. Maigne JY, Chatellier G, Faou ML, Archambau M. The treatment of chronic coccydynia with intrarectal manipulation: a randomized controlled study. Spine 2006;31(18):E621-7. DOI: 10.1097/01.brs.0000231895.72380.64. [Context Link 1, 2] View abstract...


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MEDICAL NECESSITY CRITERIA FOR MASSAGE THERAPY

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

PURPOSE

The purpose of this criteria and policy is to describe the policy and process requirements for massage/soft tissue mobilization and the medical necessity criteria for its coverage as a benefit.

POLICY

When a member’s contract covers massage as a benefit, soft tissue mobilization may be applied as part of an integrated physical therapy plan of care for the treatment of musculoskeletal neck and back conditions. A physician referral to physical therapy is required. The physical therapist will perform an evaluation, and designate treatment interventions based on their objective findings. Soft tissue mobilization will be included only if determined to be clinically indicated. When included in the plan, soft tissue mobilization will be of short duration, and specific to the region being treated.

DEFINITIONS

Maintenance Treatment/Therapy: Treatment once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

CRITERIA

A. Appropriate standard medical treatment without significant improvements, will have been attempted.

B. Documentation of previous treatment and functional impairment, including relevant history, physical findings, and evaluation must be documented for determination of appropriateness and/or as part of work-up.

C. Significant, sustainable and measurable improvement must be evident after the initial trial of Physical Therapy treatments. If objective improvements are evident through documentation, additional Physical Therapy treatments may be clinically indicated. Services are not provided for on-going chronic or maintenance therapy.
D. Soft tissue mobilization must be specific to the area involved and will not be applied for stress relief, palliative or maintenance treatment.

CONTRAINDICATIONS
Acutely inflamed joints, phlebitis (inflammation of vein(s)) or lymphangitis (inflammation of lymph vessel(s)) because of danger of embolism (obstruction of blood vessel), burns, acute dermatitis, local malignancy, osteomyelitis (inflammation of bone), local infection, advanced arteriosclerosis (hardening of arteries), advanced nephritis (inflammation of kidney(s)), and increased pain, swelling or stiffness in a joint persisting for more than two hours following soft tissue mobilization.

CLINICAL


Massage for low-back pain. [Review]
Furlan AD; Giraldo M; Baskwill A; Irvin E; Imamura M.
Cochrane Database of Systematic Reviews. (9)CD001929, 2015 Sep 01.

Massage for mechanical neck disorders. [Review]
Patel KC; Gross A; Graham N; Goldsmith CH; Ezzo J; Morien A; Peloso PM.
Cochrane Database of Systematic Reviews. (9)CD004871, 2012 Sep 12.

UI: 22972078
Title Comment
Authors Full Name: Patel, Kinjal C; Gross, Anita; Graham, Nadine; Goldsmith, Charles H; Ezzo, Jeanette; Morien, Annie; Peloso, Paul Michael J.
UR 48 Naturopathy Medical Necessity Criteria

Department: Utilization Review
Section: Alternative Medicine
Applies to: Kaiser Permanente Northwest Region
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Revised: 2/11, 10/11, 3/18, 7/18, 9/19

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR NATUROPATHIC SERVICES

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

CRITERIA

1. Naturopathic care is limited to the following conditions:
   A. Symptoms of menopause, peri-menopause, or premenstrual syndrome
   B. Chronic Irritable Bowel Syndrome
   C. Chronic Headache (defined as a headache for >15 days per month for >3 months)
   D. Chronic Eczema/Atopic Dermatitis
   E. Osteoarthritis

2. Appropriate diagnostics and specialty consultations must be performed prior to the referral.

3. Recommended standard medical therapies (allopathic care) for the condition must be documented as objectively ineffective.

Standard medical therapies (allopathic care) for the above qualifying conditions to be tried are:

A. For symptomatic menopause, peri-menopause, or premenstrual syndrome:
   i. For hot flushes/night sweats associated with menopause:
      [HRT requirement can be waived if there is documentation of a shared decision making between the appropriate clinician and the patient regrading HRT]
      - 1 oral HRT (at least 2 month trial with at least 1 dose adjustment), AND
      - 1 SSRI or NSRI (at least 1 month trial), AND
      - oral Clonidine
   ii. For PMS symptoms:
      - 3 month trial of SSRI, OR
      - 3 month trial of continuous OCP
   iii. For perimenopause bleeding:
      - 6 month trial of progestin containing IUD or OCP
   iv. For perimenopause mood disorder or hot flushes:
      - 2 month trial of low dose OCP, AND
      - 1 SSRI or NSRI (at least 1 month trial)

These criteria do not imply or guarantee approval. Please check 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. For Irritable Bowel Syndrome:
   i. IBS-D:
      • Trials of:
        -dairy holiday
        -loperamide (if BM cluster in AM, consider trial QHS dosing)
        -probiotic
        -cholestyramine
   ii. IBS-Constipation predominant:
      • minimize constipating meds (anti-cholinergics, narcotics), AND
      • Trials of:
        -fiber (note that psyllium and metamucil can cause bloating. If prone to bloating try Benefiber, Citrucel)
        -osmotic laxative (Miralax) titrated to effect- start at 17g/day, uptitrate every 3-5 days
        -probiotic
   iii. IBS with generalized abdominal pain and cramping:
      • Trials of:
        -dairy holiday
        -dicyclomine 10mg QID (can increase to 20mg QID if tolerated)
        -FODMAP diet
        -nortriptyline QHS

C. For Chronic headache:
   • Adequate trial of prophylactic treatment:
     -at least 1 antiepileptic medication, AND
     -at least 1 medication from another class (TCA or beta-blocker), AND
     -Botox (for migraine headaches only)

Adequate trial= a maximum tolerated dose of the selected medication for at least 2 months.

D. For Chronic Eczema/Atopic Dermatitis
   • failed treatment prescribed by a dermatologist

E. Osteoarthritis:
   • at least 1 month trial of regular (not PRN) use of at least 1 NSAID (prescription or OTC), AND
   • at least 2 corticosteroid injections per affected joint in the last 24 months (for knee osteoarthritis)

4. Referrals for naturopathic care must be limited to short term therapy.

5. Naturopathic care must be part of an integrated plan of care for a specific medical condition. This condition must be evaluated by the referring clinician face-to-face, telephonically, or via video or email prior to consideration of a referral to a non-plan naturopathic provider.

ADDITIONAL INFORMATION and REQUIREMENTS

1. The KPNW Complementary and Integrative Medicine (CIM) Clinic can provide patients with advice on diet, behavior modification, herb supplements, and other modalities. The clinic is appropriate for KPNW members with an interest in holistic care who are highly motivated from the standpoint of lifestyle modification. In addition, the Ob/Gyn Department has a Nurse Practitioner who is also a Doctor of Naturopathy.
2. Naturopathic care should be routed through primary care physicians and prescribed under limited circumstances.

3. Internal requests for naturopathic care are submitted as a HealthConnect External Referral Authorization Request (REF Naturopathy). The after-visit summary will instruct the member that a referral has been requested and is subject to authorization.

4. If an external referral is needed, all authorized services for naturopathic care will be provided by a member of NaturoNet through Complementary Healthcare Plans’ network. No other community providers will be authorized (for HMO members).

5. Standard authorizations are up to three visits in three months. Additional visits may be authorized when the following circumstances are met:
   A. The primary care clinician’s assessment of the patient’s condition demonstrates significant documented objective measurable improvement, AND
   B. The Treatment Extension Request provided by the Naturopath includes:
      - the patient’s initial and current symptoms. The intensity of the symptoms must be documented in measurable terms.
      - a treatment plan with measurable goals for continued improvement in symptoms and functional status and an identified target date for the conclusion of therapy.
      - documentation by the naturopath that improvement in the patient’s symptoms and/or functional status is expected to be sustainable with additional short-term treatment.
      - Treatment must have a direct therapeutic relationship to the patient’s referral diagnosis.

6. All prescriptions and/or naturopathic services are reviewed for benefit and medical necessity prior to authorization. Herbs and supplements are not covered under the prescription drug benefit. Prescription drugs must be in the Kaiser Permanente formulary to be covered.

7. Procedures, evaluations, and diagnostic testing, including laboratory tests, that are determined by a NWP Physician to be medically necessary and are ordered by a KPNW clinician will be provided within Kaiser Permanente (HMO members).

SPECIAL GROUP CONSIDERATIONS, IF BENEFIT IS COVERED
Commercial: Covered for all Washington groups as a mandate
Medicare: No coverage on Individual contracts (Group contracts may provide coverage)
Washington Medicaid: Check CM or EPIC
Oregon Medicaid: These criteria do not apply to OHP

Evidence/Source Documentation

These criteria do not imply or guarantee approval. Please check 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. NOV 19


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These criteria do not imply or guarantee approval. Please check 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. NOV 19
Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

SURGICAL INTERVENTION MEDICAL NECESSITY CRITERIA

DEFINITIONS
Temporo-mandibular Disorders (TMD) are muscular-skeletal disorders that are medical, not dental, in nature.

Temporomandibular disorders (TMD) are a heterogeneous group of pathologies affecting the temporomandibular joints, the masticatory muscles, or both. The most frequent signs and symptoms are pain or tenderness in the preauricular area or in the masticatory muscles, an alteration of the range of joint motion, and articular sounds, such as click or crepitus, during mandibular movements. For diagnostic purposes, TMD has been classified into 3 groups: muscle disorders, internal derangement (disk displacement), and other joint disorders, such as arthralgia, osteoarthritis, and osteoarthrosis. Anxiety, depression, somatization disorders, and headaches have been associated with TMD symptoms.

POLICY

TMD treatment is non-dental, non-orthodontic, non-occlusal and generally non-surgical in its approach. Characteristics of TMD:

A. TM Joint popping; clicking; grinding; catching; and locking
B. Facial pain that is not tooth related and is aggravated with use of the jaw
C. Facial pain which appears related to clenching and bruxing

Diagnostic tests that may help identify TMD:

1. Range of motion (ROM): Restricted; deviates; pain active and/or passive; limited lateral motion; roughness of motion.
2. Compressive loading—biting on tongue blade, first one side, then the contralateral side.
3. Resistive loading—asking the patient to hold, in turn, the variety of mouth positions against resistance provided by the examiner’s hand.
4. Palpation over lateral poles and intra-meatally to elicit pain and/or determine irregularities

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MEDICAL NECESSITY CRITERIA

Surgical intervention is a consideration when pain and dysfunction are persistent and the following are unresponsive to the non-surgical treatments below:

1. recurring and/or persistent lock of TM joint
2. persistent painful popping of TM joint
3. Osteoarthritis of TM joint

OTHER CONSIDERATIONS

Non-surgical treatment to consider prior to surgical intervention:

1. Physical therapy- rest and reassurance; exercise; stretching; use of heat and cold; avoidance of aggravating factors
2. Analgesics, anti-inflammatory medications
3. Soft diet (nothing firmer than consistency of scrambled eggs)
4. Moist heat if muscle; cold, if joint
5. Bite splints

SPECIAL GROUP CONSIDERATIONS: Check individual benefits in CM
GROUP COMMERCIAL: None
OREGON MEDICAID: Check the Prioritized List
WASHINGTON MEDICAID: Use Molina’s definition for medical necessity
MEDICARE: TMJ services related to splint fabrication and fitting are only covered if the TM disorder is directly attributable to a medical condition (e.g., direct result of arthritis) or accidental injury (e.g. dislocation of jaw, closed or open).

CLINICAL
ADA Presidents Council Guidelines
Guidelines of Oregon and Washington State Board of Dentistry

These criteria do not imply or guarantee approval. Please check 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.
### DEFINITIONS

Biofeedback (BFB) is a form of complementary or alternative medicine that measures a person’s bodily processes and conveys such information in real time in order to raise the person’s awareness and conscious control of the related physiological activities.

### CRITERIA FOR THE INITIATION OF BIOFEEDBACK

Biofeedback may be indicated for **1 or more** of the following:

1. Tension or migraine headache and **ALL** of the following:
   a. Home training is a component of treatment
   b. Pharmacologic treatment is inadequate or not indicated by reason of **1 or more** of the following:
      i. insufficient or no response to multiple pharmacological (medication) treatment attempts
      ii. intolerance of multiple pharmacologic treatment attempts
      iii. patient has a preference for nonpharmacologic interventions
      iv. history of long-term, frequent, or excessive use of analgesic (pain medication) or medications that can aggravate headache
      v. deficient stress-coping skills that remain a significant contributor to headache onset despite counseling of the patient by a qualified professional
      vi. pregnant patient
      vii. breast-feeding patient
      viii. patient attempting to become pregnant

2. Dyssynergic (muscle incoordination) constipation in adults as indicated by **ALL** of the following:
   a. evidence of dyssynergic constipation as indicated by **ONE or more** of the following:
      i. anorectal manometry shows dyssynergic motor pattern
      ii. non-relaxing puborectalis muscle (responsible for controlling bowel movements) while straining to expel the index finger during a rectal digital examination
      iii. proctography evidence of non-relaxing puborectalis
      iv. prolonged delay in transit time (greater than 20% retention of radiopaque markers 5 days after ingestion)
      v. prolonged expulsion of simulated stool (i.e. balloon expulsion test greater than one minute)

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*These criteria do not imply or guarantee approval. Please check 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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b) inadequate response to diet, laxatives, exercise, or hydration therapy for constipation
c) negative results of colonoscopy or barium enema
d) no evidence of hypothyroidism
e) no history of previous major gastrointestinal, pelvic or spinal surgery
f) no history of severe cardiac or renal disease
g) no use of drugs known to be constipating (i.e. narcotic pain medications)

3) Stress and/or urge urinary incontinence (inability to control urination) in females and males as indicated by ALL of the following:
   a) the patient is cognitively (mentally) intact
   b) the patient has failed a trial of pelvic muscle exercise (PME) training. A failed trial is defined as one in which there is no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of PMEs to increase periurethral muscle strength (responsible for controlling urination).

4) Voiding dysfunction/dyssynergia (muscle incoordination) in children, 5-18 years old, when indicated by ALL of the following:
   a) the patient is cognitively intact
   b) the patient has no spinal cord abnormalities that would interfere with normal voiding
   c) the patient has been evaluated by a Kaiser Permanente pediatric urologist who is recommending biofeedback based on ALL of the following:
      i) a failed trial of timed voiding
      ii) if patient is ≥12 years of age, a failed trial of proper relaxation techniques during voiding.
      iii) if patient is ≥16 years of age, a failed trial of pelvic floor exercises.
      iv) evidence of significant dyssynergia based on pelvic floor EMG during the active phase of voiding (EMG/electromyography tests the electrical activity of muscles).

Examples of voiding dysfunction/dyssynergia include: dysfunctional elimination syndrome (DES), detrusor/sphincter dyssynergia, vesicoureteric reflux, pelvic floor dysfunction.

5) Fecal incontinence when ALL of the following exist:
   a) documentation of a treatment plan including goals and frequency of treatment
   b) the patient is motivated to actively participate in the treatment plan and is responsive to care plan requirements
   c) the patient is cognitively intact and deemed capable of participating in the treatment plan by the consulting physician
   d) the patient has some degree of rectal sensation and can voluntarily contract the external anal sphincter as determined by either manometry OR physical exam findings
   e) the patient does not have existing pathology that would prevent treatment completion.

6) The following pain related conditions when at least two appropriate treatment modalities have been tried and failed:
   a) temporo-mandibular joint syndrome (NOTE: TMJ services may be a benefit exclusion)
   b) cancer pain
   c) cervical (neck) strain
CRITERIA FOR THE CONTINUATION OF BIOFEEDBACK

Treatment progress must be clearly documented in an updated plan of care/current progress summary at the end of each authorization period and/or when additional visits are being requested. Progress Note Documentation must include the following:

1. Current and previous level of functioning, including:
   - Objective tests or measurements of physical function
   - A description of the member’s current level of functioning or impairment
2. Identification of any health conditions which could impede the member’s ability to benefit from treatment
3. Objective measures of the member’s functional progress relative to each treatment goal, and a comparison to the previous progress report
4. Summary of member’s response to biofeedback, with documentation of any issues which have limited progress
5. Documentation of member’s participation in treatment as well as member/caregiver participation or adherence with a home exercise program (HEP), when applicable
6. Brief prognosis statement with clearly established discharge criteria
7. An explanation of any significant changes to the member’s plan of care and the clinical rationale for revising the plan of care
8. Recommended treatment techniques and/or modalities, their anticipated frequency and duration

Reevaluation Documentation: Retesting with norm referenced or criterion-reference standardized tools for re-evaluations is recommended annually for chronic or developmental conditions. Tests must be age appropriate for the child being tested and providers must use the same testing as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate ie due to change in client status or restricted age range of the testing tool, the provider should explain the reason for the change. If additional visits are being requested, documentation will need to support the medical necessity.

SPECIAL GROUP CONSIDERATIONS

Medicare: The Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual. Chapter 1, part 1.30.1- requires Biofeedback Therapy (done as outpatient PT) coverage for the Treatment of Urinary Incontinence if the provider deems biofeedback the desired treatment option. It is the decision of Kaiser Permanente to cover conditions in addition to urinary incontinence, in accord with the provisions of the Biofeedback medical necessity criteria. Home Biofeedback is not covered.

Also see KPNW BEAM Policy

CLINICAL

Milliman Care Guidelines, Ambulatory Care


Vasconcelos M, Lima E, Caiafa L et al. Voiding dysfunction in children; pelvic-floor exercises or biofeedback therapy; a randomized study. Pediatr Nephrol. 2006 Dec;21(12):1858-64.


REPATRIATION/TRANSFER GUIDELINES

PURPOSE

These guidelines are utilized when determining whether a patient is stable for repatriation/transfer from a non-KP facility (inpatient or ED) to a KP-contracted or Kaiser Foundation Hospital (inpatient or ED).

In addition to these guidelines, the capability of both the sending facility and the receiving facility will be considered in addition to the appropriate provider availability.

PLEASE NOTE: “Higher Level of Care” transfers are those which are done to obtain a higher level of care or service for the patient than is available at the Sending Facility. The Screening Exclusion Criteria are not used by the Regional Telephonic Medicine Center (RTMC) for transfers being considered for a higher level of care. In these cases, the sending and accepting physicians will consider both the advantages to obtaining the higher level of care and the risks of transport in order to make a decision about transfer.

SUBJECT TO CHANGE: Confirm prior to a transfer to Kaiser Sunnyside OR Kaiser Westside Medical Center that a patient weighing ≥550 lbs can be accommodated.
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MILD BURNS OR BURNS OF QUESTIONABLE SEVERITY

Stable for transfer:

a) Patients with vital signs reflecting hemodynamic stability; and
b) Patients that received adequate initial treatment; and
c) They will advise as to the need for transfer to a burn center rather than to a Kaiser Permanente facility.

Unstable for transfer (Unless higher level of care requested):

a) Patients exhibiting hemodynamic instability; or
b) Patients requiring tertiary services due to other injuries or illnesses who are at a facility capable of providing appropriate care. (E.g. Smoke inhalation at a facility offering hyperbaric treatment.)

MODERATE / SEVERE BURNS (calls from KP ED’s and NKP ED’s)

These are primarily higher level of care transfers to the burn unit at Legacy Emanuel Hospital. Generally, >20% total body surface area burn will be considered for transfer.

Candidates for Burn center: (meet any of the following):

- 2nd & 3rd degree burns of more than 10% BSA in patients under 10 and over 50 y/o;
- 2nd & 3rd degree burns of more than 15% BSA in other age groups;
- 2nd & 3rd degree burns with serious threat of functional or cosmetic impairment that involve - face, hands, feet, genitalia, perineum and major joints;
- 3rd degree burns greater than 2% BSA any age group;
- Significant electric burn injuries including lightening injury;
- Chemical injuries with serious threat of functional or cosmetic impairment;
- Inhalation injury with burn injury;
- Circumferential burns of an extremity or chest;
- Burn injury in patients with preexisting medical disorders which could complicate management, prolong recovery, or affect mortality;
- Major trauma with burns

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CARDIAC GENERAL

Diagnoses to be considered in this category include but are not limited to unstable angina, acute coronary syndrome, or “rule out” MI.

**Stable for transfer:**

Patients may be appropriate for transfer consideration (Advanced Life Support (ALS) or Critical Care Transport (CCT)) as long as the following conditions are met:

1. No persistent acute EKG changes (acute injury current ST elevation or ST depression);
2. A patient who has received fibrinolitics or has unstable angina with dynamic EKG changes but otherwise stable (as defined here) is appropriate for transfer;
3. Patient has stable vital signs, and appears hemodynamically stable;
4. Patient is free of active ischemic chest pain (Pharmaceutical intervention up to and including IV nitroglycerin is acceptable), titrate dose/amount acceptable.

**Unstable for transfer: (UNLESS HIGHER LEVEL OF CARE REQUIRED/REQUESTED)**

1. Persistent acute EKG changes (acute injury current ST elevation or ST depression);
2. Active ectopy (greater than 6 PVC's/min. or short runs of V-Tach), acute MI.

CARDIAC CATH / PTCA/PCI

Patients requiring cardiac catheterization/PTCA/PCI (per the community MD)

Transfer for primary PTCA can be considered if:

a) There is evidence of an acute MI;
b) There is an absolute contraindication to thrombolysis; and the facility in which the patient is being treated does not have the capability to perform the procedure.

AORTIC DISEASE

Criteria for management of Aortic Dissections and Aortic Aneurysms

a) Ascending Dissection - surgical emergency - requires immediate transfer to Kaiser Sunnyside MC or OHSU depending on stability and location; contact on-call cardiac surgeon to determine best disposition.
b) Type B Dissection – Call Cardiology first for advice. Cardiac Surgery needs to evaluate the case, but often medically managed in ICU;
c) Patients > 80 years of age - Cardiac Surgery needs to evaluate the case, but often medically managed;
d) Abdominal Aneurysm – Consult Vascular Surgeon on-call. This can generally be handled at any plan facility, unless higher level of care is required.

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Patients who may be considered **stable for transfer:**

a) Have responded to appropriate therapies;
b) Are not significantly hypoxic or dyspneic;
c) Remain alert without evidence of hypercapnea;
d) Maintain stable vital signs;
e) Have no persistent acute EKG changes (acute injury current ST elevation or ST depression);
f) Meet general cardiac criteria.

**Exclusion Criteria: Cardiac-EXCEPT FOR HIGHER LEVEL OF CARE REQUESTS**

**Cardiovascular/Hemodynamic**

- Hypotension or hypertension not controlled
  - SBP < 90 or >180. Check for baseline BP.
- On moderate-to-high-dose vasopressors
  - Norepinephrine >10 mcg/min >0.1 mcg/kg/min
  - Epinephrine >10 mcg/min >0.1 mcg/kg/min
  - Phenylephrine >100 mcg/min >1 mcg/kg/min
  - Dopamine >10 mcg/kg/min
  - Dobutamine >10 mcg/kg/min

- On any dose of vasopressor/inotrope without central venous access or without multiple secure peripheral catheters (central access preferred)

- Brisk ongoing hemorrhage or high risk of recurrent hemorrhage

**Other exclusion criteria:**

1. ST Elevation Myocardial Infarction (STEMI) who are within 12 hours of onset of symptoms or are having ongoing symptoms and ST elevation consistent with active ischemia.
2. Non-STEMIs whose pain/symptoms cannot be stabilized acutely with medicinal therapy and are having symptoms consistent with ongoing cardiac ischemia.
3. Ischemic syndromes with evidence of cardiogenic shock.
4. Patients with recurring sustained ventricular tachycardia or life threatening bradycardias.
5. Ischemic syndromes requiring an intra-aortic balloon pump to maintain adequate blood pressure.
6. Sustained bradycardia or tachycardia with cardiogenic shock or hemodynamic instability.
7. Valvular heart disease with cardiogenic shock and/or active ischemic symptoms.
8. Pericardial effusion with hemodynamic compromise from tamponade.
9. Patients with resuscitated sudden cardiac death on mechanical ventilation in the 24 hours post event or who are receiving therapeutic hypothermia and have not yet been re-warmed

These criteria do not imply or guarantee approval. Please check 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. NOV 19
Patients with critical illness are those requiring ICU-level care. The criteria for transfer of critically ill patients are the same regardless of whether the accepting service is Critical Care Medicine or another specialty. In all cases, there should be multisystem review of the case to determine stability for transfer.

“Lateral” transfers are those done between facilities which can provide the same level of care. This includes patients who are in an ICU at a non-plan hospital and those who are in an ED at a non-plan hospital that has an ICU bed available and that hospital can provide the services needed by the patient. For lateral transfers, the RTMC should use the Screening Exclusion Criteria below to determine which patients should be immediately excluded for transport. If there are no exclusion criteria present, then a potential accepting physician can be identified. The potential accepting physician will then review the case and integrate all the available information to determine if the patient is sufficiently stable for transport.

“Higher Level of Care” transfers are those which are done to obtain a level of care or service for the patient than is available at the Sending Facility. The Screening Exclusion Criteria are not used by RTMC for transfers being considered for a higher level of care. In these cases, the sending and accepting physicians will consider both the advantages to obtaining the higher level of care and the risks of transport in order to make a decision about transfer.

SCREENING EXCLUSION CRITERIA FOR LATERAL TRANSFERS

The below Screening Exclusion Criteria are in place for lateral transfers, and do not apply to 1) patients with the need for a level of care available at Sunnyside or Westside, and that are not available at the originating facility (e.g. coronary intervention); and 2) patients being transported due to the need for a higher level of care (SEE ABOVE).

If exclusion criteria are present, then do not pursue transfer. Even if no exclusion criteria are present, the patient still needs to be considered stable for transport by Sending and Accepting Physicians.

Exclusion Criteria
- Patients under 18 years of age for transfer to a Kaiser ICU

Cardiovascular/Hemodynamic
- Symptomatic hypertension
- SBP < 90 or MAP < 60
  - Exception: Baseline blood pressure is similarly low, and hypotension not related to primary diagnosis.
- On moderate-to-high-dose vasopressors
  - Norepinephrine >10 mcg/min >0.1 mcg/kg/min
  - Epinephrine >10 mcg/min >0.1 mcg/kg/min
  - Phenylephrine >100 mcg/min >1 mcg/kg/min
  - Dopamine >10 mcg/kg/min
  - Dobutamine >10mcg/kg/min

These criteria do not imply or guarantee approval. Please check 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. NOV 19
• On any dose of vasopressor/inotrope without central venous access or without multiple secure peripheral catheters (central access is preferred)
• Brisk ongoing hemorrhage or high risk of recurrent hemorrhage
• Other exclusion criteria as described in the Cardiac section*

Respiratory
• On ventilator with high levels of support required
  o FiO2 > 0.7
  o PEEP > 14
  o Minute ventilation > 13
  o Peak pressures > 45
• < 1 hour since intubation unless intubated for airway protection
• < 6 hours since extubation
• No ABG on current ventilator settings
• Not intubated, and requiring high-flow oxygen (> 15 L/min)
• Not intubated, questionable ability to protect airway, and vomiting
• Sat < 92% or PaO2 < 70 on settings achievable during transport, intubated or not intubated
  o BiPAP or CPAP-dependent (reference BiPAP Guidelines under Respiratory section)
  o Unable to be off BiPAP or CPAP for at least 2 hours (must demonstrate)
  o Exceptions:
    ▪ Patient is DNI
    ▪ Patient is on chronic home or SNF non-invasive ventilation and the primary acute problem is not cardio-respiratory

Neurological
• Elevated intracranial pressure (suspected or proven)
• Expanding intracranial hemorrhage or midline shift present (See NS section)
• Actively deteriorating level of consciousness or otherwise evolving neurological exam
• Received alteplase for stroke within past 24 hours and are in a Certified Stroke Center (if patient is not in a Stroke Center, transfer patient)
• Seizures: if has had 2 seizures within less than 30 min of each other, patient is excluded from transfer until 4 hours have passed without seizures and patient has returned to baseline mental status or EEG demonstrates that status epilepticus is not present
• Severe agitated delirium not safely controlled

Metabolic abnormalities
• Temp < 36 (induced or spontaneous)
• Hyperkalemia with EKG changes or K > 7 even without EKG changes
• Symptomatic hyper/hyponatremia:
  Acute seizures in setting of hyponatremia
  Acute (or presumed acute) severe hyponatremia, Na<115
  Acute severe hypernatremia, Na>165
• pH < 7.25 unless part of controlled hypoventilation strategy

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*Cardiac Exclusion Criteria (unless higher level of care request)*

1. ST Elevation Myocardial Infarction (STEMI) who are within 12 hours of onset of symptoms or are having ongoing symptoms and ST elevation consistent with active ischemia.
2. Non-STEMIs whose pain/symptoms cannot be stabilized acutely with medicinal therapy and are having symptoms consistent with ongoing cardiac ischemia.
3. Ischemic syndromes with evidence of cardiogenic shock.
4. Patients with recurring sustained ventricular tachycardia or life-threatening bradycardias.
5. Ischemic syndromes requiring an intra-aortic balloon pump to maintain adequate blood pressure.
6. Sustained bradycardia or tachycardia with cardiogenic shock or hemodynamic instability.
7. Valvular heart disease with cardiogenic shock and/or active ischemic symptoms.
8. Pericardial effusion with hemodynamic compromise from tamponade.
9. Patients with resuscitated sudden cardiac death on mechanical ventilation in the 24 hours post event or who are receiving therapeutic hypothermia and have not yet been re-warmed.

**USE OF CRITICAL CARE TRANSPORT (CCT)**

Critical Care Transport service is provided by MetroWest Ambulance.
GENERAL

Due to the nature of GI bleeds and the lack of specific markers, the RTMC MD should always overlay their medical knowledge and judgment when determining the stability for transfer of these cases.

Stable for transfer:

a) Patient has stable vital signs including orthostatics where indicated;
b) GI hemorrhage inactive without evidence of current brisk bleed;
c) Stable CBC or H/H as compared to baseline;
   1) Patients may require transfusion at the community ED prior to transfer;
   2) Transfusion may also be continued during transfer if indicated. (Note: RN transport may be needed when patient is receiving blood transfusion).

Unstable for transfer (unless higher level of care required):

a) Patient has unstable vital signs (hemodynamically unstable- see Critical Care Exclusion Criteria, pg 6-8) after resuscitation is completed;
b) Patient has an active brisk bleed from rectum or NG tube (if used), i.e. maroon-colored stool with decreasing H&H (decrease in Hgb >1 g/dl);
c) Evidence of esophageal obstruction with airway compromise or inability to manage secretions;
d) Patient requires urgent transfusion not available in the ED.
Includes patients with diagnoses such as appendicitis, cholecystitis, diverticulitis, and SBO.

**Stable for transfer:**

a) Patient has stable vital signs; and
b) Normal neurologic exam without airway compromise; and
c) Stable HCT without significant active bleeding; and
d) GS guidelines
e) If transporting to KP facility, patient is ≥16 years of age

**Unstable for transfer (unless higher level of care required):**

a) Patient has unstable vital signs (see Critical Care Exclusion Criteria, pg 6-8); or
b) Patient has active or significant potential for airway compromise or deterioration; or
c) Patients with evidence of ongoing significant bleeding.

**General Surgery Transfer Guidelines (Non-Trauma)**

**Stable for Transfer**, assuming facility and provider availability at Plan facility:

a. Patient has stable vital signs, good general appearance
b. No signs of a surgical abdomen
c. Antibiotics if applicable have been started
d. Acute abdominal series +/- abdominal/pelvic CT scan if performed does not demonstrate;
   1) Free air
   2) Acute Dissecting AAA (discussion with vascular surgeon will occur as needed)
   3) Ischemic Small Bowel
   4) Air in the Biliary Tree (not post procedural)
   5) Ruptured Appendix
   NOTE: 1), 3), 4) and 5) will be discussed with surgeon prior to transfer
e. Early Appendicitis
   1) Onset of symptoms and physical exam consistent with early presentation
   2) Reading of abdominal CT by radiologist indicates “Early Appendicitis”
f. Sending facility has no plans or opportunity to operate for >6 hours
g. If transporting to KP facility, patient is ≥16 years of age

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**CVA - Ischemic Stroke**

**Stable for transfer:**

Patient has:
1) stable vital signs;
2) stable neurologic exam; determined optimally by a neurologist at non-plan facility, if available;
3) symptoms/deficit stable;
4) head CT scan (CTA, if facility has the capability) should be done prior to making decision to transfer patient to a non-neurosurgical facility (always request that a copy of CT/CTA accompany the patient in transfer).

**Unstable for transfer (unless higher level of care request for transfer):**

Patient has:
1) unstable vital signs (see Critical Care);
2) unstable neurologic exam;
3) >1/4 hemisphere infarct
4) cerebellar or cortical hematomas with midline shift;
5) brainstem involvement
6) intracerebral hemorrhage/cerebral hematoma;
7) acute surgical intervention indicated and available at treating facility;
8) symptoms consistent with evolving stroke;
9) patient not surgical candidate but with impending demise, unless patient’s family requests transfer to Kaiser.

**Other Considerations:**

1) Receiving facility must be within 2 hours transit time.
2) The decision to administer thrombolytics for acute CVA rests with the treating physician.
3) For an anterior circulation infarct that is outside the window for appropriate thrombolytics (<3 hours) but <6 hours of onset, patient must be considered for intravascular intervention at appropriate facility for transfer.
4) For a posterior circulation infarct that is within 24 hours of onset, discuss case with KP neurologist to determine if patient is appropriate for intravascular intervention and the most appropriate facility to receive the patient.

**Exclusion Criteria: (unless higher level of care, not in a stroke center)**

**Neurological**

- Elevated intracranial pressure
- Expanding intracranial hemorrhage or midline shift present
- Actively deteriorating level of consciousness or otherwise evolving neurological exam
- Seizures: if has had 2 seizures within less than 30 min of each other, patient is excluded from transfer until 4 hours have passed without seizures and patient has returned to baseline mental status or EEG demonstrates that status epilepticus is not present
- Severe agitated delirium not safely controlled

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NOV 19
NEUROSURGERY, ADULT

Patients in Non-KP EDs

Normal CT

Patients presenting with traumatic closed head injuries with a normal CT and Glasgow Coma Scale >13 will be transferred to a KP facility (or other facility, as deemed appropriate) when observation is indicated.

Patients presenting with traumatic closed head injuries with a normal CT and Glasgow Coma Scale <13 will be transferred to KSMC and evaluated by the Neurosurgeon to determine why GCS is so low, complete any indicated toxicology screen, and conduct other tests as indicated. If admission to another service is deemed more appropriate, the RTMC will arrange the admission and the Neurosurgeon will communicate with the accepting Physician and/or family if requested.

Abnormal CTs

All acute intracranial bleeds and cervical spinal cord injuries in non-KP neurosurgical EDs should have an onsite neurosurgical consult to ensure their safe transfer if available and indicated. If it is determined that the patient is not a candidate for neurosurgical intervention, the neurosurgeon will notify the hospitalist or intensivist and the patient will be admitted to that service with neurosurgery as consult. Neurosurgeon will communicate with the family if requested.

Spine:

Patients with spinal injury and subjective or objective neurologic deficit should be transferred to KSMC. Consult spine on call. Patients less than 18 years of age should be referred to DCH.

- Reference Trauma section
- Reference Critical Care Exclusion Criteria
- Reference Higher Level of Care

NEUROSURGERY, PEDIATRIC

General issues: Need to communicate with the Pediatric Neurosurgeon on call regarding each case. All cases should be referred to OHSU/Doernbecher.

a) The patient should receive care in a setting capable of providing all services required by a child, including care for potential complications;

b) Neonatal neurosurgical cases must be in a facility with Neonatal ICU level 3-4 capability (depending on severity);

c) Patients who will likely require Pediatric ICU (PICU) services may only be transferred to Doernbecher PICU (unless also suffering severe burns which would require Legacy Emanuel PICU);

d) Patients with coma or depressed Glasgow Coma Score require pediatric intensive care services.

--All pediatric patients <18 should be cared for at Doernbecher/ OHSU by the trauma service;

--Glasgow coma score (GCS) < 10;

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Stable for transfer:

a) Patients with stable vital signs;
b) Patients with closed fracture without neurovascular compromise
   Note: Displaced acetabular fractures are not usually repatriated.
   Note: closed tibial fractures sustained with high energy mechanisms of
   injury will require some objective evidence indicating normal (or near
   normal) compartment pressures even in the setting of normal
   neurovascular status.
c) Patients with open fractures without neurovascular compromise.
   i. Grade 1, <1 cm laceration- can potentially go to OR more than 6 hours from
      the time of injury, check with on call KP orthopedist.
   ii. Grade 2, >1 cm laceration- ideal to get to OR within 6 hours from the time of
      injury, but decision of time to surgery is left to the discretion of the KP
      orthopedist.
      • Do not transfer if it has been >4 hours since the time of injury, unless
        the sending facility is unable to deliver care or get the patient to the OR
        in a timely fashion.
   iii. Grade 3 would be handled at a trauma center.
   iv. Distal phalanx can be managed with ER/urgent care washout and
      antibiotics only, does not need urgent OR.
d) Pediatric closed fractures can be handled at KSMC. Check with on-call KP
   orthopedist.

NOTE: For each case the RTMC MD is expected to provide complete information to the
orthopedist including:

• Patient’s age and gender;
• Time of the injury;
• Mechanism of the injury;
• Extent of injury including all systems;
• Current location of the patient;
• Name and phone number of the current treating physician, if requested;
• Estimated transportation time.

Unstable for transfer (Unless higher level of care is requested):

a) Patients with unstable vital signs (see Critical Care Exclusion Criteria);
b) Patients with evidence of vascular compromise;
c) Patients with evidence of compartment syndrome;
d) Patients with multiple trauma/multiple system injuries that cannot be managed
   within the Kaiser Permanente system;
e) Patients with amputation injury requiring reimplantation.
f) Gustillo Fracture Classification, Grades II-III (see description of Grade I above)
GENERAL

Mandibular fractures, facial fractures, laceration repairs, epistaxis, etc.

Stable for transfer:

a) Patient has stable vital signs;
b) Normal neurologic exam without airway compromise;
c) Stable HCT without significant active bleeding;
d) Significant oral edema should be evaluated by non-Plan ENT when available prior to transfer.

Unstable for transfer (unless higher level of care required):

a) Patient has unstable vital signs (see Critical Care Exclusion Criteria);
b) Patient has active or significant potential for airway compromise;
c) Patients with evidence of ongoing significant bleeding or epistaxis.

PEDIATRICS

GENERAL

Pediatric cases are managed by the Kaiser Pediatrician on call at Doernbecher, who can be reached by calling the OHSU transfer center at 503-494-7000 or by paging the pediatrician directly (contact number on staff availability). If the child is felt to be critically ill or injured, then the Pediatric ICU attending physician at Doernbecher would manage the case/transfer. Also of note, the Doernbecher PANDA (Pediatric and Neonatal Doernbecher Ambulance) transport team may use air transport, typically at the discretion of the pediatric ICU attending physician at DCH. Closed fractures requiring closed reduction can typically be handled at KSMC or KWMC, therefore transfer to Doernbecher may not be indicated.

Common pediatric diagnoses encountered include, but are not limited to, asthma, croup, dehydration, head injuries, infections and poisonings.

Stable for transfer:

1) Patients with vital signs reflecting hemodynamic stability;
2) Patients who received adequate initial treatment;
3) Patients accepted by Kaiser Permanente pediatric Doernbecher hospitalist MD or PICU attending on call. Appropriate mode of transfer is arranged (ACLS or PANDA).

Unstable for transfer (Unless higher level of care requested):

1) Patients exhibiting hemodynamic instability;
   NOTE: We may opt to transfer (in particular PANDA) if the sending facility is not able to stabilize as the transport team often is better skilled in getting the patient stabilized than some of our local ER’s.
2) KP pediatric MD unwilling to accept due to clinical concerns.

Decisions will be made by Doernbecher KP hospitalist and PICU attending.
Medical Clearance – The patient is determined to be medically cleared when all medical conditions have been evaluated and treated so that the patient could return home if there was no underlying psychiatric condition. The extent of the evaluation to determine medical clearance is at the discretion of the treating physician in consultation with the Brookside on call MD. Specific drug or alcohol levels are not required unless clinically pertinent to the medical clearance. However, most cases require toxicology screen.

Stable for transfer:

   a) Patients with vital signs reflecting hemodynamic stability;
   b) Patients that received adequate initial evaluation and treatment;
   c) Patients meeting medical clearance criteria for transfers directly to psych facilities.

Unstable for transfer (Unless higher level of care requested):

   a) Patients exhibiting hemodynamic instability;
   b) Patients with significant overdoses and evidence of pending cardiovascular complications (i.e.: TCA’s).
Hemodialysis patients exhibiting volume overload or electrolyte imbalance and are often in need of urgent or emergent dialysis.

**Stable for transfer:**

a) Patients with vital signs reflecting hemodynamic stability;

b) Renal failure patients presenting with serum potassium below 7.0 without EKG changes (second potassium may need to be obtained after medical therapy at the community ED);

c) Patients with appropriate mental status;

d) Patients with adequate oxygenation with low or moderate O2 supplementation.

- Before repatriating dialysis patients, make sure the nephrologist on call is notified and that dialysis capacity has not been exceeded
- Notify the hospitalist so they can admit the patient

**Unstable for transfer (Unless higher level of care requested):**

a) Patients exhibiting hemodynamic instability;

b) Renal failure patients with serum potassium above 7.0.

c) Patients with pulmonary edema not responsive to initial medical therapy and in need of emergent dialysis to avoid respiratory failure.

**RENALETRANSPLANT PATIENTS:**

The patient can receive related care at the transplant facility for a maximum of 3 months post-transplant. After 3 months the patient is usually transferred for care to their home Kaiser Permanente facility. The appropriate nephrologist on call should be consulted after hours to aid in the disposition of these cases.

**Other Organ transplants:** Refer to NTN Database for information on: Centers of Excellence (COE), transplant Coordinator’s name, Transplant MD’s name and case rate ending date.
RESPIRATORY

GENERAL

Note that the Pulmonary Service is not an admitting service at KSMC. The following sections address certain respiratory therapies that may be encountered when considering transport of patients to any accepting service.

Oxygen Therapy

Patients cannot be transported on high flow nasal cannula oxygen. Adequate oxygenation on flows up to 15 L/min by mask must be demonstrated prior to transport. Reference Critical Care Exclusion Criteria.

NIV, BiPAP, CPAP

Ventilatory support with noninvasive ventilation (NIV), BiPAP, or CPAP is not considered to be as reliable as invasive ventilation and has only been proven to be effective for a limited number of indications.

Lateral Level of Care Transfers or Transfers to a Lower Level of Care

Lateral transfers should not be initiated for patients who are dependent on NIV, Bi-pap, or CPAP. “Dependency” is defined as being unable to be off the device at least 2 hours. However, after demonstrating NIV/BiPAP/CPAP independency at the Sending Facility, NIV/BiPAP/CPAP can and should be utilized during transport if it has been a part of the treatment regimen up until that point.

Exceptions—lateral transfers may be considered in these situations:
1. NIV/BiPAP/CPAP is being used for palliative purposes
2. DNI and DNR status
3. Patient is on chronic home NIV/BiPAP/CPAP and the acute medical problem is not cardio-pulmonary
4. NIV/BiPAP/CPAP is being used for COPD or CHF, and a physician privileged in advanced airway management is part of the transport team.

In all cases of lateral transfer, an RT or nurse with competency in administering non-invasive ventilation must be part of the transport team. This implies that Critical Care transport will typically be required.

Transfers to Achieve a Higher Level of Care

Alternatives to transporting a patient on NIV, BiPAP or CPAP should be thoroughly explored before deciding on transport for a higher level of care. Consideration should be given to intubation prior to transport. Keeping the patient at the sending facility long enough to demonstrate improvement in the clinical respiratory status and in blood gas results on noninvasive therapy is strongly encouraged prior to transport.

If transport must take place using NIV, the transport team should be assembled with the best available skills in NIV and advanced airway management available in a time frame consistent with patient safety. Efforts should be made to enlist both an RT or RN with NIV competency and a physician with advanced airway management skills for the transport team.

Higher Level of Care Transports

Critical Care Transport should be used whenever possible. However, if the use of CCT would result in a delay which would put the patient at risk, then transport without the CCT can be considered as part of the decision-making process which weighs the overall risks and benefits of transfer.

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TRAUMA

GENERAL

Major, multi-system trauma would never be appropriate for repatriation to a KP hospital in the acute setting.

PENETRATING: (GUN SHOT WOUND / STAB WOUND) –DO NOT TRANSFER

Blunt Trauma:
For patient in a non-KP facility
   a) Chest: Stable for transfer if:
      1) Hemodynamically stable during 2-hour observation; and
      2) Chest x-ray, EKG without change; and
      3) ABG pH > 7.3, pO2 > 65, pCO2 < 50; and
      4) No signs of aortic disruption - CT scan or aortogram.
   b) Abdomen: Stable for transfer if:
      1) Hemodynamically stable during 2-hour observation; and
      2) CT scan performed prior to transfer shows no signs of acute injury to spleen, liver, or pancreas; no free fluid, free air, or pelvic fracture.

Trauma Criteria
For KP patients presenting at a non-KP facility. Transfer to Trauma Center if:
   a) Critical Trauma Victim (CTV): a victim of blunt or penetrating trauma, which results in any of the following alterations in vital signs.
      Respirations  < 12 or > 30
      Pulse        < 50 or > 130
      Systolic BP  < 80
   b) Moderate Trauma Victim (MTV): a victim of blunt or penetrating trauma with parameters to consider for trauma center designation including:
      1) Mechanism of injury - pedestrians struck by auto, ejection from vehicle;
      2) Unable to follow commands;
      3) Abnormal capillary refill;
      4) Age <5 or > 65 years old and with precarious previous medical histories;
      5) Prolonged extrication;
      6) Fatalities involved in the event;
      7) Adults with systolic BP < 90 or children with systolic BP <60;
      8) No spontaneous eye opening;
      9) Penetrating cranial injury;
      10) Penetrating thoracic injury between the midclavicular lines;
      11) Gunshot wound (GSW) to trunk
      12) Blunt injury to chest with unstable chest wall (flail chest);
      13) Penetrating injury to neck;
      14) Diffuse abdominal tenderness following blunt trauma;
      15) Fall from height >15 feet;
      16) Intrusion of motor vehicle into passenger space

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Patients with an acute isolated **head trauma** and persistent Glasgow Coma scale of 14 or less should be referred to KSMC.

Patients with an isolated **spinal injury** and subjective or objective neurologic deficit should be transferred to KSMC. Consult Spine on call.

**Stable for transfer:**

a) Patient has stable vital signs;
b) Stable neurologic exam without evolving deficit;
c) Determination of stability by neurosurgeon at non-Plan facility, if available;
d) Spinal fracture immobilized appropriately prior to transfer if determined to be stable by treating physician.

**Unstable for transfer (unless higher level of care):**

a) Patient has unstable vital signs;
b) Patient has unstable neurologic exam;
c) Patients with acute epidural, subdural, or subarachnoid hemorrhage, especially with midline shift (at facilities where neurosurgical service are available);
d) Patients with unstable spine fractures or spine fractures with deficit at facilities with appropriate surgical services available.

**SPECIAL GROUP CONSIDERATIONS**

*Added Choice/POS:* members may access non-KP facilities for routine and post-emergency care under their Tier 2 and Tier 3 benefits, however prior-authorization is required.
Purpose

Describes the policy, medical necessity criteria, and responsibilities for the provision of dental care under general anesthesia (GA) in an operating room (OR) of a hospital or ambulatory surgical treatment setting when a member has both Kaiser Foundation Health Plan (KFHP) medical and dental coverage and when s/he has KFHP medical coverage and non-KFHP dental coverage.

Policy

Dental services that cannot be safely performed within a KPNW dental office are considered noncovered benefits under the KFHP dental Evidence of Coverage (EOC). If a dental service under general anesthesia outside a KPNW dental office is needed, this service may be covered under the member’s Kaiser Foundation Health Plan of the Northwest (KFHPNW) medical contract.

The medical and utilization management (UM) process is the same for all patients; however, age may be a deciding factor when considering accepted community standards of care.

Definitions

- General Anesthesia (GA): A reversible state of controlled unconsciousness produced by intravenous and/or inhaled anesthetic agents which results in the total loss or partial loss of reflexes and absence of pain over the entire body.
- Operating Room (OR): An operating theatre, operating room, or a surgery suite within a hospital or ambulatory treatment center within which surgical operations are carried out.
- General dentistry: The general practice of dentistry
- Pediatric dentistry: The practice of dentistry specializing in patients generally 12 years of age and younger
- Special Needs: Conditions include, but are not limited to: Autism, Cerebral Palsy, Downs Syndrome, severe intellectual disability, paralysis, severe uncontrolled seizure disorders, or severe sensory disorders. Dental phobia is NOT considered a special need.

Medical Necessity Criteria

It is an accepted standard to provide dentally necessary dental services under general anesthesia if a physically or mentally handicapped patient (of any age) and other medically complicated patient (of any age) has a documented medical diagnosis (such as Alzheimer’s or uncontrolled...
Parkinson’s) or special needs, (such as Downs syndrome, cerebral palsy or autism) and/or other medical or developmental conditions of such a severity that the member would be at undue risk if the dental procedure were performed in the dental office.

All potentially eligible mental or physical conditions/diagnoses require oversight by a Permanente medical doctor up to and including an anesthesia review.

OTHER CONSIDERATIONS

Unless otherwise mandated by federal or State law, members are ineligible for GA if any of the following exist:

- the dental services are either cosmetic or not covered by the member's Dental Plan (such as dental implants); or
- the patient can’t be safely transported to a Kaiser Permanente facility to receive dental care; (e.g.: ventilator dependent, combative) or
- the member did not receive a “surgical clearance” from a licensed Permanente medical physician, or
- after a consultation with a licensed anesthesiologist, GA risk outweighs the benefits of dental treatment in the OR.

PROCESS

WHEN THE PATIENT HAS PDA OR COMMUNITY DENTAL AND MEDICAL COVERAGE THROUGH KFHPNW, THE EXPECTED PROCESS INCLUDES:

1) Dental consultation by a dentist with experience in hospital dentistry for all patients both with and without a PDA dentist
2) An anesthesia review via the chart when indicated based on the patient’s medical condition or risk status
3) Use of Plan facilities (coverage of non-plan facilities must be approved by the Regional Referral Center or URMD)

PROCESS STEPS:

- A treating dentist believes the work cannot be safely performed in the dental office and, in his/her opinion, general anesthesia must be used to perform necessary dental services;
- A treating dentist (community dentists or Permanente Dental Associate Dentists), will submit a request to the KPNW dentist consultant for a consultation request for general anesthesia in the OR setting because it is believed the dental care cannot be safely performed in the dental office.
- The dentist consultant evaluates the dental treatment plan and secures an anesthesia consult as necessary based on the patient’s medical condition.
- The NWP physician will make a medical determination regarding medical necessity of anesthesia and OR services.
- A medical contract benefit coverage determination will be completed.

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• The URMD will make the final coverage determination related to the provision of anesthesia, OR services and site of service. Services are expected to be provided in Plan OR rooms. If the OR is a non-plan OR outside of a Kaiser Permanente Dental Office or KP hospital, the referral must go to the Regional Referral Center for authorization.

SPECIAL GROUP CONSIDERATIONS
Policy applies to all commercial groups.
Medicare: This policy does not apply to Medicare.
Washington Medicaid: Policy does not apply, see Apple Health contract language. Anesthesia for dental care is not covered under Washington Molina Apple Health Plan Benefits. Providers of Molina members should be redirected to the Washington State Health Care Authority to request coverage.
Oregon Medicaid: Unique criteria FOR OHP Members ONLY

Health Systems Division: Medical Assistance Programs - Chapter 410, Division 123
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=243030
The purpose of hospital dentistry is to provide safe, efficient dental care when providing routine (non-emergency) dental services for OHP clients who present special challenges that require the use of general anesthesia or IV conscious sedation services in an Ambulatory Surgical Center (ASC), inpatient or outpatient setting. Hospital dentistry is intended for:

1. Children (18 or younger) who:
   a. Through age 3 and have extensive dental needs;
   b. 4 years of age or older and have unsuccessfully attempted treatment in the office setting with some type of sedation or nitrous oxide;
   c. Have acute situational anxiety, fearfulness, extreme uncooperative behavior, uncommunicative such as a client with developmental or mental disability, a client that is pre-verbal or extreme age where dental needs are deemed sufficiently important that dental care cannot be deferred;
   d. Need the use of general anesthesia (or IV sedation) to protect the developing psyche;
   e. Have sustained extensive orofacial or dental trauma;
   f. Have physical, mental or medically compromising conditions; or
   g. Have a developmental disability or other severe cognitive impairment and one or more of the following characteristics that prevent routine dental care in an office setting:
      i. Acute situational anxiety and extreme uncooperative behavior; and/or
      ii. A physically compromising condition.

2. Adults (19 or older) who:
   a. Have a developmental disability or other severe cognitive impairment and one or more of the following characteristics that prevent routine dental care in an office setting:
      i. Acute situational anxiety and extreme uncooperative behavior; and/or
      ii. A physically compromising condition
   b. Have sustained extensive orofacial or dental trauma; or

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c. Are medically fragile, have complex medical needs, contractures or other significant medical conditions potentially making the dental office setting unsafe for the client

CLINICAL

American Academy of Pediatrics Oral Health Policy 2005, Hospitalization and Hospital Operating Room Access for Dental Care of Infants, Children and Adolescents, and Persons with Special needs

PDA Dental Services Hospital Operating Room Committee: members include a general dentist; a pediatric dentist with hospital operating room privileges; a general dentist with hospital operating room privileges.

See NW Dental Care Program Policy 22: Policy and Procedure for Handling Requests for General Anesthesia in Operating Room for members with 1) KP dental coverage only; or, 2) KP dental and KP medical coverage.
Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

The purpose of these criteria is to provide coverage of limited facial enhancement to patients with HIV-associated lipodystrophy in order to alleviate the stigma associated with this condition. Due to their appearance, patients with facial lipodystrophy syndrome (LDS) may become depressed, socially isolated, and in some cases, may stop their HIV treatments in an attempt to halt or reverse this complication.

Many systemic illnesses cause bodily shape changes. Any weight loss from illness, chemotherapy, or voluntary weight loss will lead to some facial skin sagging. Kaiser Permanente does not cover the correction of these conditions. The specialist administering the injections will use his/her best judgment in determining the difference between HIV lipodystrophy and natural, age-appropriate atrophy and aging. Kaiser Permanente coverage extends to improving the gaunt look of lipodystrophy, and coverage is not meant to be a yearly touch up.

DEFINITIONS

Facial Lipodystrophy/lipoatrophy: a progressive, symmetrical loss of subcutaneous fat that results in a facial abnormality such as severely sunken cheeks. This fat loss can be a result of aging or weight loss or can arise as a complication of HIV and/or highly-active antiretroviral therapy (HAART).

Dermal filler: an injectable substance that stimulates the production of new collagen, increasing facial volume.

CRITERIA

1) Dermal filler injections are indicated for the following conditions:
   a) diagnosis of human immunodeficiency virus (HIV) and
   b) diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4, related to HIV or highly-active antiretroviral therapy (HAART) and
   c) diagnosis of depression secondary to the physical stigma of facial lipodystrophy

These criteria do not imply or guarantee approval. Please check 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. NOV 19
2) The dermal filler is approved by the Food and Drug Administration for Facial Lipodystrophy Syndrome (LDS), e.g. Sculptra® and Radiesse®.

CONTRAINDICATIONS
Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function as determined by HIV provider.

OTHER CONSIDERATIONS
Multiple sessions may be necessary to complete the therapy depending upon the severity of the lipodystrophy. Grade 3 may take up to 4 sessions; and Grade 4 may take up to 8 sessions. The following link provides photographic examples of the Carruthers grading system (scale of 1-4): www.facialwasting.org. If additional treatments are desired, repeat photos of the face will be evaluated by the IDC providers to determine if further treatments are warranted. Re-treatment is usually necessary one to two years after the initial therapy.

Radiesse® will be provided as the standard treatment unless the following criteria are met for Sculptra®:
1) Radiesse tried and not effective
2) Allergic reaction to Radiesse

SPECIAL GROUP CONSIDERATIONS
This policy/criteria apply to Medicare and Commercial group/individual members. It does not apply to Medicaid members.

CLINICAL
Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual, Chapter 1, part 250.5- Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS)- Rev. 122, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10

These criteria do not imply or guarantee approval. Please check 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. NOV 19
DEFINITIONS
Qualified Provider- as it pertains to Applied Behavior Analysis (ABA), providers considered qualified to evaluate and diagnose an Autism Spectrum Disorder are Developmental Pediatricians, Psychologists and Psychiatrists.

ABAS III-Adaptive Behavior Assessment System, 3rd Edition provides a complete assessment of adaptive skills by assessing composite norms for three general areas of adaptive behavior: conceptual, social and practical.

POLICY
Kaiser Foundation Health Plan of the NW (KFHPNW) has reviewed the best available literature related to Applied Behavior Analysis (ABA) and consulted with internal Licensed Behavior Analysts. The literature points to potential (particularly in pre-school-aged children) evidence supporting ABA as an effective EARLY INTERVENTION treatment modality for behaviors associated with autism. ABA is the most empirically validated and clinically endorsed intervention for autism spectrum disorders. ABA will be covered when patients, providers and programs meet the following conditions:

CRITERIA:

Member
1. The member has had a documented diagnostic assessment and final diagnosis of an Autism Spectrum Disorder (ASD) by:
   a) a qualified Kaiser Permanente provider or multi-disciplinary team appropriately licensed and trained in the diagnosis and treatment of autism; or
   b) a qualified non-Kaiser Permanente provider whose evaluation and diagnosis has been reviewed and confirmed by a qualified Kaiser Permanente provider or multi-disciplinary team appropriately licensed and trained in the diagnosis and treatment of autism; AND

2. There is documentation of a severe challenging behavior and/or communication and social interaction issues, clearly related to characteristics of ASD that:
a) presents a health or safety risk to self or others (such as self-injury, aggression toward others, destruction of property, elopement, severe disruptive behavior); OR
b) presents a significant functional interference within the home and/or community (as demonstrated by scores ≥ 2 SD below the mean on ABAS-III); AND

3. There is a reasonable expectation on the part of a qualified treating practitioner or multidisciplinary team that the individual’s behavior will improve significantly with ABA therapy.

ABA Provider

1. The lead behavioral therapist providing treatment and/or clinical supervision must meet criterion a or b, in addition to c below:
   a) is a mental health professional licensed to practice independently in the state in which the ABA is provided; or
   b) is currently certified by the BACB (Behavior Analyst Certification Board) as a BCBA (Board Certified Behavior Analyst); and
   c) is approved by the Health Plan; and

2. Clinical Oversight of supervised staff must be included if utilizing staff with the following credentials:
   a) RBT (Registered Behavior Technician)
      The RBT must be supervised for at least 5% of service hours provided and one of those supervised visits must be face-to-face with the supervising practitioner per month;
   b) BCaBA (Board Certified assistant Behavior Analyst)
      The BCaBA must be supervised by a BCBA for at least 2% of service hours provided per month.

3. Family members may not be paid providers.

ABA Program

1. After a Permanente evaluation and diagnosis, Permanente will submit an internal referral for ABA services if deemed appropriate after the evaluation. Upon conclusion of the evaluation, the parent will be provided with a letter outlining the next steps to take to determine which ABA provider they would like to receive services through. After the parent chooses a provider, the ABA provider will then contact PDEV UM to initiate an external referral to that provider when the provider and patient are ready to begin services. The ABA provider will then review historical data and collect additional information to initiate the assessment and determine treatment goals. After the initial assessment is completed, the provider will submit the assessment results and treatment goals to PDEV UM and the treatment plan will be reviewed for medical necessity to ensure the patient is receiving the appropriate ABA therapy. Treatment plans will be reviewed at least every six months to ensure the patient is progressing throughout the treatment. Treatment plans should not be submitted prior to 10 days before the authorization expires to ensure the data provided reflects the current treatment with the patient; AND

2. The services offered are not duplicative of services offered by or required of the school/educational system; AND

These criteria do not imply or guarantee approval. Please check 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. NOV 19
3. The program, unless explicitly authorized as part of the treatment plan, will not include other services/therapies; AND

4. The presence and active participation of an adult caregiver or parent/foster parent/legal guardian is addressed in the child’s treatment plan, including, as appropriate, family education, support and training.

Continuation Criteria

ALL of the following must be reviewed and approved (or denied) by the appropriate utilization management reviewer:

1. The criteria for treatment must continue to be met. The patient will need to be reassessed by a Qualified Provider upon the appearance of new maladaptive behaviors that meet the medical necessity criteria.

2. The provider will submit an updated treatment plan no more than 10 days before the authorization expires. The treatment plan should include the progress toward goals since the previous authorization period and the plan for the authorization period being requested.

3. The individual treatment plan must include:
   a. Patient demographics including:
      • Full name, date of birth, age, identified gender, contact information, medical record number (MRN), and primary diagnosis
   b. Reason for referral
   c. Psychosocial/background information
   d. Clinical and historical information
   e. Assessment procedures and results
   f. Observable and measurable baseline data
   g. Observable and measurable treatment goals
   h. Behavior support plan (if needed)
   i. Risk/benefit analysis
   j. Parent goals/involvement requirements
   k. Recommendation on the number of units/hours that are being requested for treatment. This should include the CPT codes of the services being requested and a clinical summary that justifies the number of units/hours that are being recommended.
   l. Coordination of care with other providers supporting the patient.
   m. Criteria for discharge from treatment
   n. Crisis management plan
      i. This should address any medical, behavioral, or environmental concerns.

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NOV 19
o. Supervision Protocol (only applies if utilizing BCaBA and/or RBT providers)
   i. Frequency and duration of supervision per month
   ii. Team members involved.

4. There is documentation that progress toward goals have been made and that there is a reasonable expectation the patient will improve significantly with the continuation of ABA services.

**Transition to Discharge**

1. Transition Plan to discharge must be submitted to PDEV UM within 3 months of the discharge date and the Plan must include how services will be transitioned to the next level of care recommended.

2. Upon discharge, the provider will submit a case closure summary signed by the parent/guardian to PDEV within 30 days of discharge. The case closure summary will include:
   a. Date of discharge
   b. How treatment will be maintained
   c. Any recommended support services

**Criteria for Discharge**, ONE of the following must be met:

1. No significant, measurable improvement has been documented in the patient's targeted behavior(s) reasonably attributable to the services provided or, after a period of 6 months of appropriate treatment, there is no reasonable expectation that termination of the current treatment would put the patient at risk for decompensation or the recurrence of signs and symptoms that necessitated treatment.
   - For changes to be “significant”, they must result in improved function, be durable over time beyond the end of the actual treatment session, and be generalizable outside the treatment setting.

2. Treatment is making the symptoms persistently worse.

3. The patient has achieved adequate stabilization of the challenging behavior and less-intensive modes of therapy are appropriate.

4. The patient demonstrates an inability to maintain long-term gains from the proposed plan of treatment.

**SPECIAL GROUP CONSIDERATIONS**

Applies to all commercial groups (including Feds, PEBB, OEBB) and Medicare
Washington Medicaid: Does not apply to WA Medicaid members.
Oregon Medicaid: Check LineFinder

**CLINICAL**

1. The Permanente Medical Group (TPMG) Practice Guidelines for Behavioral Health Treatment Services Available to Members with Autism Spectrum Disorder
3. Behavior Analyst Certification Board (BACB)- Professional and Ethical Compliance Code for Behavior Analysts

These criteria do not imply or guarantee approval. Please check 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. NOV 19
Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

MAXILLOFACIAL ANOMALIES POLICY and MEDICAL NECESSITY CRITERIA

The purpose of these criteria is to define KFHPNW coverage of limited maxillofacial prosthetic services included as part of a medical treatment plan for members with a maxillofacial anomaly when medically necessary to restore function.

ORS 743A.148 and 743.706 require health benefit plans to provide coverage for maxillofacial prosthetic services when necessary for restoration and management of head and facial structures that cannot be replaced with living tissue and are defective because of disease, trauma, or birth and developmental deformities when performed for the purpose of controlling or eliminating infection; controlling or eliminating pain; or restoring facial configuration or function.

Note that separate policies/criteria exist for coverage of:
1. dental and orthodontic services for treatment of craniofacial anomalies (UR 67),
2. general anesthesia for dental procedures performed in an inpatient/ambulatory operating room (UR 56),
3. surgical interventions for temporo-mandibular disorders (UR 49).

DEFINITIONS

Adjunctive treatment (as defined by ORS 743.706): secondary or ancillary prosthetic services provided in conjunction with the primary treatment of a medical condition.

Maxillofacial: related to or involving the bony structures of the upper and lower jaw and the face.

Prosthesis: an artificial replacement or substitute for a body part or function, either internal or external.

CRITERIA: Prosthetic Services for treatment of a MAXILLOFACIAL ANOMALY

NOTE: although dental implants are excluded from medical coverage, prosthetic services (including dental implants) must be covered when ALL of the following criteria are met.

1) An anomaly affecting the head and facial structures exists that are defective:
   - Because of disease, trauma, birth or developmental deformity; AND
   - Not due to the result of bacterial disease or poor hygiene, i.e. common dental and/or periodontal disease.

2) The requested prosthetic services are a necessary adjunctive treatment for the purpose of:
   - Controlling or eliminating infection
   - Controlling or eliminating pain
   - Restoring facial configuration or functions such as speech, swallowing, or chewing, but not including cosmetic procedures rendered to improve the normal range of conditions.

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--a Participating speech pathologist or other appropriate Participating specialist has
determined that the **inability to speak or swallow** (or ineffectiveness) is the
result of missing teeth; OR
--an appropriate Participating specialist has determined that the **inability to chew**
(or ineffectiveness) is the result of missing teeth.

3) An appropriate Participating specialist agrees that the success and sustainability of the prosthesis is
likely and that the prosthesis is expected to improve function (e.g. the bone and/or oral structures
can support the prosthesis).

4) The service(s) is not requested in order to alter the alignment of teeth unless necessary for
retention of a maxillofacial prosthesis.

5) The requested prosthesis is necessary for restoration and management of head and facial
structures that cannot be replaced with living tissue.

6) The requested prosthetic services are the least costly, clinically appropriate treatment as
determined by a Participating Provider.

**CONTRAINdications:** Bone or tissue cannot sustain a prosthesis

**SPECIAL GROUP CONSIDERATIONS**

**OR/WA Commercial:** Applies to all commercial groups

**Oregon Medicaid:** Criteria do not apply as mandate not applicable to OR Medicaid

**Medicare:** Criteria do not apply as mandate not applicable to Medicare. Local Coverage Determination
L33738 requires coverage of facial prostheses when there is a loss or absence of **facial tissue** due to disease,
trauma, surgery or a congenital defect (e.g. obturator and other facial prostheses). See the EOC for coverage
of routine dental care, including dentures.

**Washington Medicaid:** Criteria do not apply as mandate not applicable to WA Medicaid. If services are
provided by a dentist or oral surgeon for dental diagnoses they are covered through DSHS FFS. The
exception to this would be in the ED (the health plan is responsible for services provided in ED). Please see
the following excerpt from the Benefit Index:

Excluded are services provided by dentists and oral surgeons for dental diagnoses, and anesthesia for
dental care. (HO-BH Contract Exhibit A 3.6.3.6)

Covered through WA Medicaid Fee-For-Service for:

1) Children under age 21 through DSHS Fee-For-Service. (HCA Dental Related Services Medicaid
   Provider Guide)

2) Effective 7/1/11 verifiably pregnant women; aged and disabled adults age 21 and over residing in
   one of the following:
   • Nursing home.
   • Nursing facility wing of a state veteran’s home.
   • Privately operated intermediate care facility for the intellectually disabled (ICF/ID).
   • State-operated Residential Habilitation Center (RHC).

3) Effective 7/1/11 aged and disabled adults age 21 and over under an Aging and Disability Services
   Administration (ADSA) 1915 (c) waiver program.

4) Effective 10/1/11 disabled adults age 21 and over under Division of Developmental Disabilities.
   (HCA Dental Related Services Medicaid Provider Guide page B.1)

These criteria do not imply or guarantee approval. Please check 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.  NOV 19
REFERENCES:

Commercial Medical EOC EXCLUSIONS: Dental Services. Dental care including dental x-rays; dental services following accidental injury to teeth; dental appliances; dental implants; orthodontia; and dental services necessary for or resulting from medical treatment such as surgery on the jawbone and radiation treatment is limited to: (a) emergency dental services; or (b) extraction of teeth to prepare the jaw for radiation treatment.

The EOC also excludes “dental appliances and dentures” under DME section.

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Internal & Outside Referral Guidelines:

Kaiser Foundation Health Plan (KFHP) provides Sexual Reassignment Surgery (SRS) for the treatment of patients with gender dysphoria who meet the medical criteria below. Members whose employer groups do not cover Transgender Surgery but who wish to access these services out of pocket, will be evaluated according to the same medical criteria.

Covered Sexual Reassignment Surgeries and Procedures are limited to:

Male-to-Female (MtF): Clitoroplasty, Intersex Surgery, Labiaplasty, Orchiectomy, Penectomy, Vaginoplasty, Breast Augmentation. Tracheal Shave and facial hair removal as well as surgical area hair removal by electrolysis or laser are covered when referred by a Gender Pathways provider.

Female-to-Male (FtM): Glansoplasty, Hysterectomy, Intersex Surgery, Mastectomy with Chest Reconstruction, Metoidioplasty, Mons Resection, Penile Implant, Phalloplasty, Salpingo-Oophorectomy, Scrotoplasty, Testicular Prosthesis, Urethroplasty, Vaginectomy.

Genital Surgery Clinical Review Criteria:

Members are eligible for genital surgery coverage if they meet all of the following criteria:

1. Member is at least 18 years old; and
2. Member has been diagnosed with persistent, well-documented gender dysphoria, i.e.
   a. Member experiences discomfort or distress that is caused by a discrepancy between person’s gender identity and that person’s sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics); and
   b. Member’s gender dysphoria is not due to a chromosomal disorder; and
   c. Member’s gender dysphoria is not due to a psychiatric disorder (such as schizophrenia); and
3. Member has the capacity to make fully informed decisions and to consent to treatment; and
4. If significant medical or mental health concerns are present, they are well controlled; and
5. Member has completed a program of gender identity treatment, as evidenced by all of the following:
   a. Member has undergone or is in the process of completing 12 continuous months of hormone therapy as appropriate to the patient’s gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones); and
   b. Member has a referral for SRS from a qualified mental health professional who has independently assessed the patient. A letter, signed by the mental health professional, may be sent or the assessment and the recommendation can be documented in the patient’s chart. The referral letter or chart note is expected to cover the following recommended content:
      i. The client’s general identifying characteristics
      ii. Results of the client’s psychosocial assessment, including any diagnoses;

1 Coverage for the treatment of gender dysphoria resulting from a chromosomal disorder is included in the member’s medical coverage.
iii. The duration of the mental health professional’s relationship with the client, including the type of evaluation and therapy or counseling to date;

iv. 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;

v. A statement about the fact that informed consent has been obtained from the patient;

vi. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this; and

c. FtM members requesting metoidioplasty or phalloplasty and MtF members requesting vaginoplasty must have undergone or be in the process of completing 12 continuous months of living in a gender role that is congruent with their gender identity.

**Mastectomies with Chest Reconstruction Clinical Review Criteria:**

FtM members are eligible for Mastectomies with Chest Reconstruction (areola tattooing, including touch-ups, are covered when the areola can’t be salvaged and the tattooing is referred by a Gender Pathways provider) if they meet all of the following criteria:

1. Member is at least 18 years old*; and

2. Member has been diagnosed with persistent, well-documented gender dysphoria, i.e.
   a. Member experiences discomfort or distress that is caused by a discrepancy between person’s gender identity and that person’s sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics); and
   b. Member’s gender dysphoria is not due to a chromosomal disorder; and
   c. Member’s gender dysphoria is not due to a psychiatric disorder (such as schizophrenia); and

3. Member has the capacity to make fully informed decisions and to consent to treatment; and

4. If significant medical or mental health concerns are present, they are reasonably well controlled; and

5. Member has one referral for breast/chest surgery from a qualified mental health professional who has independently assessed the patient. For providers working within a multidisciplinary specialty team, a letter may not be necessary; rather, the assessment and the recommendation can be documented in the patient’s chart. The referral is expected to cover the following recommended content:

   i. The client’s general identifying characteristics
   
   ii. Results of the client’s psychosocial assessment, including any diagnoses;
   
   iii. The duration of the mental health professional’s relationship with the client, including the type of evaluation and therapy or counseling to date;
   
   iv. 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;
   
   v. A statement about the fact that informed consent has been obtained from the patient;
   
   vi. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this; and

*For FtM members under the age of 18, chest surgery can be carried out on adolescents 16 years or older after ample time of living in the desired gender role and after one year of testosterone treatment. Adolescent FtM patients seeking chest surgery must also meet criteria 2-6 above and must have parental consent or be legally emancipated.

**Breast Augmentation Clinical Review Criteria:** (see Special Group Considerations)

MtF members are eligible for Breast Augmentation if they meet all of the following criteria:

1. Single letter of referral from a qualified mental health professional; and

2. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; and

3. Capacity to make a fully informed decision and to consent for treatment; and

Coverage for the treatment of gender dysphoria resulting from a chromosomal disorder is included in the member’s medical coverage.
4. Age 18 years or older (Note: age requirement will not be applied to augmentation in Male-to-Female patients if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention); and
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; and
6. Twelve months of living in a gender role that is congruent with their gender identity (real life experience) and
7. 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.

The plan will determine authorization and consent to care based on medical necessity from the documentation outlined in 1-7 above. The criteria above apply for only initial male to female augmentation mammoplasty, any additional breast augmentation after an initial mammoplasty is considered a cosmetic procedure, and therefore, a contract exclusion.

**Surgical Revisions:**

Surgical revisions following gender-confirming surgery may be considered medically necessary if at least one of the following is true as determined by a physician board-certified in plastic surgery (or other specialty physician, as appropriate):

- Revision would result in improved function; OR
- Revision is likely to result in relief of pain associated with the gender confirming surgery; OR
- Revision is intended to change a physical appearance that is NOT within normal anatomic variation consistent with the member’s gender identity.

Surgical revision of prior gender-confirming surgery will not be covered 1) when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight or 2) when determined by the reviewing physician to be necessary due only to deficiencies associated with the original surgery, in which case any revisions would be provider liability.

**Surgical Reversals**

Surgery to reverse partially or fully completed gender reassignment is considered not medically necessary except in the case of a serious medical barrier to completing gender reassignment or the development of a serious medical condition necessitating reversal.

**Definitions:**

<table>
<thead>
<tr>
<th>Male-to-Female SRS Procedures:</th>
<th>Female-to-Male SRS Procedures:</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Clitoroplasty: creation of clitoris</td>
<td>-Glansoplasty: procedure to give the head of the neophallus the appearance of a genetic male glans</td>
</tr>
<tr>
<td>-Labiaplasty: creation of labia</td>
<td>-Hysterectomy: removal of uterus</td>
</tr>
<tr>
<td>-Orchiectomy: removal of testicles</td>
<td>-Mastectomy: removal of the breasts</td>
</tr>
<tr>
<td>-Penectomy: removal of penis</td>
<td>-Metoidioplasty: creation of micro-penis using the clitoris</td>
</tr>
<tr>
<td>-Vaginoplasty: creation of vagina</td>
<td>-Mons resection: removal of excess skin to improve access and visibility of the penis</td>
</tr>
<tr>
<td>-Breast Augmentation: surgical procedure to increase the size of the breasts</td>
<td>-Penile implant: implantation of artificial penis</td>
</tr>
<tr>
<td></td>
<td>-Phalloplasty: creation of penis, with or w/o urethra</td>
</tr>
<tr>
<td></td>
<td>-Salpingo-Oophorectomy: removal of fallopian tubes and ovaries</td>
</tr>
</tbody>
</table>

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Scrotoplasty: creation of scrotum
Testicular Prosthesis: implantation of artificial testes
Urethroplasty: creation of urethra within the penis
Vaginectomy: removal of vagina

Intersex surgery: genital reconstructive surgery including surgery performed for the purpose of transforming normal adult genitalia of one sex to that of the other (also referred to as sexual reassignment surgery)

Special Group Considerations
These criteria apply to OR/WA Commercial members EXCEPT that the Breast Augmentation Criteria do not apply to WA PEBB members. See WA PEBB Breast Augmentation Surgery Criteria.

These criteria apply to Medicare.

These criteria do NOT apply to WA Medicaid/Molina.

OHP (Oregon Medicaid) see OHP Prioritized List, Guideline Note 127 for treatment of Gender Dysphoria.

References:
- Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version. The World Professional Association for Transgender Health (WPATH)
- Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. The Endocrine Society, 2009

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These criteria do not imply or guarantee approval. Please check 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. NOV 19
Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

CRANIOFACIAL ANOMALIES POLICY and MEDICAL NECESSITY CRITERIA

The purpose of these criteria is to define KFHPNW coverage of limited dental and orthodontic services associated with congenital craniofacial anomalies when medically necessary to restore function.

Oregon House Bill 4128 requires health benefit plans to provide coverage for dental and orthodontic services for the treatment of craniofacial anomalies if the services are medically necessary to restore function.

Note that separate policies/criteria exist for coverage of:
1. Maxillofacial prosthetic services for treatment of maxillofacial anomalies (UR 64),
2. general anesthesia for dental procedures performed in an inpatient or ambulatory operating room (UR 56),
3. surgical interventions for temporo-mandibular disorders (UR 49).

DEFINITIONS

Congenital: present at birth

Craniofacial Anomaly (as defined by Oregon House Bill 4128): a physical disorder identifiable at birth that affects the bony structures of the face or head, including but not limited to: cleft palate, cleft lip, craniosynostosis, craniofacial microsomia and Treacher Collins syndrome. It does not include:
- Temporomandibular joint disorder (TMJ)
- Developmental maxillofacial conditions that result in overbite, crossbite, malocclusion or similar developmental irregularities of the teeth.

CRITERIA:

Dental and Orthodontic Services as part of a treatment plan for CRANIOFACIAL ANOMALIES are covered when ALL of the following criteria are met.

NOTE: When the patient has one of the diagnoses listed in criterion 1 (including attachment), a referral to the Craniofacial Clinic (for HMO members) will be authorized for the member’s condition to be assessed. The KP multi-disciplinary Craniofacial Clinic team will make the clinical decision as to medical necessity and treatment plan that may include dental and orthodontic services necessary to restore physical function.

1) A congenital anomaly exists affecting the bony structures of the face or head which disrupts function and includes at least one of the following (see Attachment for more possible diagnoses):
   - Cleft palate and/or cleft lip
   - Craniosynostosis
   - Craniofacial microsomia
   - Mandibulofacial Dysostosis (Treacher Collins Syndrome)

2) The indication for dental and/or orthodontic services is directly related to the craniofacial anomaly.
The requested services are not related to treatment of a temporo-mandibular joint disorder or developmental maxillofacial condition resulting in an overbite, crossbite, malocclusion or similar developmental irregularity of the teeth.

3) Dental and/or orthodontic services for the treatment of craniofacial anomalies are medically necessary to restore function.

SPECIAL GROUP CONSIDERATIONS

OR/WA Commercial: Applies to all commercial groups

Oregon Medicaid: Mandate Not applicable to OR Medicaid; benefit coverage TBD

Added Choice/POS: members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

Medicare: Mandate Not applicable to Medicare.

Washington Medicaid: Mandate Not applicable to WA Medicaid: If services are provided by a dentist or oral surgeon for dental diagnoses they are covered through DSHS FFS. The exception to this would be in the ED (the health plan is responsible for services provided in ED). See the Apple Health Benefit Index for more information:

REFERENCES:

COMMERCIAL Medical EOC EXCLUSIONS: Dental Services. Dental care including dental x-rays; dental services following accidental injury to teeth; dental appliances; dental implants; orthodontia; and dental services necessary for or resulting from medical treatment such as surgery on the jawbone and radiation treatment is limited to: (a) emergency dental services; or (b) extraction of teeth to prepare the jaw for radiation treatment. The EOC also excludes “dental appliances and dentures” under DME section.

Relevant part of Limited Dental Services Exclusions
The following dental Services are not covered, except where specifically noted to the contrary in the EOC:
  • Extraction of teeth, except as described in the “Covered Dental Services” section.
  • Orthodontics, except as described in the “Covered Dental Services” section.

Relevant part of Covered Dental Services
We cover dental Services only as described below:
  • Dental and orthodontic Services for the treatment of craniofacial anomalies if the Services are Medically Necessary to improve or restore function.

Oregon House Bill 4128: https://legiscan.com/OR/text/HB4128/id/586611
ATTACHMENT: ICD 10 diagnosis codes for skull, facial and jaw anomalies:

**Cleft palate, not otherwise specified: Q35.9**
- Formerly ICD 9: 749.00 – 749.25

**Congenital anomalies/malformations of skull and face bones, not otherwise specified: Q75.0**
This code applies to:

- Absence of skull bones
- Acrocephaly
- Congenital deformity of skull or facial bones
- Craniosynostosis
- Crouzon's disease
- Delayed closure of anterior fontanel
- Goldenhar syndrome
- Hypertelorism
- Imperfect fusion of skull
- Mandibulofacial dysostosis
- Oculomandibular dysostosis
- Oxycephaly
- Platybasia
- Premature closure of cranial sutures
- Robin syndrome
- Tower skull
- Treacher Collins syndrome
- Trigonocephaly

**Congenital deformities and asymmetry of skull, face, and jaw: Q67.0** (These may or may not be congenital anomalies but will be evaluated further by the Craniofacial Clinic team.)

- Unless otherwise specified below, this code applies to:
  - Compression facies Q67.1
  - Depressions in skull
  - Deviation of nasal septum, congenital
  - Dolichocephaly Q67.2
  - Plagiocephaly Q67.3
  - Potter's facies
  - Squashed or bent nose, congenital

These criteria do not imply or guarantee approval. Please check 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.
ASSISTED REPRODUCTIVE TECHNOLOGY MEDICAL NECESSITY CRITERIA

DEFINITIONS

**ART**- Assisted Reproductive Technology refers to procedures in which pregnancy is attempted through the manipulation of sperm and egg outside the body, such as in vitro fertilization (IVF) or gamete intra-fallopian transfer (GIFT).

**IVF**- In-vitro fertilization involves retrieving an egg from the woman, combining with sperm in a lab, observing and raising the embryos in the lab for 3 to 5 days, then transferring the resulting embryo back into her uterus.

**GIFT**- Gamete intra-fallopian transfer is a modified version of in vitro fertilization (IVF). GIFT involves retrieving an egg from the woman, combining with sperm in a lab then immediately transferring the unfertilized egg and sperm into her fallopian tube with fertilization taking place in the fallopian tube instead of in a laboratory dish.

**ZIFT**- Zygote intra-fallopian transfer is a modified version of in vitro fertilization (IVF). ZIFT involves retrieving an egg from the woman, combining with sperm in a lab then transferring the fertilized egg (called a zygote) into her fallopian tube before cell division takes place. The zygote is transferred the next day after fertilization occurs.

**IUI**- Intra-uterine insemination is the placement of washed and concentrated sperm via a catheter into a woman's uterus when she is ovulating. It is often combined with superovulation medicine to increase the number of available eggs, which can result in multiple gestation.

CRITERIA

Assisted reproductive technology may be indicated when A-C below are present:

A. Female 45 years or younger with use of autologous oocytes and 1, 2 and 3 below.

1. Infertility, as defined by **1 or more** of the following:
   a) Failure to conceive after regular unprotected sexual intercourse for 1 year or more for female 34 years or younger
   b) Failure to conceive after regular unprotected sexual intercourse for 6 months or more for female 35 years old or older
   c) Female with cancer chemotherapy-induced ovulatory failure (eg, from cyclophosphamide)
   d) Female with history of bilateral oophorectomy
e) Female with impending infertility due to planned cancer treatment for cure (e.g., chemotherapy or oophorectomy)

f) Male partner is HIV positive and **ALL** of the following:
   i. Adherent with highly active antiretroviral therapy
   ii. Washed sperm needed for insemination to prevent HIV transmission to female partner

g) Male partner with infertility due to cancer therapy (e.g., orchiectomy or chemotherapy)

h) Male partner with nonobstructive azoospermia or severe oligospermia

i) Male partner with paraplegia, and sperm retrieval needed to achieve pregnancy (e.g., electro-ejaculation or surgical sperm retrieval)

j) Prior failed cycle of in vitro fertilization or intracytoplasmic sperm injection

2. Infertility evaluation and treatment performed, as indicated by **1 or more** of the following:

a) Female with impending infertility due to planned cancer treatment for cure (e.g., chemotherapy or oophorectomy)

b) Female with infertility due to oophorectomy or cancer treatment and **ALL** of the following:
   i. No evidence of tumor recurrence, as indicated by **1 or more** of the following:
      ▪ Two years or more after completion of cancer treatment for gynecologic tumors
      ▪ Two years or more after completion of hematopoietic stem cell transplant
      ▪ Three years or more after initial diagnosis in female with breast cancer without axillary lymph node involvement
      ▪ Five years or more after initial diagnosis in female with breast cancer with axillary lymph node involvement
      ▪ After completion of adjuvant tamoxifen, if appropriate, for breast cancer
   ii. Patient had embryo or oocyte cryopreservation prior to oophorectomy or cancer treatment.

c) Hysterosalpingogram shows absent or nonpatent fallopian tube (e.g., from prior ectopic pregnancy or pelvic inflammatory disease)

d) In vitro fertilization or intracytoplasmic sperm injection needed, as indicated by **1 or more** of the following:
   i. Cryopreserved sperm needed from male partner (e.g., after chemotherapy)
   ii. Prior in vitro fertilization or intracytoplasmic sperm injection cycle resulted in failed fertilization or pregnancy
   iii. Surgical sperm retrieval needed for azoospermia or severe oligospermia in male partner

e) Treatment for infertility, including specific disorders, as indicated by **1 or more** of the following:
   i. Anovulatory female without polycystic ovary syndrome or other endocrinopathy and **1 or more** of the following:
      ▪ For female 34 years or younger: trial of at least 4 cycles of clomiphene citrate or letrozole and intrauterine insemination
      ▪ For female 35 to 37 years of age: trial of at least 3 cycles of clomiphene citrate or letrozole and intrauterine insemination
      ▪ For female 38 years or older: proceed with in vitro fertilization or 2-3 cycles of intrauterine insemination without gonadotropin.
ii. Endocrinopathy in female (eg, hypothyroidism, adrenal disorders, pituitary tumor)

iii. Endometriosis

iv. Failure of 12 cycles of intrauterine insemination

v. Hypogonadotrophic hypogonadism in male partner

vi. Intrauterine pathology (eg, adhesions, polyps)

vii. Pelvic adhesions

viii. Polycystic ovary syndrome, treated with **ALL** of the following:
- Other causes of infertility ruled out or treated (eg, thyroid disease, hyperprolactinemia, male factor infertility)
- Treated with at least 6 cycles of clomiphene citrate or letrozole

ix. Repair of varicocele in male partner

x. Retrograde ejaculation in male partner treated with pharmacotherapy

xi. Submucosal leiomyomas

xii. Tubal anastomosis (ie, reversal of tubal ligation)

f) Unexplained infertility and **ALL** of the following:

i. Conventional treatment of unexplained infertility has failed, as indicated by **1 or more** of the following:
   - For female 34 years or younger: trial of at least 4 cycles of controlled ovarian stimulation (eg, clomiphene citrate or letrozole) and intrauterine insemination
   - For female 35 to 37 years of age: trial of at least 3 cycles of controlled ovarian stimulation (eg, clomiphene citrate or letrozole) and intrauterine insemination
   - For female 38 years or older: proceed with in vitro fertilization or 2-3 cycles of intrauterine insemination without gonadotropin.

ii. Normal female serum levels of **ALL** of the following:
   - Anti-Mullerian hormone
   - Estradiol
   - FSH
   - Progesterone (in midluteal phase)
   - Prolactin
   - TSH

iii. Normal hysterosalpingogram or sonohysterography

iv. Normal sperm count, motility, and morphology in male partner

3. **1 or more** of the following:
   a) Embryo cryopreservation needed for impending infertility due to planned cancer treatment
   b) Maximum number of embryos to be transferred is consistent with current evidence to limit risk of multiple-birth pregnancies, as indicated by **1 or more** of the following:
      i. One fresh or frozen single-embryo transfer for female 36 years or younger during first 3 in vitro fertilization cycles
      ii. Up to 2 fresh or frozen embryos transferred for female 36 years or younger after first 3 failed single-embryo transfer in vitro fertilization cycles
      iii. One fresh or frozen single-embryo transfer for female 37 years of age during first in vitro fertilization cycle
iv. Up to 2 fresh or frozen embryos transferred for female 37 years of age after first failed in vitro fertilization cycle
v. Up to 2 fresh or frozen embryos transferred for female 38 years of age if prognosis is favorable and/or additional embryos are available for cryopreservation
vi. Up to 3 fresh or frozen embryos transferred for female 38 years of age if prognosis is unfavorable and no additional embryos are available for cryopreservation
vii. Up to 3 fresh or frozen embryos transferred for female 39 to 40 years of age if prognosis is favorable and/or additional embryos are available for cryopreservation
viii. Up to 4 fresh or frozen embryos transferred for female 39 to 40 years of age if prognosis is unfavorable and no additional embryos are available for cryopreservation
ix. Up to 5 fresh or frozen embryos transferred for female 41 to 45 years of age

B. No hydrosalpinx or after treatment with tubal occlusion or salpingectomy
C. No prior in vitro fertilization cycle, or maximum number of prior in vitro fertilization cycles has not exceeded a total of 6 cycles without a live birth

SPECIAL GROUP CONSIDERATIONS

ART is typically excluded from coverage. Check CM for exceptions or limitations.

Cryopreservation is typically excluded from coverage unless the member has coverage for ART, in which case, the associated cryopreservation is also covered. The Exclusion is applied when cryopreservation is requested/billed as a distinct procedure aside from a covered ART procedure. When cryopreservation is covered, procedures to obtain eggs/sperm are also covered.
ORTHOGNATHIC SURGERY MEDICAL NECESSITY CRITERIA

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

PURPOSE

The purpose of these criteria is to define KFHPNW coverage for orthognathic surgery to treat a limited number of medical conditions, as mandated by WAC 284-43-5640.

DEFINITIONS

Orthognathic Surgery- the surgical correction of abnormalities of the mandible and/or maxilla. The underlying abnormality may be present at birth or may become evident as the patient grows and develops or may be the result of traumatic injuries.

Malocclusion- imperfect positioning of the teeth when the jaws are closed. The condition may also be referred to as an irregular bite, crossbite, or overbite.

Congenital- a condition present at birth such as a cleft lip or cleft palate.

CRITERIA

Orthognathic surgery and supplies are covered for any of the following:

1) conditions resulting from a skeletal malocclusion which resulted from TMJ arthritis, ankylosis, trauma or tumor and is not amenable to orthodontic therapy alone.

2) sleep apnea with a referral from the Sleep Medicine department. Patient must have documented severe OSA (obstructive sleep apnea) or the patient has documented mild-moderate OSA with severe symptoms (based on Epworth Sleepiness Scale) with an identifiable dentofacial deformity such as maxillary or mandibular hypoplasia. Patient is also either intolerant or unable to use CPAP.

3) a congenital anomaly with a referral from the Cranio-facial Clinic.

Orthognathic surgery to treat other developmental skeletal malocclusions is not covered.
SPECIAL GROUP CONSIDERATIONS

Although this is a WA State mandate, the coverage criteria will be universally applied to all lines of business beginning 1/1/17 except as follows:

Washington and Oregon Medicaid- these criteria do not apply to Medicaid.

Added Choice/POS: members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

REFERENCES

WAC 284-43-5640; Essential health benefit categories, section (3)b,iii,B
CAROTID ENDARTERECTOMY MEDICAL NECESSITY CRITERIA

DEFINITIONS
Carotid stenosis- Narrowing of the blood vessels (carotid arteries) in the neck restricting the blood flow to brain and head.

CRITERIA
Procedure is indicated for 1 or more of the following:

- Within the past 6 months the patient has had a symptomatic event on the same side of the brain or retina as a carotid lesion (i.e. carotid-related transient ischemic event or nondisabling stroke) and the procedure is judged appropriate as indicated by ALL of the following:
  - Significant carotid artery stenosis as indicated by 1 or more if the following:
    - Carotid stenosis ≥70% by noninvasive imaging
    - Carotid stenosis ≥50% by catheter-based imaging
    - Carotid stenosis ≥50% by noninvasive imaging with corroboration (e.g. by magnetic resonance angiogram or CT angiogram)
  - Patient not at high risk for perioperative complications or death

- Patient is asymptomatic but procedure is judged appropriate as indicated by ALL of the following:
  - Carotid artery stenosis ≥70% by noninvasive imaging
  - Patient at low perioperative risk for complications or death
  - Medical management and risk factor modification (e.g. antiplatelet therapy, diabetes control, smoking cessation, treatment of hypertension and hyperlipidemia) are not preferred

SPECIAL GROUP CONSIDERATIONS
These criteria do not apply to OR/WA Medicaid

CLINICAL REFERENCES
MCG, Inpatient and Surgical Care Guidelines for Carotid Endarterectomy

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BOTULINUM TOXIN INJECTION FOR CHRONIC MIGRAINE PROPHYLAXIS

Policy Number: 0005
Effective Date: May 1 2015
Reviewed Date: May 29, 2019
Next Review: May 2020

BACKGROUND

CLINICAL BACKGROUND

Chronic migraine (CM) is a type of chronic daily headache that can be severely disabling. Individuals diagnosed with CM must have experienced headaches for at least 15 days per month for more than three months, with headaches on at least eight days that possessed migrainous features (IHS 2018). Approximately three million adults in the United States (1.3% of the population) are estimated to be affected by CM (Natoli 2010). One in five of these individuals are occupationally disabled. Research has also shown that CM is associated with reduced quality of life (Bigal 2008, Dodick 2006).

Treatment for chronic migraine typically includes pharmacotherapy, but may include complementary treatments such as changes in diet, sleep, and exercise. Acute pharmacotherapy includes options such as simple analgesics, non-steroidal anti-inflammatory drugs, triptans and ergotamines. Preventive pharmacotherapy options include antidepressants, anticonvulsants, beta-blockers, calcium channel blockers and botulinum type A (e.g., BTA or Botox) injections (Chawla 2011). Currently, Botox is the only drug specifically FDA-approved for chronic migraine prophylaxis. The use of BTA for chronic migraine involves injections into the muscles of the head and neck approximately every 12 weeks.

POLICY AND CRITERIA

Injection of onobotulinumtoxinA (Botox) may be considered medically necessary for chronic migraine prophylaxis when both of the following criteria are met:

- Diagnosis of chronic migraine as described by the International Headache Society Classification with attacks occurring for 15 or more days per month for more than 3 months, of which at least 8 days per month are migraine headache; AND
- Member has documented failure of (or intolerance to) prophylactic migraine medications from at least 3 different drug classes. Each trial must have lasted at least 2 months. Classes include:
  - Anti-depressants
  - Anti-convulsive medications
  - Beta blockers
  - Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers

Members meeting the above criteria may receive no more than 4 treatments in a 12 month period.

If a previous trial of botulinum toxin injection for chronic migraine prophylaxis has NOT produced at least a 7 day reduction in monthly frequency of migraines or reduced total headaches duration by at least 100 hours per month, additional injections are considered NOT medically necessary.

RATIONALE

EVIDENCE BASIS

Northwest Permanente Evidence-based Medicine Services reviewed the evidence on botulinum toxin for migraine prophylaxis in 2015. Findings and conclusions were as follows:
Aurora 2010 (n = 679) reported results from the Phase III Research Evaluating Migraine Prophylaxis Therapy I (PREEMPT I) study, assessing the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. PREEMPT I consisted of a 24-week, double-blind, parallel-group, placebo-controlled phase followed by a 32-week, open-label phase. Investigators assessed the frequency of headache episodes (the primary outcome of interest), as well as numerous secondary outcomes, including the frequency of headache days, the frequency of migraine days, and the frequency of migraine episodes. The study reports no improvement in reduction of headache episodes over placebo (p = 0.344). However, the study does report that BTA produced a 7% reduction in headache days over placebo, meaning that patients receiving BTA injections had, on average, 1.4 fewer headache days per month than those receiving placebo (p = 0.006, 95% CI: -2.40, -0.40).

Diener 2010 (good-quality RCT): Diener et al. (n = 705) reported results from the Phase III Research Evaluating Migraine Prophylaxis Therapy II (PREEMPT II) study, assessing the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. Like PREEMPT I, PREEMPT II consisted of a 24-week, double-blind, parallel-group, placebo-controlled phase followed by a 32-week, open-label phase. Whereas the primary outcome of interest in PREEMPT I was the frequency of headache episodes, PREEMPT II focused instead on the frequency of headache days. Investigators also measured numerous secondary outcomes, including the frequency of headache episodes, the frequency of migraine days, and the frequency of migraine episodes. The study reports that BTA produced an 11.5% reduction in headache days over placebo, i.e., 2.3 fewer headache days per month (p < 0.001, 95% CI: -3.25, -1.31).

Dodick 2010 (pooled data from two good-quality RCTs detailed above): Dodick et al. (n = 1384) pooled data from the PREEMPT I and PREEMPT II studies to address again the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. Again, investigators focused on the mean change from baseline in frequency of headache days, and reported that BTA produced a 9% decrease in mean headache days over placebo, i.e., 1.8 fewer headache days per month (-8.4 BTA vs -6.6 placebo, p < 0.001, 95% CI: -2.52, -1.13; Number Needed to Treat [NNT] = 9 for one person to experience at least a 50% reduction in the frequency of headache days).

Within both PREEMPT I and PREEMPT II, there is a potential for “unblinding” of the study participants to their treatment group allocation. Because BTA produces a numbing sensation and physical differences in facial appearance following injection, it is possible that participants were able to determine whether they were receiving BTA or placebo. This has the potential to result in ascertainment bias that may bias these studies’ results. However, investigators did expend rigorous effort to conduct a double-blind study, and we do not see room for methodological improvement to overcome this potential issue with subject masking to the receipt of active drug versus placebo.

In both trials, more than 60% of participants reported acute headache pain medication overuse. The International Classification of Headache Disorders 2nd edition (ICHD-2) does not classify patients with acute head pain medication overuse as having chronic migraine: “migraine headache occurring on 15 or more days per month for more than three months in the absence of medication overuse.” If practitioners are using the ICHD-2 criteria for chronic migraine, their patient population would differ from the PREEMPT I study population. It is important to take this difference into consideration when attempting to generalize these findings.

There were significant differences between the treatment and placebo groups at baseline in both PREEMPT I (Aurora 2010) and in the pooled analysis of PREEMPT I and PREEMPT II (Dodick 2010). The placebo group had significantly more baseline headache episodes (Aurora 2010: placebo = 13.4, BTA = 12.3, p = 0.023; Dodick 2010: placebo = 13.0, BTA = 12.2, p = 0.004) and migraine episodes (Aurora 2010: placebo = 12.7, BTA = 11.5, p = 0.006; Dodick 2010: placebo = 12.2, BTA = 11.4, p = 0.004) than the treatment group. The treatment group reported significantly more cumulative headache hours (Aurora 2010: placebo = 274.9, BTA = 295.7, p = 0.022; Dodick 2010: placebo = 281.22, BTA = 295.93, p = 0.021) at baseline. If there is a differential in the magnitude of the placebo response among individuals with more or less frequent headaches or among individuals reporting more or less headache hours these imbalances in baseline characteristics might act as confounders. Because the placebo

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response is particularly relevant when measuring patient-reported outcomes (Hróbjartsson 2010) as was done in these trials, these possible confounders should be considered when interpreting study findings.

All studies report that treatment with 155 Units (U) to 195 U of BTA every 12 weeks over 24 weeks was well-tolerated. Pooled results from PREEMPT I and PREEMPT II showed that 62.4% of individuals receiving BTA reported adverse events, compared to 51.7% receiving placebo. Serious adverse events were reported by 4.8% of individuals receiving BTA compared to 2.3% receiving placebo. Additionally, 3.8% of those receiving BTA discontinued because of adverse events, compared to 1.2% of those receiving placebo. Adverse events most frequently cited for discontinuation of the study were neck pain (0.6%), muscular weakness (0.4%), headache (0.4%) and migraine (0.4%). No deaths were reported within either group. Both PREEMPT I and PREEMPT II had 32-week open label phases following the 24-week randomized, double-blind phases to study adverse events further.

Additional literature published between 2015 and 2016 identified only reports of new analyses of previously reported data, including 4 subgroup analyses, 1 pooled analysis, 1 systematic review, 1 meta-analysis, and 1 cost-effectiveness analysis. None of the reported analyses alter the conclusions of the previous review.

Authors of a more recent Cochrane review did not identify any additional literature (Herd 2018). In that review, authors also performed a meta-analysis combining results of the relevant RCTs. The pooled mean difference between botulinum toxin and placebo showed a benefit of approximately three fewer migraine-days per month in the treatment group (-3.1, 95% CI -4.7 to -1.4). In another meta-analysis, the authors excluded trials at high risk of bias, leaving the PREEMPT 1 and PREEMPT 2 trials (Aurora 2010 and Diener 2010, respectively). While there was still a significant benefit in favor of the treatment group, the estimate was somewhat smaller, with a mean reduction of two fewer migraine-days per month.

RELEVANT GUIDELINES

The American Academy of Neurology (AAN) reviewed evidence related to BTA for various indications, including migraine prophylaxis, in their 2008 guideline (Naumann 2008). An updated literature search in 2016 informed the following guidelines regarding chronic migraine:

**Strong Evidence** OnaBoNT-A should be offered as a treatment option to patients with CM to increase the number of headache-free days (Level A).

**Moderate Evidence** OnaBoNT-A should be considered to reduce headache impact on health-related quality of life (Level B).

The AAN 2016 guideline was reaffirmed in 2019 with no changes.

In guidelines issued by the National Institutes for Clinical Excellence (NICE), botulinum toxin type A is recommended as a treatment option for chronic migraine. NICE states the following:

1.1 **Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):**

   - That has not responded to at least three prior pharmacological prophylaxis therapies and
   - Whose condition is appropriately managed for medication overuse

1.2 **Treatment with botulinum toxin type A that is recommended according to 1.1 should be stopped in people whose condition:**

   - Is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) or
   - Has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months

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1.3 People currently receiving botulinum toxin type A that is not recommended according to 1.1 and 1.2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

## CODES

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<thead>
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<th>Description</th>
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<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)</td>
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<td>J0585</td>
<td>Botulinum toxin type A, per unit [Botox]</td>
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<td>G43.001 – G43.919</td>
<td>Migraine headache</td>
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## REFERENCES


### POLICY HISTORY

<table>
<thead>
<tr>
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<th>Action</th>
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<tbody>
<tr>
<td>May 1, 2015</td>
<td>New policy</td>
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<tr>
<td>June 27, 2017</td>
<td>Calcium channel blockers removed as a class of prophylactic medication as suggested by clinician reviewer due to lack of efficacy</td>
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<tr>
<td>April 24, 2018</td>
<td>Definition of chronic migraine updated to reflect 3rd edition of ICHD</td>
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<tr>
<td>May 29, 2019</td>
<td>No policy changes; literature and guideline updates with no substantive changes.</td>
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ELECTIVE SURGERY

Policy Number: 0004  
Effective Date: March 17, 2015  
Reviewed Date: June 28, 2019  
Next Review: July 2020

BACKGROUND

CLINICAL BACKGROUND

Elective surgery is surgery that is subject to choice, either by the patient or doctor. The procedure may be beneficial to the patient but does not need to be done at a particular time. Elective surgery is surgery that is non-emergent. The majority of surgeries performed are elective, with more than 85% being elective as estimated by a study of the Nationwide Inpatient Sample (Ingraham 2011). Although there may be less risk associated with elective procedures, there remains potential for morbidity and mortality with many of these procedures. This policy is intended to ensure that patients scheduled to undergo surgery with increased risk of mortality or morbidity are receiving appropriate care.

POLICY AND CRITERIA

Elective surgical procedures may be considered medically necessary when ALL of the following criteria (A-D) are met:

A. The patient is expected to benefit in terms of prolonging of life, symptom improvement, or quality of life improvement;

B. The patient is deemed to be an acceptable candidate for surgery as determined by the surgeon performing the procedure AND has documented one of the following
   a. The patient’s 30-day risk of death or serious complication resulting from surgery is estimated to be less than 2% as calculated by a validated risk assessment tool; OR
   b. The patient’s 30-day risk of death or serious complication is estimated to be less than 10% as calculated by a validated risk assessment tool AND there is at least a 20% probability (i.e., 1 in 5 chance) of clinically significant benefit to the patient as judged by two physicians with expertise in the field; OR
   c. The patient’s 30-day risk of death or serious complication is estimated to be more than 10% as calculated by a validated risk assessment tool AND there is at least a 20% probability (i.e., 1 in 5 chance) of clinically significant benefit to the patient as judged by three physicians with expertise in the field.

C. The patient does not have any significant comorbidities that are believed to limit life expectancy or functional status such that the patient would be unable to realize the expected benefits of surgery.

D. The patient has been abstinent from smoking for at least 4 weeks prior to scheduling surgery, except in cases of reproductive, cancer-related or diagnostic surgeries.

Validated risk assessment tools include:

- ACS NSQIP Surgical Risk Calculator
- P-POSSUM
- RCRI

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**RATIONALE**

**EVIDENCE BASIS**
Ingraham evaluated the incidence of surgery-related morbidity, serious morbidity, and mortality among patients undergoing elective surgery between 2005 and 2008 across the United States (Ingraham 2011). Overall mortality was reported to be 0.8%, while serious morbidity was 4.7%, and overall morbidity was 8.8%. The most common elective procedures were cholecystectomy, hernia repair, colectomy, and mastectomy.

Similarly, in another 2011 retrospective analysis, the 30-day mortality following elective surgery was 0.43% (Sessler 2011). The most common procedures were knee arthroplasty, nephrectomy, prostatectomy, spinal fusion, hysterectomy, and colorectal resection.

In another study that evaluated surgical risk by day-of-the-week for elective surgeries, authors reported that overall mortality risk ranged from 0.55% to 0.82% (Aylin 2013). The authors also specified rates per procedure for high-risk procedures, including excision of the esophagus and/or stomach (2.58% to 4.92%), excision of the colon and/or rectum (2.01% to 5.73%), coronary artery bypass graft (1.76% to 2.26%), repair of aortic aneurysm (3.22% to 6.93%), and excision of the lung (1.71% to 3.92%). Combined mortality rates for lower risk procedures ranged from 0.17% to 0.24%. Estimates from the Aylin study may not be completely representative of practice in the United States because data came from English hospitals. According to a 2005 study of all surgical procedures, the overall 30-day risk of mortality for all procedures ranges between 0.7% and 1.7% (Boyd 2005).

**EXPLANATION AND RATIONALE**
The identified evidence indicates that the average 30-day mortality for all elective procedures is between about 0.5% and 2.0%. Based on this threshold, this policy sets a threshold of 2% risk of mortality before an additional clinical expert opinion is needed to determine medical appropriateness. If the patient's predicted risk of 30-day mortality is greater than 2% (i.e., higher than average), an additional opinion should be obtained from another specialist clinician in the field to determine whether the patient's likelihood of benefit is great enough to justify the high-risk procedure. If the 30-day mortality risk exceeds 10%, two additional clinician opinions must evaluate and deem the procedure medically appropriate.

**REFERENCES**


EPIDURAL STEROID INJECTIONS

Policy Number: 0001  
Effective Date: Jan 20 2015  
Reviewed Date: June 27, 2019  
Next Review: July 2020

BACKGROUND

CLINICAL BACKGROUND (excerpted directly from Hayes 2017)

“Approximately 25% of the adults in the United States reported low back pain in the past 3 months (Deyo et al., 2006), and low back pain is a global health issue that is likely to increase over future decades (Hoy et al., 2012). In addition, sciatica, or leg pain originating from injury to or pressure on the sciatic nerve, is also a common cause of pain and disability, with reports of this condition ranging from 1.2% to 43% of patients with low back pain (Konstantinou and Dunn, 2008; Lewis et al., 2011). According to some estimates, the total annual economic cost for patients with low back pain in the United States approaches $100 billion (Crow and Willis, 2009).

Despite the increased sensitivity of diagnostic tools in detecting abnormalities in the structures of the lumbar spine, the cause of back pain may remain unknown in many patients. However, if back pain is not due to malignancy or underlying infection, 90% of patients will experience symptom resolution in ≤ 2 months. Causes that are identified include herniation of a lumbar intervertebral disc and spinal stenosis, or narrowing of the spinal canal (Valat et al. 2010; Jacobs et al., 2011). Conservative treatments for low back pain and sciatica include rest, analgesics, and anti-inflammatory medications; physical therapy; and advice regarding posture and exercise (Manchikanti et al., 2012a).

If symptoms persist, injections of local anesthetics and/or steroids along the nerve root or into the epidural space can provide a nonsurgical treatment option for some patients. Since low back pain and sciatica may also be due to other potentially serious spinal conditions, such as spinal tumor, infection, fracture, or cauda equina syndrome, these conditions must be ruled out based on medical history, physical examination, and laboratory and imaging studies before epidural steroid injections (ESIs) are considered (WebMD Medical Reference, 2012).

The rationale for the use of ESIs to treat low back pain and sciatica rests on the idea that steroids reduce inflammation and decrease pain by inhibition of inflammatory mediators such as phospholipase A2, stabilization of hyperexcitable nerve membranes, and reduction of capillary permeability.

Delivery of steroids directly into the epidural space exposes the spinal nerve roots to higher concentrations of medications for a longer period of time than systemic administration. Although positive reports of pain reduction by ESIs have led to widespread acceptance and prescription of this treatment, some studies have suggested that steroids do not provide additional pain relief beyond the anesthetic that is typically included in ESIs, and safety concerns have been raised (Price et al., 2005; Abdi et al., 2007).”

POLICY AND CRITERIA

For patients initiating epidural steroid treatment
The patient may receive up to 2 epidural steroid injections at least 2 weeks apart to determine adequacy of response if the following criteria are met:

A) The patient has neck or back pain with a radicular component, AND
B) Pain has been present for at least 1 month duration without improvement despite medical treatment OR has severe radicular pain from an acute disc herniation, AND

C) The patient has none of the following contraindications for epidural steroid injection:
   a. Use of Coumadin or platelet inhibitors, or other signs of compromised blood clotting status
   b. Local site infection
   c. Ongoing infection (acute viral or bacterial illness)
   d. Patient refusal
   e. Allergy to steroid or anesthetics

Additional injections for patients not experiencing at least 50% reduction in pain during the 6 weeks following the first injection are not medically necessary.

For patients with documented prior positive response

D) The patient has experienced a documented reduction in pain of at least 50% during the 6 weeks following the previous injection; AND

E) The patient has NOT received an epidural steroid injection within the previous 6 weeks for the same pain; AND

F) The patient has NOT received 3 epidural steroid injections within the last year for the same pain.

Repeat injections extending beyond 12 months will be reviewed for continued medical necessity.

**RATIONALE**

**EVIDENCE BASIS**

“For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed, with some trials finding moderate short-term benefits and others finding no differences. There is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. For nonradicular low back pain, there is likewise no convincing evidence that injections and other interventional therapies are effective, while there is consistent evidence that facet joint steroid injection, prolotherapy and intradiscal steroid injections are no more effective than sham therapies.” (HERC 2017)

“For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others found no differences versus placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials that compared epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, there are case reports of paralysis and infections. There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection, or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though one higher-quality trial found that if...
an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes.” (HERC 2017)

“There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms. Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects. Although chymopapain chemonucleolysis is effective for radiculopathy due to herniated lumbar disc, it is less effective than discectomy and is no longer widely available in the United States, in part due to risk of severe allergic reactions. Three trials suggest that intradiscal steroid injection has similar efficacy to chemonucleolysis, although none were placebo controlled.” (HERC 2017)

“For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions. Trials of IDET and radiofrequency denervation reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings, making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to one to two small placebo-controlled randomized trials (botulinum toxin injection, epidural steroid injection for nonradicular low back pain, PIRFT and sacroiliac joint steroid injection), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty…or other medications). (HERC 2017)

**RELEVANT GUIDELINES**

In guidelines issued by the American Society of Interventional Pain Physicians (ASIPP), patients may receive diagnostic injections (no more than two) at least one week apart (preferably two). If patients experience at least a 50% reduction in pain, they are eligible for therapeutic injections, to be provided every two to three months if there is evidence of at least 8 weeks of at least 50% pain relief. (ASIPP 2009).

**CODES**

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<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level</td>
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<td>64484</td>
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<td>J1020</td>
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ICD-10 Code | Description
---|---
M47.20 – M47.28 | Other spondylosis with radiculopathy
M50.10 – M50.13 | Cervical disc disorder with radiculopathy
M51.14 – M51.17 | Intervertebral disc disorders with radiculopathy
M53.0 – M53.1 | Cervicocranial – cervicobrahial syndrome
M53.81 – M53.83 | Other specified dorsopathies [cervical region]
M54.10 – M54.18 | Radiculopathy
M54.2 | Cervicalgia
M54.30 – M54.5 | Sciatica and lumbago
M54.6 | Pain in thoracic spine
M54.9 | Dorsalgia, unspecified

REFERENCES


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BACKGROUND

CLINICAL BACKGROUND (excerpted from CMS 2018)

Cancer is the result of genetic changes to deoxyribonucleic acid (DNA) that can be inherited or acquired during the lifetime. While each cancer may have unique genetic changes that could vary among cells of the same tumor type, there are certain mutations that commonly cause cancer, including mutations to tumor suppressor genes, DNA repair genes, or proto-oncogenes. Moreover, metastatic cancer cells and cells of the original cancer usually have some molecular features in common, such as the presence of changes to specific chromosomes containing DNA.

Sequencing technology such as next generation sequencing (NGS) is used to read the order of nucleotide molecules on DNA has improved to more effectively provide detailed information on multiple types of GAs simultaneously. The NGS oncology panel tests also provide patients and their providers a more comprehensive genetic profile of cancer and information relevant to potential cancer treatments. NGS oncology panel tests hold potential for patients and providers in optimizing (personalizing) therapies that target specific characteristics of individual patient cancers. However, it is important that these tests produce valid results that are useful in guiding therapies to improve outcomes for patients with advanced cancer.

F1CDx is a next generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB), using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The Foundation Medicine F1CDx is intended to be used in accordance with the approved therapeutic product labeling. Additionally, F1CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. The F1CDx assay is a single-site assay performed at Foundation Medicine, Inc. intended to be used as a companion diagnostic to identify patients that may benefit from treatment following detection of specific genetic changes.

POLICY AND CRITERIA

FoundationONE testing may be considered medically necessary when ALL of the following criteria are met:

1. Patient currently has relapsed, refractory, metastatic, or advanced stage III or IV cancer; AND
2. Patient has not been previously tested using the same NGS test for the same primary diagnosis of cancer (repeat testing may occur when a new primary cancer diagnosis is made); AND
3. Patient has decided to seek further cancer treatment; AND
4. Testing is performed in a CLIA (Clinical Laboratory Improvement Amendments)-certified laboratory; AND
5. Testing is ordered by a treating physician; AND
6. Testing is NOT being performed as part of a clinical trial.

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EVIDENCE BASIS

CMS reviewed evidence regarding next generation sequencing for cancer indications in their national coverage analysis (CMS 2018) prior to issuance of their national coverage determination. Their findings are as follows:

“Based on the evidence reviewed, patient characteristics most likely to benefit from molecular diagnostic tests are patients having recurrent, metastatic, or advanced stage IV cancer (see Takeda et al 2015, Johnson et al 2014, and Ross et al 2016 including 55%, 85%, and 80% patients with stage IV disease, respectively). However, not every cancer is described clinically consistently by stages in the publications reviewed. For example, Ali-Rohil et al 2016 described patients with squamous cell carcinoma as having advanced cancer, and studies that include patients with liver cancers such as Kim et al 2015 could use a liver cancer specific staging system, such as the Barcelona Clinic Liver Cancer (BCLC) system, or the Cancer of the Liver Italian Program (CLIP) system, or the Okuda system, or chosen to include a liver function classification such as the Child-Pugh score for cirrhosis, or simply described such cancer by the extent to which the tumor could be removed surgically. The American Joint Committee on Cancer (AJCC) established an evidence-based anatomic staging, which can be used to communicate cancer through standardized terms found in their Cancer Staging Manual for the tumor node metastasis (TNM) staging system. In contrast, the SEER program uses summary stages of in situ, localized, regional, distant, and unknown to focus on categorizing how far a cancer has spread from a point of origin. There can be limitations also to the ability to clinically use or report staging. For examples, cancers which are not typically treated surgically, or cancers that are treated surgically after treatment with anti-cancer agents, could under-estimate tumor stage. In addition to staging of cancers, the evidence demonstrates that recurrent cancers could also benefit from additional diagnostic laboratory testing using NGS (Meric-Bernstam et al 2015, Swisher et al 2017). Therefore, based on the evidence review we proposed that a diagnostic laboratory test using NGS be covered for patients with recurrent, metastatic, or advanced stage IV cancer.

Of the 25 studies added to the evidence and analysis, one tissue based study (Yates et al., 2017) provided evidence supporting the proposed determination on clinical validity of diagnostic laboratory tests using next generation sequencing for metastatic breast cancer and additionally relapsed breast cancer, supporting expansion of the patient criteria included for coverage. An additional randomized trial (Long et al., 2017) provided stronger evidence supporting the proposed determination on clinical utility (higher overall survival and relapse free survival) of BRAF V600 mutations treated with adjuvant dabrafenib plus trametinib in stage III melanoma and supporting inclusion of stage III cancers in this final decision.

Research is ongoing to identify the extent of acquired mutations due to treatment with chemotherapy or radiation. Indeed researchers are continuing to identify the molecular markers involved in invasion (Friedl and Alexander 2011) and metastasis (Roubaud et al. 2017) to further develop tests that may predict a higher risk of a more aggressive cancer or the likelihood of response to one or more treatments. However, this research has not yet demonstrated the improvements of patients with advanced cancer and their health outcomes after performing multiple diagnostic laboratory tests using NGS. Therefore, we proposed to cover NGS as a diagnostic laboratory test if the patient has not previously received the same diagnostic laboratory test using NGS.

Furthermore, a patient who is no longer seeking treatment for his or her advanced cancer could not benefit from further diagnostic laboratory testing as such results would not be used to select from available treatments for the patient’s cancer. The FDA-label indicates that diagnostic laboratory tests using NGS are intended to be used to identify patients who may benefit from treatment following detection of specific genetic alterations. Therefore, we proposed that a diagnostic laboratory test using NGS be covered for a patient who decided to seek further cancer treatment (e.g., therapeutic chemotherapy) and remains a candidate for further therapy.

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Companion Diagnostic with Analytical and Clinical Validity: A companion diagnostic provides information that is essential for the safe and effective use of a corresponding drug or biological product. These types of tests help the treating physician select a particular therapeutic product for their patient based on the test results. The indications for use of a companion diagnostic approved or cleared by the FDA therefore includes the analytical and clinical validity, as well as the clinical utility to support covering companion diagnostic laboratory tests and for this coverage determination we have outlined specific coverage requirements in section I. We acknowledge that clinical utility includes demonstration that the patients have improvements in health outcomes from clinical studies using a companion diagnostic test that has been analytically and clinically validated. In order to provide evidence demonstrating improvements in health outcomes, we expect that the test will serve to directly manage the patient’s cancer in two specific ways. First, when the validated test is essential for the use of one or more therapeutic interventions and second, when the validated test identifies patients in the same population who have been previously studied to benefit from such therapeutic interventions. To this end, FDA approval ensures that the device has been analytically and clinically validated in the population previously studied to support CMS to identify the patient health outcomes associated with the benefit of a specific therapeutic intervention as described on the FDA label.

Health outcomes of interest: We believe based on the evidence review that the health outcomes of interest were best summarized by Jardim et al. (2015). Specifically, the investigators performed a meta-analysis of 57 randomized and 55 non-randomized trials representing a total of 38,104 patients to compare efficacy outcomes between approved treatments. The analysis of the study identified that personalized therapy is associated with increased clinical benefit across tumor types and markers as demonstrated substantially higher response rates, longer time to disease progression, and longer overall survival. Systematic evidence reviews and meta-analysis that are well designed and include a number of comparable trials representing a large pool of patients such as the analysis by Jardim et al. provide a strong level of evidence. In addition, 5 observational studies reported improvements in progression free survival for patients studied, including Haslem et al. 2017, Hortbogyi et al. 2016, Johnson et al. 2016, Radovich et al. 2016, and Swisher et al. 2017. Improvements in overall survival were reported in observational studies including Hortbogyi et al. 2016, Javle et al. 2016, Schwaederle et al. 2016b, Singhi et al. 2017, and Wheler et al. 2013. While observational studies in general represent a lower level of evidence, the studies do provide consistent supportive evidence across a broad number of patients with cancer.”

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<th>ICD-10 Code and Description</th>
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<td>C00.4 Malignant neoplasm of lower lip, inner aspect</td>
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<td>C00.5 Malignant neoplasm of lip, unspecified, inner aspect</td>
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<td>C00.6 Malignant neoplasm of commissure of lip, unspecified</td>
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NOV 19
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These criteria do not imply or guarantee approval. Please check 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.
C40.91 Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92 Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0 Malignant neoplasm of bones of skull and face
C41.1 Malignant neoplasm of mandible
C41.2 Malignant neoplasm of vertebral column
C41.3 Malignant neoplasm of ribs, sternum and clavicle
C41.4 Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9 Malignant neoplasm of bone and articular cartilage, unspecified
C43.0 Malignant melanoma of lip
C43.10 Malignant melanoma of unspecified eyelid, including canthus
C43.11 Malignant melanoma of right eyelid, including canthus
C43.11 Malignant melanoma of right upper eyelid, including canthus
C43.12 Malignant melanoma of right lower eyelid, including canthus
C43.12 Malignant melanoma of left eyelid, including canthus
C43.121 Malignant melanoma of left upper eyelid, including canthus
C43.122 Malignant melanoma of left lower eyelid, including canthus
C43.20 Malignant melanoma of unspecified ear and external auricular canal
C43.21 Malignant melanoma of right ear and external auricular canal
C43.22 Malignant melanoma of left ear and external auricular canal
C43.30 Malignant melanoma of unspecified part of face
C43.31 Malignant melanoma of nose
C43.39 Malignant melanoma of other parts of face
C43.4 Malignant melanoma of scalp and neck
C43.51 Malignant melanoma of anal skin
C43.52 Malignant melanoma of skin of breast
C43.59 Malignant melanoma of other part of trunk
C43.60 Malignant melanoma of unspecified upper limb, including shoulder
C43.61 Malignant melanoma of right upper limb, including shoulder
C43.62 Malignant melanoma of left upper limb, including shoulder
C43.70 Malignant melanoma of unspecified lower limb, including hip
C43.71 Malignant melanoma of right lower limb, including hip
C43.72 Malignant melanoma of left lower limb, including hip
C43.8 Malignant melanoma of overlapping sites of skin
C43.9 Malignant melanoma of skin, unspecified
C44.00 Unspecified malignant neoplasm of skin of lip
C44.01 Basal cell carcinoma of skin of lip
C44.02 Squamous cell carcinoma of skin of lip
C44.09 Other specified malignant neoplasm of skin of lip
C44.101 Unspecified malignant neoplasm of skin of unspecified eyelid, including canthus
C44.102 Unspecified malignant neoplasm of skin of right eyelid, including canthus
C44.1021 Unspecified malignant neoplasm of skin of right upper eyelid, including canthus
C44.1022 Unspecified malignant neoplasm of skin of right lower eyelid, including canthus
C44.109 Unspecified malignant neoplasm of skin of left eyelid, including canthus
C44.1091 Unspecified malignant neoplasm of skin of left upper eyelid, including canthus
C44.1092 Unspecified malignant neoplasm of skin of left lower eyelid, including canthus
C44.111 Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.112 Basal cell carcinoma of skin of right eyelid, including canthus
C44.1121 Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122 Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.119 Basal cell carcinoma of skin of left eyelid, including canthus
C44.1191 Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192 Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.121 Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.122 Squamous cell carcinoma of skin of right eyelid, including canthus
C44.1221 Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222 Squamous cell carcinoma of skin of right lower eyelid, including canthus

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<td>C49.A9</td>
<td>Gastrointestinal stromal tumor of other sites</td>
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<td>C4A.10</td>
<td>Merkel cell carcinoma of unspecified eyelid, including canthus</td>
</tr>
<tr>
<td>C4A.11</td>
<td>Merkel cell carcinoma of right eyelid, including canthus</td>
</tr>
<tr>
<td>C4A.111</td>
<td>Merkel cell carcinoma of right upper eyelid, including canthus</td>
</tr>
<tr>
<td>C4A.112</td>
<td>Merkel cell carcinoma of right lower eyelid, including canthus</td>
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<td>C50.229</td>
<td>Malignant neoplasm of upper-inner quadrant of unspecified male breast</td>
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C50.311 Malignant neoplasm of lower-inner quadrant of right female breast
C50.312 Malignant neoplasm of lower-inner quadrant of left female breast
C50.319 Malignant neoplasm of lower-inner quadrant of unspecified female breast
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C50.322 Malignant neoplasm of lower-inner quadrant of left male breast
C50.329 Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411 Malignant neoplasm of upper-outer quadrant of right female breast
C50.412 Malignant neoplasm of upper-outer quadrant of left female breast
C50.419 Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421 Malignant neoplasm of upper-outer quadrant of right male breast
C50.422 Malignant neoplasm of upper-outer quadrant of left male breast
C50.429 Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511 Malignant neoplasm of lower-outer quadrant of right female breast
C50.512 Malignant neoplasm of lower-outer quadrant of left female breast
C50.519 Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521 Malignant neoplasm of lower-outer quadrant of right male breast
C50.522 Malignant neoplasm of lower-outer quadrant of left male breast
C50.529 Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611 Malignant neoplasm of axillary tail of right female breast
C50.612 Malignant neoplasm of axillary tail of left female breast
C50.619 Malignant neoplasm of axillary tail of unspecified female breast
C50.621 Malignant neoplasm of axillary tail of right male breast
C50.622 Malignant neoplasm of axillary tail of left male breast
C50.629 Malignant neoplasm of axillary tail of unspecified male breast
C50.811 Malignant neoplasm of overlapping sites of right female breast
C50.812 Malignant neoplasm of overlapping sites of left female breast
C50.819 Malignant neoplasm of overlapping sites of unspecified female breast
C50.821 Malignant neoplasm of overlapping sites of right male breast
C50.822 Malignant neoplasm of overlapping sites of left male breast
C50.829 Malignant neoplasm of overlapping sites of unspecified male breast
C50.911 Malignant neoplasm of unspecified site of right female breast
C50.912 Malignant neoplasm of unspecified site of left female breast
C50.919 Malignant neoplasm of unspecified site of unspecified female breast
C50.921 Malignant neoplasm of unspecified site of right male breast
C50.922 Malignant neoplasm of unspecified site of left male breast
C50.929 Malignant neoplasm of unspecified site of unspecified male breast
C51.0 Malignant neoplasm of labium majus
C51.1 Malignant neoplasm of labium minus
C51.2 Malignant neoplasm of clitoris
C51.8 Malignant neoplasm of overlapping sites of vulva
C51.9 Malignant neoplasm of vulva, unspecified
C52 Malignant neoplasm of vagina
C53.0 Malignant neoplasm of endocervix
C53.1 Malignant neoplasm of exocervix
C53.8 Malignant neoplasm of overlapping sites of cervix uteri
C53.9 Malignant neoplasm of cervix uteri, unspecified
C54.0 Malignant neoplasm of isthmus uteri
C54.1 Malignant neoplasm of endometrium
C54.2 Malignant neoplasm of myometrium
C54.3 Malignant neoplasm of fundus uteri
C54.8 Malignant neoplasm of overlapping sites of corpus uteri
C54.9 Malignant neoplasm of corpus uteri, unspecified
C55 Malignant neoplasm of uterus, part unspecified
C56.1 Malignant neoplasm of right ovary
C56.2 Malignant neoplasm of left ovary
C56.9 Malignant neoplasm of unspecified ovary

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<td>Malignant neoplasm of body of penis</td>
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<td>Malignant neoplasm of other specified male genital organs</td>
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<td>C67.6</td>
<td>Malignant neoplasm of ureteral orifice</td>
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C67.7 Malignant neoplasm of urachus
C67.8 Malignant neoplasm of overlapping sites of bladder
C67.9 Malignant neoplasm of bladder, unspecified
C68.0 Malignant neoplasm of urethra
C68.1 Malignant neoplasm of paraurethral glands
C68.8 Malignant neoplasm of overlapping sites of urinary organs
C68.9 Malignant neoplasm of urinary organ, unspecified
C69.00 Malignant neoplasm of unspecified conjunctiva
C69.01 Malignant neoplasm of right conjunctiva
C69.02 Malignant neoplasm of left conjunctiva
C69.10 Malignant neoplasm of unspecified cornea
C69.11 Malignant neoplasm of right cornea
C69.12 Malignant neoplasm of left cornea
C69.20 Malignant neoplasm of unspecified retina
C69.21 Malignant neoplasm of right retina
C69.22 Malignant neoplasm of left retina
C69.30 Malignant neoplasm of unspecified choroid
C69.31 Malignant neoplasm of right choroid
C69.32 Malignant neoplasm of left choroid
C69.40 Malignant neoplasm of unspecified ciliary body
C69.41 Malignant neoplasm of right ciliary body
C69.42 Malignant neoplasm of left ciliary body
C69.50 Malignant neoplasm of unspecified lacrimal gland and duct
C69.51 Malignant neoplasm of right lacrimal gland and duct
C69.52 Malignant neoplasm of left lacrimal gland and duct
C69.60 Malignant neoplasm of unspecified orbit
C69.61 Malignant neoplasm of right orbit
C69.62 Malignant neoplasm of left orbit
C69.80 Malignant neoplasm of overlapping sites of unspecified eye and adnexa
C69.81 Malignant neoplasm of overlapping sites of right eye and adnexa
C69.82 Malignant neoplasm of overlapping sites of left eye and adnexa
C69.90 Malignant neoplasm of unspecified site of unspecified eye
C69.91 Malignant neoplasm of unspecified site of right eye
C69.92 Malignant neoplasm of unspecified site of left eye
C70.0 Malignant neoplasm of cerebral meninges
C70.1 Malignant neoplasm of spinal meninges
C70.9 Malignant neoplasm of meninges, unspecified
C71.0 Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1 Malignant neoplasm of frontal lobe
C71.2 Malignant neoplasm of temporal lobe
C71.3 Malignant neoplasm of parietal lobe
C71.4 Malignant neoplasm of occipital lobe
C71.5 Malignant neoplasm of cerebral ventricle
C71.6 Malignant neoplasm of cerebellum
C71.7 Malignant neoplasm of brain stem
C71.8 Malignant neoplasm of overlapping sites of brain
C71.9 Malignant neoplasm of brain, unspecified
C72.0 Malignant neoplasm of spinal cord
C72.1 Malignant neoplasm of cauda equina
C72.20 Malignant neoplasm of unspecified olfactory nerve
C72.21 Malignant neoplasm of right olfactory nerve
C72.22 Malignant neoplasm of left olfactory nerve
C72.30 Malignant neoplasm of unspecified optic nerve
C72.31 Malignant neoplasm of right optic nerve
C72.32 Malignant neoplasm of left optic nerve
C72.40 Malignant neoplasm of unspecified acoustic nerve

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<td>Malignant neoplasm of other cranial nerves</td>
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<tr>
<td>C7A.021</td>
<td>Malignant carcinoid tumor of the cecum</td>
</tr>
<tr>
<td>C7A.022</td>
<td>Malignant carcinoid tumor of the ascending colon</td>
</tr>
<tr>
<td>C7A.023</td>
<td>Malignant carcinoid tumor of the transverse colon</td>
</tr>
<tr>
<td>C7A.024</td>
<td>Malignant carcinoid tumor of the descending colon</td>
</tr>
<tr>
<td>C7A.025</td>
<td>Malignant carcinoid tumor of the sigmoid colon</td>
</tr>
<tr>
<td>C7A.026</td>
<td>Malignant carcinoid tumor of the rectum</td>
</tr>
<tr>
<td>C7A.029</td>
<td>Malignant carcinoid tumor of the large intestine, unspecified portion</td>
</tr>
<tr>
<td>C7A.090</td>
<td>Malignant carcinoid tumor of the bronchus and lung</td>
</tr>
<tr>
<td>C7A.091</td>
<td>Malignant carcinoid tumor of the thymus</td>
</tr>
<tr>
<td>C7A.092</td>
<td>Malignant carcinoid tumor of the stomach</td>
</tr>
<tr>
<td>C7A.093</td>
<td>Malignant carcinoid tumor of the kidney</td>
</tr>
<tr>
<td>C7A.094</td>
<td>Malignant carcinoid tumor of the foregut, unspecified</td>
</tr>
<tr>
<td>C7A.095</td>
<td>Malignant carcinoid tumor of the midgut, unspecified</td>
</tr>
<tr>
<td>C7A.096</td>
<td>Malignant carcinoid tumor of the hindgut, unspecified</td>
</tr>
<tr>
<td>C7A.098</td>
<td>Malignant carcinoid tumors of other sites</td>
</tr>
<tr>
<td>C7A.1</td>
<td>Malignant poorly differentiated neuroendocrine tumors</td>
</tr>
</tbody>
</table>
C7A.8 Other malignant neuroendocrine tumors  
C80.0 Disseminated malignant neoplasm, unspecified  
C80.1 Malignant (primary) neoplasm, unspecified  
C80.2 Malignant neoplasm associated with transplanted organ

REFERENCES


These criteria do not imply or guarantee approval. Please check 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. NOV 19
INTRAOPERATIVE NEUROMONITORING

Policy Number: 0013
Effective Date: March 2019
Reviewed Date: March 2019
Next Review: March 2020

BACKGROUND

CLINICAL BACKGROUND

Intraoperative neurophysiologic monitoring (IONM) is a practice utilizing various procedures to evaluate the integrity of neural pathways during surgery. Techniques used in IONM include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), electroencephalography (EEG), and electromyography (EMG). By monitoring neural activity using these techniques, a neurophysiologist may be able to mitigate adverse effects by identifying and communicating changes to the surgical team.

POLICY AND CRITERIA

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

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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
  - 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

These criteria do not imply or guarantee approval. Please check 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.
- Oculomotor
- Recurrent laryngeal
- Spinal accessory
- Superior laryngeal
- Trochlear

### SPINAL PROCEDURES

<table>
<thead>
<tr>
<th>Procedure</th>
<th>SSEP (with or without MEP)</th>
<th>EEG</th>
<th>EMG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsal rhizotomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction of scoliosis</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction of deformity involving traction on the spinal cord</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinal cord tumor removal</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery due to traumatic injury to spinal cord</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery for AV malformation of spinal cord</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### NON-CRANIAL VASCULAR PROCEDURES

<table>
<thead>
<tr>
<th>Procedure</th>
<th>SSEP (with or without MEP)</th>
<th>EEG</th>
<th>EMG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid artery surgery</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arteriography w/ test occlusion of carotid artery</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep hypothermic circulatory arrest</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal aortic procedures (due to risk of ischemia to spinal cord)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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| Surgery of aortic arch, its branch vessels, or thoracic aorta | ✔ |

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<table>
<thead>
<tr>
<th>INTRACRANIAL PROCEDURES*</th>
<th>SSEP (with or without MEP)</th>
<th>EEG</th>
<th>EMG</th>
</tr>
</thead>
<tbody>
<tr>
<td>95925, 95926, 95927, 95938</td>
<td>95928, 95929, 95939</td>
<td>95822, 95955</td>
<td>95860, 95861, 95867, 95868, 95870</td>
</tr>
<tr>
<td>Microvascular decompression of cranial nerves</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Removal of acoustic neuroma, congenital auricular lesions, cranial base lesions</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cholesteatoma, including mastoidotomy or mastoidectomy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Vestibular neurectomy for Meniere’s</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Removal of cranial nerve neuromas affecting any of following nerves:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abducens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glossopharyngeal</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hypoglossal</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Oculomotor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent laryngeal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinal accessory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Superior laryngeal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trochlear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep brain stimulation</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Endolymphatic shunt for Meniere’s disease</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Oval or round window graft</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Removal of cavernous sinus tumors</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Resection of brain tissue near primary motor cortex and requiring brain mapping</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Resection of epileptogenic brain tissue or tumor</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Other intracranial vascular procedures (e.g. aneurysm repair, intracranial AV malformation)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

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*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:

- 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.

RATIONALE

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 al. 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 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 the Congress of 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).

### CODES

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General neuromonitoring</strong></td>
<td></td>
</tr>
<tr>
<td>95940</td>
<td>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)</td>
</tr>
<tr>
<td>95941</td>
<td>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)</td>
</tr>
<tr>
<td>G0453</td>
<td>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)</td>
</tr>
<tr>
<td><strong>Somatosensory-evoked potentials (SSEP)</strong></td>
<td></td>
</tr>
<tr>
<td>95925</td>
<td>Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs</td>
</tr>
<tr>
<td>95926</td>
<td>Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs</td>
</tr>
<tr>
<td>95927</td>
<td>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</td>
</tr>
<tr>
<td>95938</td>
<td>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</td>
</tr>
<tr>
<td><strong>Motor evoked potentials (MEP)</strong></td>
<td></td>
</tr>
<tr>
<td>95928</td>
<td>Central motor evoked potential study (transcranial motor stimulation); upper limbs</td>
</tr>
<tr>
<td>95929</td>
<td>Central motor evoked potential study (transcranial motor stimulation); lower limbs</td>
</tr>
<tr>
<td>95939</td>
<td>Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs</td>
</tr>
<tr>
<td><strong>Brainstem auditory evoked potentials (BAEP)</strong></td>
<td></td>
</tr>
<tr>
<td>92585</td>
<td>Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive</td>
</tr>
<tr>
<td>92586</td>
<td>Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited</td>
</tr>
<tr>
<td><strong>Electroencephalography</strong></td>
<td></td>
</tr>
</tbody>
</table>

These criteria do not imply or guarantee approval. Please check 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.  **NOV 19**
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95822</td>
<td>Electroencephalogram (EEG); recording in coma or sleep only</td>
</tr>
<tr>
<td>95955</td>
<td>Electroencephalogram (EEG) during non-intracranial surgery (e.g., carotid surgery)</td>
</tr>
</tbody>
</table>

Electromyography

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95860</td>
<td>Needle electromyography; 1 extremity with or without related paraspinal areas</td>
</tr>
<tr>
<td>95861</td>
<td>Needle electromyography; 2 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95867</td>
<td>Needle electromyography; cranial nerve supplied muscle(s), unilateral</td>
</tr>
<tr>
<td>95868</td>
<td>Needle electromyography; cranial nerve supplied muscles, bilateral</td>
</tr>
<tr>
<td>95870</td>
<td>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</td>
</tr>
</tbody>
</table>

Experimental and Investigational for Intraoperative Monitoring Use

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95907-95913</td>
<td>Nerve conduction studies</td>
</tr>
<tr>
<td>95930</td>
<td>Visual evoked potential (VEP) testing central nervous system, checkerboard or flash</td>
</tr>
<tr>
<td>95937</td>
<td>Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method</td>
</tr>
</tbody>
</table>

**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.
Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures

Policy Number: 0008
Effective Date: August 1, 2015
Reviewed Date: March 19, 2019
Next Review: March 2020

BACKGROUND

CLINICAL BACKGROUND (extracted from KP MTAT 2010)

Usual Care for Sedation During Colonoscopy and Routine Upper Endoscopy Procedures
Traditional sedation for routine colonoscopy and upper endoscopy procedures, including esophagoduodenoscopy (EGD), has involved a benzodiazepine with or without an opioid. These agents have known antidotes and are usually administered by a registered nurse (RN) under the supervision of an endoscopist.

Administration of Propofol (Source: verbatim from Singh et al., 2008; Vargo et al., 2009)
In recent years propofol (2, 6-di-isopropylphenol) has increasingly been utilized as an alternative method of sedation in endoscopy suites. Propofol was initially introduced in 1989 and has since then been widely used in critical care units and emergency departments for providing sedation. Although propofol is associated with a more rapid onset of action, its use for sedation during endoscopy by non-anesthesiologists in many parts of the world (particularly North America) has been limited by concerns of potential side-effects. This agent has also been administered by anesthesiologists and certified registered nurse anesthetists (CRNAs) within KP SCAL for endoscopy procedures. Emergency medicine physicians also appear to be privileged for at least select medical centers for GI procedures. Unlike other standard sedation agents, propofol does not have an antidote/reversal agent.

There are several key terms and definitions related to methods for the administration of propofol. Several terms and definitions were summarized recently in a position statement from the American Gastroenterological Association (AGA) (Vargo et al., 2009):

Monitored Anesthesia Care (MAC): Monitored anesthesia care (MAC) is the service provided by an anesthesia specialist to the patient undergoing a diagnostic or therapeutic procedure. In many instances, although not all, MAC results in deep sedation, and the normal airway protective reflexes may be lost. MAC can include general anesthesia with endotracheal intubation.

Standard Sedation: Standard sedation refers to the administration of intravenous drugs, usually a benzodiazepine and an opioid, under the supervision of an endoscopist. A level of moderate sedation is usually targeted.

Nonanesthesiologist-administered propofol (NAAP) Administration of propofol under the direction of a physician who has not be trained as an anesthesiologist. Propofol may be used either alone or in combination with 1 or more additional agents. A level of moderate-to-deep sedation is targeted with NAAP.

Nurse-administered propofol sedation (NAPS) Describes the administration of propofol as a single agent under the direction of a physician who has not been trained as an anesthesiologist. A level of deep sedation is targeted with NAPS.

Balanced propofol sedation (BPS) (Source: Vargo et al., 2009) Administration of the combination of a benzodiazepine, and opioid, and propofol under the direction of a physician who is not an anesthesiologist. The opioid and benzodiazepine are each given as a single dose, which is followed by small incremental doses of propofol administered to achieve a target level of moderate sedation.

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Another potential method for administering propofol involves computer assistance.

**Computer Assisted Propofol Administration (CAPS)** The SEDASYS (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) system is a computer-assisted personalized sedation that integrates a suite of patient monitors (pulse oximetry, capnometry, EKG, noninvasive blood pressure (NIBP), and patient responsiveness) with oxygen and computer-controlled propofol delivery. Details on the published evidence on computer-assisted personalized sedation (CAPS) can be found in a SCPMG Technology Assessment and Guidelines Unit (TAG) assessment from February 2009.

### POLICY AND CRITERIA

Monitored anesthesia care (MAC) is considered medically necessary during gastrointestinal endoscopic procedures when there is documentation by the operating physician and/or the treating anesthesiologist that demonstrates any of the following higher risk situations exist:

A. Prolonged or therapeutic endoscopic procedure requiring deep sedation; OR
B. A history of anticipated intolerance to standard sedatives; OR
C. Increased risk for complication due to severe comorbidity. American Society of Anesthesiologists ASA class III physical status or greater; OR
D. Pediatric age group (16 years or younger); OR
E. Pregnancy; OR
F. History of active drug or alcohol abuse; OR
G. Morbid obesity (BMI > 45); OR
H. Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); OR
I. Spasticity or movement disorder complicating procedure; OR
J. Increased risk for airway obstruction due to anatomic variant including ANY of the following:
   a. Documented history of previous problems with anesthesia or sedation; OR
   b. History of stridor or severe sleep apnea requiring oxygen and BIPAP; OR
   c. Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy 21; OR
   d. Presence of oral abnormalities including but not limited to a small oral opening (less than 3 cm in an adult), high arched palate, macroglossia, tonsillar hypertrophy, or a non-visible uvula (not visible when tongue is protruded with patient in sitting position, e.g., Mallampati class greater than II), as documented by anesthesia; OR
   e. 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
   f. Jaw abnormalities including but not limited to micrognathia, retrognathia, trismus, or significant malocclusion as documented by anesthesia.

### RATIONALE

**EVIDENCE BASIS**

A 2010 Kaiser Permanente review of monitored anesthesia care for gastrointestinal disorders reported findings from systematic reviews, meta-analyses, randomized controlled trials, and published internal data (KP MTAT 2010). Their findings included the following:

“There is good evidence of improved patient satisfaction and reductions in discharge and 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. These criteria do not imply or guarantee approval. Please check 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. NOV 19
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 (ASA 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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REFERENCES


Kaiser Permanente Medical Technology Assessment Team. Administration of propofol during routine colonoscopy or upper endoscopy. February 2010.


VanNatta ME, Rex DK. Propofol alone titrated to deep sedation versus propofol in combination with opioids and/or benzodiazepines and titrated to moderate sedation for colonoscopy. Am J Gastroenterol 2006;101(10):2209-2217.


Pre-implantation Genetic Diagnosis

Policy Number: 0009
Effective Date: August 1, 2015
Reviewed Date: May 31, 2019
Next Review: May 2020

BACKGROUND

CLINICAL BACKGROUND (excerpted verbatim from NHS 2013)

“Preimplantation genetic testing is a technique used in reproductive medicine to identify inherited genetic defects in embryos created through in vitro fertilization (IVF). Preimplantation genetic diagnosis (PGD) can be offered when one or both parents have, or are carriers of, a known genetic abnormality; testing is performed on embryos created through IVF to determine whether they are at risk of genetic disease.

The use of PGD enables couples at risk of passing on an inherited disorder to decrease the risk of having an affected child significantly... PGD represents the only way for parents to have an unaffected child to whom they are both biological parents, without risking the need for termination of pregnancy. PGD is one of several reproductive options available for couples at risk of passing on a genetic condition, but the fact that the technology requires a highly skilled technical team and laboratory set up means it is significantly more expensive than the more common prenatal diagnosis option (PND)... The two commonly used post-conception diagnosis procedures [for PND] are amniocentesis and chorionic villus sampling (CVS) at 16 and 11 weeks, respectively. If the fetus is found to have the genetic condition of concern, the parents have to make difficult decisions about whether or not to opt for termination of the pregnancy. Termination of pregnancy is not an acceptable option for some couples.”

DESCRIPTION OF THE TECHNOLOGY (excerpted verbatim from Dahdouh 2015)

“PGD requires IVF with or without intra-cytoplasmic sperm injection (ICSI), embryo biopsy for DNA sampling, genetic testing, and selected embryo transfer. DNA can be extracted from the oocytes (polar bodies) or from embryonic cells as one blastomere from a cleavage-stage embryo or 5 to 10 trophectoderm cells from a blastocyst-stage embryo. The genetic material is then tested for either single-gene mutations, using molecular biology techniques (PCR, PCR-multiplex), or for chromosomal translocation and de novo aneuploidy, using cytogenetic techniques such as FISH or CCS. The latter is the emergency new cytogenetic technique that consists of identifying the whole chromosomal complement (24 chromosomes). CCS can be accomplished through microarray technology such as aCGH and SNP or through qPCR. As the cells are being tested, the embryos remain in IVF media culture. If the biopsied cell or cells are shown to be unaffected for the genetic disorder in PGD or to carry a euploid embryo in PGS, then that particular embryo is considered an apt candidate for transfer into the uterus.”

POLICY AND CRITERIA

Pre-implantation genetic diagnosis is considered medically necessary when BOTH of the following criteria are met:

1. 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; AND

2. One of the following clinical circumstances must be documented:
   a. One genetic parent has a balanced, reciprocal translocation or Robertsonian translocation; OR

These criteria do not imply or guarantee approval. Please check 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. One genetic parent has a single gene autosomal dominant disorder; OR

\textbf{c. Both genetic parents are known carriers of the same autosomal recessive disorder; OR}

\textbf{d. The female genetic parent is a known carrier of an X-linked disorder.}

The biopsy procedure to obtain a cell sample from an embryo and perform the necessary genetic testing for PGD is covered when the above criteria 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).

PGD is considered NOT medically necessary when the above-outlined criteria are not met.

\textbf{RATIONALE}

\textbf{EVIDENCE BASIS}

There is moderate strength of evidence that pre-implantation genetic diagnosis may accurately identify the presence of single gene defects in high-risk embryos of couples with a known genetic disorder. Estimates of sensitivity range from 96% to 99%, and estimates of specificity range from 80% to 85%.

There is low strength of evidence that pre-implantation genetic diagnosis does not affect neonatal outcomes such as birth weight.

There is insufficient evidence to estimate the cost-effectiveness of PGD compared to traditional prenatal testing in couples with a known genetic disorder because no studies have formally evaluated this question.

In May 2015, the Society of Obstetricians and Gynaecologists of Canada performed a comprehensive review of the literature regarding preimplantation genetic diagnosis and screening (Dahdouh 2015). The review was conducted to inform SOGC recommendations regarding preimplantation genetic testing, which are outlined under the Guidelines section of this document. The Dahdouh review did not directly report findings regarding the diagnostic accuracy of preimplantation genetic diagnosis. However, the references discussed in the Dahdouh review provided the additional detail needed. The estimated sensitivity of PGD for single gene mutations was between 96.6% and 99.2%, with estimated false negative rates between 0.8% and 3.4%. False positives were more common, with rates between 9.1% and 14.3% (Dreesen 2008 and Dreesen 2013 in Dahdouh 2015).

“Generally, the most reliable PCR-PGD protocols employ multiplex PCR. In addition to amplification of a DNA fragment encompassing the mutation site, extra fragments containing linked polymorphisms are amplified to avoid misdiagnosis due to ADO, and at least one highly polymorphic marker is amplified to detect possible contamination. Another strategy used to decrease ADO is blastocyst biopsy, with frozen embryo transfer for PGD of monogenic diseases. It has been associated with higher genotyping and implantation rates and lower amplification failure and ADO than traditional blastomere biopsy.”

Eldar-Geva (2014) performed a prospective analysis of 242 children born after PGD, along with 242 born after intracytoplasmic sperm injection (ICSI) and 733 born after spontaneous conception. Authors compared neonatal outcomes and reported that birth weight among babies born after PGD was not significantly different from those born after spontaneous conception. The overall low birth weight rate was 4.4% for PGD (compared to 12.0% for ICSI and 5.7% for spontaneous conception), and intrauterine growth restriction rate was 5.1% for PGD (compared to 9.5% for ICSI and 5.5% for spontaneous conception). Authors made the following conclusion: “Embryo biopsy itself did not cause intrauterine growth restriction or low birth weight compared with SC, despite lower gestational ages with PGD. The worsened outcomes in ICSI compared with PGD pregnancies may be due to the infertility itself.”

Dreesen (2014) reported the sensitivity and specificity of PGD for identification of monogenic diseases as part of the ESHRE PGD consortium study. Authors performed a retrospective analysis of 940
untransferred embryos, and estimated sensitivity of 99.2% and specificity of 80.9%. Overall, 93.7% of embryos were correctly classified. Authors noted that diagnostic accuracy was statistically significantly better when PGD was performed on two cells than one cell (p=0.001).

RELEVANT GUIDELINES

**American College of Obstetricians and Gynecologists**
ACOG issued a committee opinion in March 2009 (reaffirmed 2014) that addressed preimplantation genetic screening, which differs from preimplantation genetic diagnosis. Although the ACOG guideline on PGS does not make recommendations regarding PGD, it notes the following:

"Preimplantation genetic screening differs from preimplantation genetic diagnosis (PGD) for single gene disorders. In order to perform genetic testing for single gene disorders, PGD was introduced in 1990 as a component of in vitro fertilization programs. Such testing allows the identification and transfer of embryos unaffected by the disorder in question and may avoid the need for pregnancy termination (1). Assessment of polar bodies as well as single blastomeres from cleavage stage embryos has been reported, although the latter is the approach most widely practiced. Preimplantation genetic diagnosis has become a standard method of testing for single gene disorders, and there have been no reports to suggest adverse postnatal effects of the technology. Preimplantation genetic diagnosis has been used for diagnosis of translocations and single-gene disorders, such as cystic fibrosis, X-linked recessive conditions, and inherited mutations, which increase one's risk of developing cancer."

In October 2015, a committee opinion on "Identification and Referral of Genetic Conditions in Pregnancy" addressed the use of PGD. The committee made the following recommendation for those with a known causative mutation:

"Patients with established causative mutations for a genetic condition, and who desire prenatal genetic testing, should be offered preimplantation genetic testing with in vitro fertilization by a reproductive endocrinologist or prenatal diagnostic testing once pregnancy is established."

In March 2017, ACOG issued a committee opinion entitled "Carrier Screening for Genetic Conditions" (ACOG 2017). Specifically with regard to hemoglobinopathies, the authors state the following regarding preimplantation genetic diagnosis:

"Couples at risk of having a child with a hemoglobinopathy may benefit from genetic counseling to review their risk, the natural history of these disorders, prospects for treatment and cure, availability of prenatal genetic testing, and reproductive options. Prenatal diagnostic testing for the mutation responsible for sickle cell disease is widely available. Testing for α-thalassemia and β-thalassemia is possible if the mutations and deletions have been previously identified in both parents. These DNA-based tests can be performed using chorionic villi obtained by chorionic villus sampling or using cultured amniotic fluid cells obtained by amniocentesis. For some couples, preimplantation genetic diagnosis in combination with in vitro fertilization may be a desirable alternative to avoid termination of an affected pregnancy. Preimplantation genetic diagnosis has been successfully performed for sickle cell disease and most types of β-thalassemia."

**American Society of Reproductive Medicine**
The ASRM issued a practice committee opinion on preimplantation genetic diagnosis. The committee opinion outlines the following as indications for PGD:

"PGD is indicated for couples at risk for transmitting a specific genetic disease or abnormality to their offspring. For carriers of autosomal dominant disorders, the risk that any given embryo may be affected is 50%, and for carriers of autosomal recessive disorders, the risk is 25%. For female carriers of X-linked disorders, the risk of having an affected embryo is 25% (half of male embryos). PGD also can be performed and may be elected by patients who carry mutations such as BRCA1 that do not cause a specific disease but are thought to confer significantly increased risk for a disease. In some cases, there may be more than one indication for PGD, such as when..."
human leukocyte antigen (HLA) matching is performed in conjunction with testing for a specific mutation.

For individuals who carry a balanced chromosomal translocation, inversion, or other structural chromosomal rearrangement, there is increased risk that their gametes will have an unbalanced genetic composition due to excess missing genetic material. An embryo derived from the union of such an unbalanced gamete with a partner’s normal gamete also will have an unbalanced genetic composition and may be identified using telomeric probes specific for the loci of interest that must be selected for individual patients, according to their unique abnormality.”

Overall, the ASRM practice committee opinion made the following recommendations regarding PGD (ASRM 2007):

- “Before PGD is performed, genetic counseling must be provided to ensure that patients fully understand the risk for having an affected child, the impact of the disease on an affected child, and the limitations of available options that may help avoid the birth of an affected child.
- PGD can reduce the risk for conceiving a child with a genetic abnormality carried by one or both parents if that abnormality can be identified with tests performed on a single cell.
- Prenatal diagnostic testing to confirm the results of PGD is encouraged strongly because the methods used for PGD have technical limitations that include the possibility for a false negative result.”

ASRM also issued an ethics committee opinion specifically addressing the use of PGD for serious adult-onset conditions. The committee made the following conclusions:

“After careful review and consideration, the Committee concludes, based on the arguments outlined above, that PGD for adult-onset conditions is ethically justified when the condition is serious and no safe, effective interventions are available. The Committee further concludes that reproductive liberty arguments ethically allow for PGD for adults-onset conditions of lesser severity or penetrance. In the latter cases, the application of the technology hinges on evidence that PGD is a relatively low-risk procedure; this evidence may change. The complexity of the scientific, psychological, and social issues involved in this arena compels the Committee to strongly recommend that an experienced genetic counselor play a major role in counseling patients considering such procedures.”

Society of Obstetricians and Gynaecologists of Canada (SOGC)
The SOGC guideline recommendations are based off the systematic review by Dahdouh and colleagues (2015). Authors made the following recommendations, with the overall quality of the evidence assessment and classification of the recommendation noted in parentheses (see Appendix I for the rating key used by SOGC):

1. Before preimplantation genetic diagnosis is performed, genetic counselling must be provided by a certified genetic counsellor to ensure that patients fully understand the risk of having an affected child, the impact of the disease on an affected child, and the benefits and limitations of all available options for preimplantation and prenatal diagnosis. (III-A)
2. Couples should be informed that preimplantation genetic diagnosis can reduce the risk of conceiving a child with a genetic abnormality carried by one or both parents if that abnormality can be identified with tests performed on a single cell or on multiple trophectoderm cells. (II-2B)
3. Invasive prenatal or postnatal testing to confirm the results of preimplantation genetic diagnosis is encouraged because the methods used for preimplantation genetic diagnosis have technical limitations that include the possibility of a false result. (II-2B)
4. Trophectoderm biopsy has no measurable impact on embryo development, as opposed to blastomere biopsy. Therefore, whenever possible, trophectoderm biopsy should be the method of choice in embryo biopsy and should be performed by experienced hands. (I-B)
5. Preimplantation genetic diagnosis of single-gene disorders should ideally be performed with multiplex polymerase chain reaction coupled with trophectoderm biopsy whenever available. (II-2B)

6. The use of comprehensive chromosome screening technology coupled with trophectoderm biopsy in preimplantation genetic diagnosis in couples carrying chromosomal translocations is recommended because it is associated with favourable clinical outcomes. (II-2B)

7. Before preimplantation genetic screening is performed, thorough education and counselling must be provided by a certified genetic counsellor to ensure that patients fully understand the limitations of the technique, the risk of error, and the ongoing debate on whether preimplantation genetic screening is necessary to improve live birth rates with in vitro fertilization. (III-A)

8. Preimplantation genetic screening using fluorescence in situ hybridization technology on day-3 embryo biopsy is associated with decreased live birth rates and therefore should not be performed with in vitro fertilization. (I-E)


European Society for Human Reproduction and Embryology (ESHRE)

In 2011, the ESHRE made recommendations regarding multiple aspects of PGD testing (Harton 2011). Relevant to this review are recommendations made regarding inclusion/exclusion criteria specific to amplification-based PGD:

**Inclusion**

2.6. Testing can be carried out for confirmed pathogenic germline mutation(s) that have been identified in one parent for dominantly inherited diseases or in each parent for recessively inherited disorders giving a disease recurrence risk of 50 or 25%, respectively.

2.7. The germline mutation(s) is known to be causative of serious health effects that may manifest at birth, in childhood or as an adult.

2.8. For recessive and some X-linked (e.g. Duchenne muscular dystrophy) disorders, where a single germline mutation has been diagnosed in the proband and only one parent, it is acceptable to offer diagnosis if the pathogenic genotype can be attributed to a single gene and there is sufficient family history to identify a haplotype linked to the germline mutation.

2.9. Exclusion testing can be carried out for late-onset disorders, such as Huntington’s disease to avoid presymptomatic testing of the partner with a family history of the disease (Sermon 2002; Moutou 2004; Jasper 2006; Pecina 2009 in ESHRE 2011).

**Exclusion**

2.10. Where the genetic diagnosis is uncertain, for example, owing to genetic/molecular heterogeneity or uncertain mode of inheritance and recurrence risk is low (e.g. 10%).

**CODES**

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D61.01 – D61.09 Constitutional aplastic anemia
E75.02 Tay-Sachs disease
E75.19 Other gangliosidoses
E75.4 Neuronal ceroid lipofuscinosis
E72.00 – E72.9 Other disorders of amino-acid metabolism
E84.0 – E84.9 Cystic fibrosis
G71.0 Muscular dystrophy
G71.2 Congenital myopathies
Q05.0 – Q05.9 Spina bifida
Q06.0 – Q06.9 Other congenital malformations of spinal cord
Q87.40 – Q87.89 Marfan’s syndrome
Q90.0 – Q99 Chromosomal abnormalities, not elsewhere classified
Z14.1 Cystic fibrosis carrier
Z14.8 Genetic carrier of other disease
Z81.0 Family history of intellectual disabilities
Z82.0 Family history of epilepsy and other diseases of the nervous system
Z83.2 Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z83.31 – Z83.49 Family history of other endocrine, nutritional, and metabolic diseases
Z82.79 Family history of other congenital malformations, deformations and chromosomal abnormalities
Z84.89 Family history of other specified conditions

REFERENCES


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POLICY HISTORY

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<tr>
<td>March 21, 2017</td>
<td>Updated literature search; ACOG 2015 and ACOG 2017 committee opinions added; language revised to specify that “biopsy” procedure is the procedure covered to obtain cells for testing; ICD-9 codes replaced with ICD-10 codes.</td>
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<td>April 27, 2018</td>
<td>Updated literature search identified relevant European guidelines regarding best practices for preimplantation genetic diagnosis of cystic fibrosis; no change in policy.</td>
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<tr>
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These criteria do not imply or guarantee approval. Please check 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. NOV 19
TRIGGER POINT INJECTIONS FOR MYOFASCIAL PAIN

Policy Number: 0003
Effective Date: March 19, 2016
Reviewed Date: July 5, 2019
Next Review: July 2020

BACKGROUND

CLINICAL BACKGROUND (extracted verbatim from Hayes 2013)

"Myofascial pain syndrome is a chronic condition affecting the connective tissue (i.e., fascia) surrounding the muscles that is characterized by pain and inflammation. A key characteristic of this condition is the presence of one or more myofascial trigger points (TPs) that are located in the muscle or muscle fascia. TPs are hyperirritable and exquisitely tender spots found in a taut, palpable band of skeletal muscle. Stimulation of TPs by either firm compression (palpation) or needle penetration can elicit local pain and tenderness, as well as motor dysfunction and autonomic dysfunction. However, palpation or other stimulation of TPs may also cause a pattern of referred pain that spreads or radiates distally to a target area that is characteristic of each muscle. Snapping (or rapid) palpation at or fast needle insertion into a TP may elicit a local twitch response (LTR), or a brisk contraction of the muscle fibers in and around the TP. Patients may have active TPs, or active and latent TPs. Active TPs cause pain at rest whereas latent TPs do not produce spontaneous pain, but instead may limit movement and cause muscular weakness.

TPIs involve the injection of a solution via a needle directly into the myofascial TP. The injectate may contain a local anesthetic, steroid, botulinum toxin, nonsteroidal anti-inflammatory drug (NSAID), 5-HT antagonist, or a combination of these substances. The goal of TPI therapy is to alleviate pain and restore function by inactivating the TP."

POLICY AND CRITERIA

Trigger point injections of anesthetic and/or corticosteroid for myofascial pain may be considered medically necessary when the following criteria are met

- Local pain lasting longer than 3 months with all of the following:
  - Tenderness and/or weakness; AND
  - Motion restriction; AND
  - A palpable band that produces referred pain when compressed
- Documented failure or contraindication to standard conservative management (e.g., physical therapy, pharmacotherapy, or cardiovascular exercise); AND
- Injections are provided as part of a comprehensive, multidisciplinary pain program; AND
- No more than 4 injections are provided per session.

Those who exhibit at least 50% improvement in pain level and at least three months of improved function may be eligible for up to 4 sessions per year, at least 3 months apart. Additional injections are considered NOT medically necessary if these criteria are not met.

RATIONALE

EVIDENCE BASIS

Northwest Permanente Evidence-based Medicine Services reviewed the evidence on trigger point injections for myofascial pain in 2015. A recent, good quality technology assessment from Hayes provided most findings from the evidence base (Hayes 2013). A bridge search from the date of the Hayes...
report through May 2018. Six additional relevant studies were identified, including four randomized trials, one non-randomized trial, and one systematic review. Findings in subsequently published studies did not significantly differ from those reported in the Hayes review, and conclusions regarding the safety and efficacy of trigger point injections for myofascial pain remain the same.

Findings and conclusions of the Hayes review were as follows:

“The literature search identified 1 prospective study with 193 patients that investigated factors associated with the outcome of TPI for myofascial pain syndrome (Hopwood 1994). Thirty-one factors were identified for analysis based on published literature of mixed groups of pain patients, physicians' views of clinical importance, and ease of assessment in a typical clinical setting. Factors were analyzed via univariate and logistic regression analyses both for independent association with short-term treatment outcome and for magnitude of risk of failure associated with each factor following adjustment for other factors. The univariate analysis determined that an elevated risk of treatment failure was associated with unemployment arising from pain, inability of analgesic medication to provide pain relief, constant pain, high levels of pain-at-its worst and pain at-its least, extended duration of pain, alterations in social pursuits, and lower ability to cope with pain. Alcohol use was associated with lower risk for treatment failure according to the univariate analysis. The logistic regression analysis found that only unemployment, prolonged pain duration, and change in social activities were independently associated with treatment outcome.

In a randomized, double-blind trial, Hong (1994) compared lidocaine TPI and dry needling for relief of myofascial trigger points in patients that did or did not exhibit a local twitch response (LTR). Patients that showed an LTR during treatment exhibited statistically significant improvements from baseline in pain intensity, pressure pain threshold (PPT), and range of motion (ROM) immediately after treatment. However, for those patients that did not display an LTR, there was no change from baseline in pain intensity, PPT, or ROM. Thus, the beneficial effects of TPI and dry needling appear to depend upon the elicitation of an LTR during treatment.

Comparative Efficacy of TPI Versus Dry Needling: Three of the reviewed studies compared TPI therapy to dry needling for treatment of myofascial pain syndrome (Hong 1994; Ay 2010; Eroglu 2013). Findings from all 3 studies suggest that TPI is not superior to dry needling for reducing pain intensity and improving range of motion.

Duration of Treatment Benefit: Limited evidence pertaining to the duration of treatment benefit of TPI was available. Follow-up duration only extended up to 3 months following cessation of treatment. Only 4 studies reported data from more than 2 follow-up assessments after the end of treatment (Ferrante et al., 2005; Göbel 2006; Ozkan 2011; Seo 2013); 3 of these studies evaluated BTX-A TPIs and 1 study (Ozkan 2011) evaluated TPIs with lidocaine. The final follow-up assessment in 3 studies was 12 weeks after end of treatment, with 3 to 6 in-person total assessments (excluding baseline) depending on the outcome measure and the study (Ferrante 2005; Göbel 2006; Ozkan 2011). The fourth study included a total of 8 assessments up to 16 weeks posttreatment (Seo 2013). This evidence was insufficient to draw any conclusions about how long treatment efficacy persists after TPI therapy.

Trigger Point Injections as an Adjunct to Other Pain Management Strategies: In a systematic review of TPI for chronic nonmalignant pain, the authors note that most of the studies included in the review evaluated TPI as a stand-alone treatment. However, they indicate that the procedure is routinely used as an adjunctive to other therapies in clinical practice and the effectiveness of TPI may be underestimated in research studies where TPI is a stand-alone therapy (Scott 2009)."

RELEVANT GUIDELINES

The American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRA) Task Force on Chronic Pain Management evaluated the efficacy of TPIs for patients with chronic pain. The guideline concluded that there was insufficient literature to determine efficacy, but
concluded that TPIs may be considered for treatment of myofascial pain when included as part of a multimodal pain management program due to evidence from observational studies.

The Colorado Division of Workers’ Compensation issued a guideline entitled “Chronic pain disorder medical treatment guidelines” that addressed trigger point injections for myofascial pain. The guideline notes that “trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other active treatment modalities.” The guideline also states that “patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 3 months. A positive result would include a return to baseline function, return to increased work duties, and measureable improvement in physical activity goals including return to baseline after an exacerbation.” The guideline specifies that optimum treatment consists of 4 sessions per year, with no more than 4 injections per session.

### CODES

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<td>Injection(s); single or multiple trigger point(s), three or more muscles</td>
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<td>Myalgia (excl. myositis)</td>
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### REFERENCES


VISCOSUPPLEMENTATION (INTRA-ARTICULAR HYALURONIC ACID INJECTIONS) FOR OSTEOARTHRITIS

Policy Number: 0002  
Effective Date: February 17, 2015  
Reviewed Date: July 3, 2019  
Next Review: July 2020

BACKGROUND

CLINICAL BACKGROUND (excerpted directly from HERC 2014)

Osteoarthritis (OA) is the most common form of chronic articular disease, affecting approximately 27 million adults in the United States. The most commonly affected joint is the knee, with prevalence estimates ranging from 12% to 16%. To date, there is no known cure for OA nor is there a disease-modifying agent. Optimal management generally requires a combination of both nonpharmacological and pharmacological therapies, and joint replacement surgery or a joint salvage procedure may be considered for selected patients with severe symptomatic OA who have not obtained adequate pain relief and functional improvement from medical therapy. Pharmacological therapy generally begins with acetaminophen, followed by nonsteroidal anti-inflammatory drugs (NSAIDs) if sufficient pain relief is not obtained. There is a small risk of systemic adverse effects with NSAIDs. Aspiration of fluid followed by intraarticular injection of a corticosteroid ameliorates pain in some patients, but duration of relief is usually limited to one to three weeks. Additionally, repeated intraarticular injections of corticosteroids have the potential to cause postinjection flare, infection, and progressive, long-term cartilage damage.

Recently, viscosupplementation with hyaluronan has been introduced as an alternative intraarticular injection therapy for OA. Hyaluronans are also known as sodium hyaluronate or hyaluronic acid (HA). Hyaluronic acid is a normal component of synovial fluid and cartilage. The viscous nature of the compound allows it to act as a joint lubricant, whereas its elasticity allows it to act as a shock absorber. Hyaluronic products are characterized by their molecular weight, which varies according to the source of the compound and method of preparation. Five HA products are currently marketed in the United States: Euflexxa® (Ferring), Hyalgan® (SanofiAventis), Orthovisc® (Anika Therapeutics), Supartz® (Seikagaku Corporation), and Synvisc® (Genzyme). Synvisc is a derivative of HA that consists of cross-linked polymers; the compound is referred to as Hylan G-F 20. Hyaluronate preparations have been approved by the Food and Drug Administration (FDA) for treatment of pain associated with OA of the knee in patients who have not had an adequate response to nonpharmacological, conservative treatment and simple analgesics.”

POLICY AND CRITERIA

Intra-articular hyaluronic acid injections for osteoarthritis are considered not medically necessary.

RATIONALE

EVIDENCE BASIS

The Kaiser Permanente Interregional New Technologies Committee reviewed the evidence on viscosupplementation in 2012. Their findings and conclusions were as follows:

“The current body of evidence on single treatment course of viscosupplementation for osteoarthriticis of the knee consisted of over 60 RCTs including over 9000 patients derived from 9 systematic reviews and/or meta-analyses. Findings from available assessments and systematic reviews found positive results in favor of viscosupplementation compared to placebo. One recent review including 54 RCTs with...
a total of 7545 patients found IA-HA to be effective at 4 weeks, reaches peak effectiveness at 8 weeks and exert a residual effect at 24 weeks post-treatment compared to placebo.1 Another review of 7 RCTs including a total of 606 patients found that corticosteroids were more effective than HAs in the short-term (up to 4 weeks), whereas HAs may be more effective in the long-term (4 – 26 weeks).2 Two RCTs published subsequent to the reviews reported mixed results with one study finding significant pain reduction and patient’s global assessment improvement in favor of HA over placebo, while the other found no significant differences in pain, function, patient’s global assessment, and responder rates between HA and placebo.3,4 One of the RCTs also noted a substantial placebo effect (84%) detected.4

Assessments, one meta-analysis and recent RCTs found no significant difference in risk of adverse events for HA compared to placebo; however, adverse event data were often poorly reported. One review noted an increase in frequency of minor local acute reactions. A recent meta-analysis, which also included some data from unpublished trials, indicated that viscosupplementation had an increased risk for serious adverse events.5

A CTAF review from 2012 reviewed the body of evidence on repeated courses of viscosupplementation for osteoarthritis of the knee. The review included a total of 9 studies (3 RCTs, 1 nonrandomized controlled trial and 6 cohorts) including 2305 patients. Four studies found that repeated courses of HA showed improvement in pain outcomes (VAS, WOMAC scores) and responder criteria compared to single treatment. One RCT reported 4 courses of HA over 2.5 years improved clinical symptoms compared to placebo. Two lower-quality uncontrolled studies (n=411) suggested more clinical improvement after >2 courses of HA than after single course treatment; however, the lack of appropriate controls preclude definitive conclusion on the true magnitude of effect. A subsequent open-label trial including 433 patients who completed a prior randomized placebo-controlled trial also suggested that patients who completed extension trial had further improvements in pain (VAS), stiffness (WOMAC), and patient’s global assessment scores.6

Results are unclear for safety of repeated HA treatments. The CTAF review concluded that repeated IA-HA injections for OA-K met CTAF criteria for safety for osteoarthritis treatment when compared with usual care, based on one RCT that showed similar AEs between repeated HAs and controls. A subsequent open-label trial found that 4.8% had events considered related to IA-HA. Conversely, a Hayes Assessment referenced an open-label extension of another RCT examining 3 different HAs that found non-significant trend toward greater AEs in Synvisc vs. Orthovisc or Ostenil groups in 1st course (2.2% difference; 95% CI, −2.4 – 6.7) and trend was more pronounced following 2nd course (6.4% difference; 95% CI, 0.6 – 12.2). Additional, well-designed RCTs are need to elucidate the safety of repeated HA treatments.

At least 5 RCTs including a total of 1746 patients have examined different formulations of HA agents, either head-to-head or versus placebo. Two RCTs compared Orthovisc vs. Synvisc vs. placebo/Ostenil, while 1 RCT assessed Synvisc with Artzal/Supartz and placebo, 1 RCT evaluated OrthoVisc with Supartz and placebo, and 1 RCT investigated Hylan G-F 20 to sodium HA. Most trials reported no significant differences in HA treatment arms. It is difficult to determine if any one HA agent is superior to another based on the available sparse and limited data from these trials.

Overall the evidence on viscosupplementation had considerable uncertainty due to the presence of large placebo effect, variable trial quality and a high risk of publication bias. A majority of publications were industry-sponsored and there is a high risk of treatment contamination due to concomitant use of other pharmacologic therapies.” (INTC 2012)

“There is sufficient evidence that a single course of intra-articular hyaluronic acid injection is not more effective than conventional therapy, including NSAIDS, nonprescription analgesics, exercise, physical therapy and injectable corticosteroids, in improving pain and function.

There is insufficient evidence to determine whether or not repeated treatment using intra-articular hyaluronic acid injections is a medically appropriate treatment option.
There is insufficient evidence to determine the relative safety and effectiveness of any one HA product versus another.” (INTC 2012)

A bridge search was conducted from the date of the INTC report through June 2018. No evidence was identified that alter the conclusions made by the INTC.

A 2015 Cochrane review evaluated the use of hyaluronic acid for ankle osteoarthritis (Witteveen 2015). The review included six RCTs, of which three compared the treatment to placebo, one compared to exercise therapy, one compared to botulinum toxin injection in conjunction with exercise therapy, and the last compared differing dosages of hyaluronic acid. All studies were considered to be of low quality. Authors concluded that there is insufficient data to support use of hyaluronic acid for ankle osteoarthritis at this time.

Three studies were identified that evaluated the use of hyaluronic acid for osteoarthritis of the hip joint. These studies included one case series (Migliore 2012), a placebo-controlled RCT (Richette 2009), and a non-randomized controlled trial (Migliore 2009). The case series (Migliore 2012) reported improved functional improvement following hyaluronic acid injections, but the lack of a control group limits conclusions that can be drawn based upon these findings. Richette (2009) reported that three months following treatment, there were no differences in the magnitude of pain decrease. Authors concluded that there was no significant benefit of hyaluronic acid over placebo. Migliore (2009) reported on outcomes among 42 individuals with hip osteoarthritis treated with hyaluronic acid injections or local analgesia. There was a statistically significant difference in functional and pain measures at 3-month and 6-month follow-up for the hyaluronic acid group, but it is unclear whether these differences are clinically significant. There were no differences in other measures, including analgesic use.

**RELEVANT GUIDELINES**

The American Academy of Orthopedic Surgeons (AAOS) updated their clinical practice guideline on treatment of osteoarthritis of the knee in 2013. Based on their review of 14 studies (including three high-strength studies and 11 moderate-strength studies), they make the following strong recommendation: “We cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.” The guideline noted that the strength of the recommendation was based on lack of efficacy, not on potential for harm.

In guidelines issued by the National Institutes for Clinical Excellence (NICE), hyaluronic acid injections for osteoarthritis are recommended against (NICE 2014).

Milliman Care Guidelines on hyaluronic acid injections (ACG: A-0306) indicate that “there are currently no clinical indications for this technology.”

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27447 Arthroplasty, knee condyle and plateau; medial and lateral
J7321 Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
J7323 Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7324 Hyaluronan or derivative, Orthovisc, for intra-articular injection
J7325 Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1mg

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REFERENCES


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