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.

POLICY AND 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 exhibit 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 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
      7. cancer 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: See MCG A-0329 “Acupuncture”.
Washington Medicaid: Acupuncture is not covered.
Oregon Medicaid: Covered for certain conditions, check Linefinder
RATIONAL

EVIDENCE BASIS

A 2018 Agency for Healthcare Research and Quality (AHRQ) systematic review of noninvasive nonpharmacological interventions for chronic pain reports that acupuncture improved function and/or pain for at least 1 month when used for chronic low back pain, chronic neck pain, and fibromyalgia. This review notes that effects across included studies were mostly small and that there was a paucity of long term evidence. Additionally, no evidence suggested serious harms from acupuncture, but data on harms was limited in the included studies. 2021 National Institute for Health and Care Excellence (NICE) guidance addressing the management of chronic primary pain includes a recommendation for a single course of acupuncture or dry needling to manage chronic primary pain. The basis for this recommendation included an evidence review that found that several (k=27) studies showed a reduction in pain and improvement in quality of life in the short term (up to 3 months) following acupuncture compared to usual care or sham acupuncture. The guideline notes substantial variation in the type and intensity of acupuncture interventions used.

Chronic Migraine and Chronic Tension-Type Headache

A 2022 Health Technology Assessment commissioned by the Washington State Health Care Authority reports that acupuncture was associated with reductions in the number and severity of headache days compared with sham and active treatments for individuals with chronic migraine. Strength of evidence was generally low and included studies had a high risk for bias. A 2018 Hayes health technology assessment of the effectiveness of acupuncture for episodic and chronic tension-type headache and episodic migraine reports that a large body of evidence suggests that acupuncture may offer a modest benefit for improving rates of response and reducing frequency in patients with episodic or chronic tension-type headaches or episodic migraines and that acupuncture may aide in a near-term reduction in analgesic use among patients. The report notes that the evidence is of low-quality and thus uncertainty about the true effect remains.

Knee Osteoarthritis

A 2018 Hayes health technology assessment of the efficacy and safety of acupuncture for the treatment of osteoarthritis of the knee reports that a moderate-sized body of evidence shows short-term (±3 months) benefits for pain and function in patients with osteoarthritis of the knee who received acupuncture compared to sham acupuncture or no intervention. The overall quality of the evidence for acupuncture for osteoarthritis of the knee was low and inconsistencies in the evidence yield uncertainty in the effect of acupuncture compared to conventional drug treatment.

PTSD

Per MCG, 25th Edition (2022)

For posttraumatic stress disorder (PTSD), evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A systematic review of 7 randomized controlled trials with 709 patients with PTSD found low-quality evidence favoring acupuncture over control interventions (eg, sham acupuncture, paroxetine, cognitive behavioral therapy, or usual care) for improving PTSD symptoms and depression 1 to 6 months after treatment. The authors noted a need for additional sufficiently powered trials to increase the confidence in these findings.

REFERENCES

2. NICE. Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain. NICE Guideline No. 163. United Kingdom: National Institute for Health and Care Excellence; April 2021.


6. Andrew C. Ahn, MD, MPH; Mark D. Aronson, MD; Lisa Kunins, MD; UpToDate Acupuncture. 2020 Oct 27.


Northwest Region Utilization Review

UR 61: Applied Behavior Analysis (ABA)
Medical Necessity Criteria

Department: Behavioral Health
Section: KPNW Region
Applies to: KPNW Region
Review Responsibility: UROC
Subject Matter Expert: Sara Cuthill, MD; Brandon Duft, MD; Kristen Morris, BCBA

Number: UR 61
Effective: 10/24/12
Last Reviewed: 3/19, 3/21, 3/22
Last Revised: 3/18, 5/20, 3/23

DEFINITIONS

Applied Behavior Analysis- the science of behavior, with a history extending back to the early 20th century. Its guiding philosophy is behaviorism, which is based on the premise that attempts to improve the human condition through behavior change (e.g., education, behavioral health treatment) will be most effective if behavior itself is the primary focus.

BACB- The Behavior Analyst Certification Board, Inc.® (BACB®) is a corporation established in 1998 to meet professional credentialing needs identified by behavior analysts, governments, and consumers of behavior analysis services. The BACB’s certification requirements, examination content, and procedures undergo regular review according to established standards for organizations that grant professional credentials. All BACB requirements and examination content are developed by experts in the discipline.

BCBA- The Board-Certified Behavior Analyst® (BCBA®) is a graduate-level certification in behavior analysis. Professionals certified at the BCBA level are independent practitioners who provide behavior analysis services.

BCaBA- The Board-Certified Assistant Behavior Analyst® (BCaBA®) is an undergraduate-level certification in behavior analysis. Professionals certified at the BCaBA level provide behavior analysis services under the supervision of Board-Certified Behavior Analyst® (BCBA®).

Mid-Level Provider- Mid-Level Providers assist in the supervision and deliver of behavior analytic services and practice under the direction of the BCBA.

Mid-Level Providers must meet the following criteria:

(A) Possesses a Bachelor of Arts or Science Degree and has either:

1. Twelve semester units in applied behavior analysis and one year of experience in designing and/or implementing behavior modification intervention services; or

2. Two years of experience in designing and/or implementing behavior modification intervention services.

(B) Is registered appropriately with the state in which services are provided

Technician- Technicians assist in delivering behavior analysis services and practice under the direction and close supervision of a BCBA Supervisor, who is responsible for all work technicians perform. Technicians must meet state guidelines of where they provide services.
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 evidence supporting ABA as an effective 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 TO RECEIVE MEDICALLY NECESSARY BEHAVIOR ANALYTIC SERVICES:

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; AND
   c) demonstrates behaviors that are developmentally inappropriate and pose a significant obstacle to the member’s performance of developmentally appropriate daily functioning including self-help and communication

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

ABA Assessment

1) Assessment for the development of the behavior analytic treatment plan will be completed by the external ABA provider.

2) Assessment will be completed of skill deficits, maladaptive behavior, and restrictive behaviors.

3) Direct assessment is required of the member to identify appropriate treatment interventions.
ABA Treatment

1. After assessment is completed by the external ABA Provider, a treatment plan outlining appropriate interventions will be sent to KP ABA department for review.

2. Treatment plans must be reviewed at a minimum of every 6 months, unless more frequent submission is requested by KP to ensure the health and safety of the member.

3. Treatment plans will include data supporting that behavior analytic services remain appropriate for the member and is making progress on the identified reason for referral.

4. The services offered cannot be a duplicative of service offered by or required of the school/educational system; AND

5. The treatment plan will only include identified evidence-based behavior analytic interventions

6. The presence and 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.

Both assessment methods and treatment interventions, must meet BACB treatment and ethical guidelines.

Continuation Criteria

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

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

2. The external ABA Provider will submit an updated treatment plan no more than 10 days before the authorization expiration date, to ensure the most up to date data is presented within the report.

3. The treatment plan should include the data identifying progress or regression for each goal from the previous authorization period and the identified goals for the next authorization period. If data identifies regression on a goal, a rationale should be provided to identify adjustments in the intervention package or barriers to treatment.

Transition to Discharge

1. Transition Plan to discharge must be submitted to the ABA department within 3 months of the planned discharge date.
   a. Transition plan must include how services will be faded to the next level of care recommended.

2. Upon discharge the provider will submit a case closure summary signed by the parent/guardian to KP ABA Department within 30 days of discharge.
   a. This case closure summary will include:
i. Date of discharge
ii. How treatment will be maintained
iii. Any recommended support services
iv. Data indicating that member has met criteria for discharge and reason for referral has been addressed

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

1. No significant, measurable improvement has been documented on 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.
   a. 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.

5. Parent/Guardian has requested termination of treatment.

**SPECIAL GROUP CONSIDERATIONS**

Applies to all commercial groups and Medicare
Washington Medicaid: Does not apply to WA Medicaid members.
Oregon Medicaid: Check LineFinder

**RATIONALE**

**EVIDENCE BASIS**

A 2014 Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review evaluated behavioral interventions for children with ASD, including ABA-based early intensive behavioral and developmental intervention. The review reports that young children receiving such interventions display improvements in aspects of cognitive functioning, adaptive skills, language and communication skills, and social skills, and that children in these interventions displayed more improvement than children receiving other types of interventions.

A 2016 AHRQ systematic review in support of the United States Preventive Services Task Force’s recommendations on screening for ASD in young children evaluated the evidence for treatment and reports similar findings to the 2014 AHRQ report – namely that studies showed statistically significantly greater cognitive improvements and language outcomes in the ABA-based intervention arms than in the comparator arms.
REFERENCES

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


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 and sperm 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.

POLICY AND CRITERIA

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

A. Individual 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) Individual or partner with infertility due to medical or surgical treatment (e.g., chemotherapy, radiotherapy, gonadotoxic medication, oophorectomy, orchiectomy)
d) Individual with impending infertility due to planned cancer treatment for cure (e.g., chemotherapy or oophorectomy)

e) 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

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

g) Individual with nonobstructive azoospermia or severe oligospermia

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

i) 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) Individual with impending infertility due to planned cancer treatment for cure (e.g., chemotherapy or oophorectomy)
   b) Individual with infertility due to medical or surgical treatment (e.g., chemotherapy, radiotherapy, gonadotoxic medication, oophorectomy) 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 individual with breast cancer without axillary lymph node involvement
         - Five years or more after initial diagnosis in individual 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 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 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 donor 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

x. Retrograde ejaculation 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 and sonohysterography

iv. Normal sperm count, motility, and morphology

3. 1 or more of the following:

a) Embryo or egg 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 individual 36 years or younger during first 3 in vitro fertilization cycles

   ii. Up to 2 fresh or frozen embryos transferred for individual 36 years or younger after first 3 failed single-embryo transfer in vitro fertilization cycles

   iii. One fresh or frozen single-embryo transfer for individual 37 years of age during first in vitro fertilization cycle
iv. Up to 2 fresh or frozen embryos transferred for individual 37 years of age after first failed in vitro fertilization cycle

v. Up to 2 fresh or frozen embryos transferred for individual 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 individual 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 individual 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 individual 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 individual 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 may be excluded from coverage. Check CM for exclusions or limitations.

OR PEBB- Check infertility benefit with each request as to whether females must be diagnosed as infertile to qualify for infertility treatment.

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.

RATIONAL

EVIDENCE BASIS

MCG reviewed the evidence on assisted reproductive technology (ART) in 2022. Their findings are provided below:

For infertility, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Guidelines recommend mature oocyte, embryo, or sperm cryopreservation prior to planned chemotherapy.1-4 Multiple-embryo transfer is associated with an increased risk for multiple-gestation pregnancies and pregnancy complications, including cesarean birth, preeclampsia, premature delivery, and low-birth-weight infants.5,6 Additionally, analysis of a US database found a significant adverse effect on intrauterine growth for live singleton and twin births resulting from transfer of multiple embryos.7 Guidelines on the number of embryos to transfer have been developed by professional societies in order to optimize healthy live births and minimize multiple-gestation pregnancies.8-10 Assisted reproductive technology registries from 36 European countries for 2008 show an overall distribution of the transfer of 1, 2, 3, and 4 or more embryos as 22.4%, 53.2%, 22.3%, and 2.1%, respectively, resulting in proportions of singleton, twin, and triplet deliveries of 78.3%, 20.7%, and 1.0%, respectively.11 A systematic review and meta-analysis of
randomized controlled trials concluded that increasing the number of single-embryo transfer attempts to 3 cycles using fresh or frozen embryos in women younger than 36 years results in a cumulative live birth rate similar to double-embryo transfer and reduces the likelihood of multiple births by 94%. A meta-analysis of individual patient data from randomized trials reported that elective single-embryo transfer resulted in a lower pregnancy rate than double-embryo transfer in a fresh in vitro fertilization cycle; however, the difference was almost completely overcome by an additional frozen single-embryo transfer cycle. Additionally, the rate of multiple-gestation pregnancy and risk of preterm birth and delivery of a low-birth-weight infant were decreased with single-embryo transfer. A systematic review and meta-analysis reported that elective single-embryo transfer is associated with decreased risk of preterm birth and low birth weight as compared with double-embryo transfer, but with higher risk of preterm birth as compared with spontaneously conceived singleton infants. A multicenter randomized controlled trial of 1650 women with infertility found that frozen single blastocyst transfer was associated with an improved singleton live birth rate compared with fresh single blastocyst transfer (50% vs 40%, respectively). However, frozen single blastocyst transfer was also associated with a higher risk of preeclampsia (3.1% vs 1.0%, respectively) which the authors advise warrants additional evaluation. A national registry study of the outcomes by number of embryos transferred (124,148 IVF cycles, 32,732 cycles with complete outcomes data available) reported that the odds of live birth were similar regardless of whether 1, 2, or 3 embryos were transferred; however, all adverse perinatal outcomes (multiple births, prematurity, small for gestational age) occurred more frequently when 3 or more embryos were transferred. The odds of live birth were higher with double-embryo transfer in all age groups; however, the association was stronger in women older than 40 years. Multiple birth risk increased with double-embryo transfer in all age groups, but was substantially lower in women age 40 years and older. The authors concluded that the findings supported restricting embryo transfer to fewer than 3.

A practice guideline recommends that women age 35 to 40 years be considered for elective single-embryo transfer if they have top-quality blastocyst-stage embryos available for transfer.

For women age 40 to 42 years, another practice guideline recommends double-embryo transfer.

REFERENCES


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 of the following serious co-morbid conditions at the time of initiation of physician-directed therapy for obesity and/or referral to the Severe Obesity Program:
   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 PC0₂ >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 i.e. 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.

OR

2. BMI is ≥40 Kg/m² with no co-morbid condition at the time of initiation of physician-directed therapy for obesity and/or referral to the Severe Obesity Program;

AND

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

AND,

4. Members with a history of tobacco products* use must have a documented “quit” date ≥6 months prior to referral for consultation.

   *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

5. 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 in and completion of all sessions of Kaiser Permanente NW Health Engagement and Wellness Service weight management course.
NOTE: Currently, the bariatric surgical procedures offered are limited to laparoscopic Roux-en-Y Gastric Bypass (RNYGB) and laparoscopic sleeve gastrectomy. The type of surgical procedure performed is up to the clinical discretion of the surgeon.

Roux-en-Y Gastric Bypass (RYGBP) is a procedure that restricts the size of the stomach by stapling shut 90% of the lower stomach and bypassing the nearby intestine.

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.

OTHER REQUIREMENTS

After the bariatric surgery referral, but prior to bariatric surgery, the member must 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 TO BE DETERMINED PRE-OPERATIVELY BY THE SURGEON

1. Current pregnancy or desire for pregnancy in the next 18 months
2. Alcohol or substance abuse within the last year
3. Nicotine use, including *tobacco products and nicotine replacement therapy (NRT) **products within 6 months prior to surgery
   - **NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.
4. 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.
5. Endogenous reasons for obesity i.e. Cushing’s disease
6. 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.

7. 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 malabsorbive and restrictive components will not be offered revisional operative procedures (ie stomal narrowing, band over bypass or pouch reductions) because of inadequate weight loss or weight regain. Those whose operative anatomy have broken down (ie gastric-gastric fistulae) will be considered for revisions as indicated by risk/benefit ratios.

**RATIONALIE**

**EVIDENCE BASIS**

The KP National Guideline Program clinical practice guideline recommendations include a summary of the evidence relevant to selecting patients for bariatric surgery. Brief excerpts from that evidence summary are included here:

“Efficacy:
- Weight loss: In obese adults, bariatric surgery produces greater weight loss and maintenance of lost weight than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight.
Weight loss at 2 to 3 years following a variety of surgical procedures in adults with presurgical BMI ≥30 varies from a mean of 20% to 35% of initial weight and a mean difference from nonsurgical comparators of 14% to 37% depending on procedure. (SOE: High)

Mean weight loss at 10 years following a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) is approximately 16% of initial weight, representing a mean weight regain of 7%. (SOE: Low)

- Comorbidities: In obese adults, bariatric surgery generally results in more favorable impact on obesity-related comorbidity conditions than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss.
  
  - Glycemic control
    - At 2 to 3 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve a mean weight loss of 20% to 35%, there is a ↓ in FPG, insulin and incidence of T2DM and there is a greater likelihood of diabetes remission among those with T2DM at baseline. Remission was defined variously depending on the study. (SOE: high)
    - At 10 years, incidence and prevalence of T2DM are lower in those who have undergone surgery. However, among those in whom T2DM remits after surgery, diabetes may recur over time. (SOE: low)
  
  - Blood pressure control
    - At 2 to 3 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, blood pressure or use of blood pressure medication is reduced compared with nonsurgical management. Blood pressure tends to increase over time, and at 10 years post-surgery, there is no difference in mean SBP or the incidence of new cases of hypertension in those who underwent bariatric surgery compared to those who did not undergo surgery. (SOE: low)
    - Among obese adults with baseline hypertension, a greater percentage is in remission at 2 to 3 years and 10 years following bariatric surgery compared with nonsurgical management. (SOE: low)
  
  - Cholesterol and lipid control
    - At 2 to 3 years and 10 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, serum TG levels are lower, HDL-C levels are higher, TC-to-HDL-C ratio is lower, and changes in TC or LDL-C levels are inconsistent compared with nonsurgical management. (SOE: low)
  
  - Quality of life
    - Most measures of health-related quality of life (HRQOL) are improved at 2 and 10 years following bariatric surgery. (SOE: moderate)

- Total mortality
  - Total mortality is decreased compared with nonsurgical management at mean follow-up of 11 years after undergoing a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) in patients with mean BMI >40 who achieve a mean long-term weight loss of 16% (SOE: low)

- CVD risk
  - There are insufficient data on the efficacy of bariatric surgical procedures for weight loss and maintenance or CVD risk factors 2 or more years post-surgery in patients with a BMI <35.
Complications:
Perioperative (≤30 days) and longer term (>30 days) complications following bariatric surgery vary by procedure and patient-derived risk factors.

- **Roux-en-Y Gastric Bypass.**
  - When performed by an experienced surgeon, perioperative complications following laparoscopic gastric bypass:
    - Consist of a major adverse outcome in approximately 4% to 5%, including mortality (0.2%), DVT and/or pulmonary embolism (PE) (0.4%), and a requirement for reoperation (3% to 5%). Rates of any complication, major or minor, range from 2% to 18%. (SOE: moderate)
    - Are less frequent for the laparoscopic approach than for open incision. (SOE: moderate)
    - When performed by an experienced surgeon, perioperative complications following open gastric bypass:
      - Consist of a major adverse outcome in approximately 8%, including mortality (2%), DVT/PE (1%), and reoperation (5%). (SOE: low)
  - When performed by an experienced surgeon, perioperative complications following gastric bypass (laparoscopic or open):
    - Are associated with extremely high BMI, inability to walk 200 feet, history of DVT/PE, and history of obstructive sleep apnea. (SOE: low)

- **Laparoscopic Sleeve Gastrectomy**
  - There is insufficient evidence to establish the incidence of perioperative and longer-term complications.

**REFERENCES**

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)

The following bariatric surgery procedures are reasonable and necessary under specified conditions for the treatment of complications of morbid obesity:

A. Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS): 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>
</tr>
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<tbody>
<tr>
<td>A. Have a body-mass index (BMI) $\geq$ 35 kg/m$^2$, and</td>
</tr>
<tr>
<td>B. Have at least one co-morbidity related to obesity (see the following Medicare website for a complete list of ICD-10 codes associated with qualifying co-morbidity diagnoses for medically necessary bariatric surgery: Article - Billing and Coding: Bariatric Surgery Coverage (A53028) (cms.gov), and</td>
</tr>
<tr>
<td>C. Have documentation in the medical record or referral that clearly demonstrates the failure of reasonable non-invasive/non-surgical treatments for obesity with which the beneficiary has been compliant.</td>
</tr>
</tbody>
</table>
The following are the minimum specifications to be documented in order to demonstrate the beneficiary has been previously unsuccessful with medical treatment for obesity:

1. Participation in and completion of all sessions of Kaiser Permanente NW Health Engagement and Wellness Service weight management course, or

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.

**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.

Procedures determined by CMS to be not reasonable and necessary for the treatment of morbid obesity (primary ICD-10-CM diagnosis code E66.01) are:

1. Open adjustable gastric banding (billed with a Not Otherwise Classified (NOC) code)
2. Open sleeve gastrectomy;
3. Open and laparoscopic vertical banded gastroplasty
4. Intestinal bypass surgery; and,
5. Gastric balloon for treatment of obesity

**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**

*Article - Billing and Coding: Bariatric Surgery Coverage (A53028) (cms.gov)*
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 pharmacologic treatment is inadequate or not indicated by reason of 1 or more of the following:
   a) insufficient or no response to multiple pharmacological (medication) treatment attempts
   b) intolerance of multiple pharmacologic treatment attempts
   c) patient has a preference for nonpharmacologic interventions
   d) history of long-term, frequent, or excessive use of analgesic (pain medication) or medications that can aggravate headache
   e) deficient stress-coping skills that remain a significant contributor to headache onset despite counseling of the patient by a qualified professional
   f) pregnant patient
   g) breast-feeding patient
   h) 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 or paradoxic movement of pelvic floor on 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)
      vi) internal prolapse
      vii) levator spasm/proctalgia fugax
   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
7) Muscle re-education of specific muscle groups when ALL of the following are met:
   a) the patient has one or more of the following:
      i. pathological muscle abnormalities of spasticity
      ii. incapacitating muscle spasm
      iii. muscle weakness
   b) conventional treatments (heat, cold, massage, exercise, support) have not been successful

**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

**CRITERIA FOR DISCHARGE**

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

1. Member no longer demonstrates functional impairment or has achieved goals set forth in the POC or has returned to their prior level of function
2. Member has adapted to impairment with assistive/adaptive equipment or devices
3. 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.
4. Member is unable to participate in the plan of care due to medical, psychological, or social, complications
5. Member (and/or family/caregiver) is non-compliant with Home Exercise Program and/or lacks participation in scheduled therapy appointments

**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. NOT COVERED: treatment of ordinary muscle tension, psychosomatic conditions and home biofeedback are not covered.

Also see KPNW BEAM Policy

NOTE:
This policy is informed by CMS coverage requirements for biofeedback and internal clinical expert opinion.

CLINICAL

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.


BOTULINUM TOXIN INJECTION FOR CHRONIC MIGRAINE PROPHYLAXIS

Policy Number: 0005
Effective Date: May 1, 2015
Reviewed Date: July 19, 2022
Next Review: July 2023
Clinical Reviewer: Lisa Wall, DNP

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 (HIS 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, CGRP antagonists, 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), and CGRP antagonists. 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 5 (five) 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 number of migraines, or severity of headaches by 3/10 points, or reduced total headaches duration by at least 100 hours per month, additional injections are considered NOT medically necessary.
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 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. **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

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

<table>
<thead>
<tr>
<th>CPT or HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)</td>
</tr>
<tr>
<td>J0585</td>
<td>Botulinum toxin type A, per unit [Botox]</td>
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<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>G43.001 – G43.919</td>
<td>Migraine headache</td>
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### REFERENCES


### POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>May 1, 2015</td>
<td>New policy</td>
</tr>
<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>
</tr>
<tr>
<td>April 24, 2018</td>
<td>Definition of chronic migraine updated to reflect 3rd edition of ICHD</td>
</tr>
<tr>
<td>May 29, 2019</td>
<td>No policy changes; literature and guideline updates with no substantive changes.</td>
</tr>
<tr>
<td>May 15, 2020</td>
<td>No policy changes; literature and guideline updates with no substantive changes.</td>
</tr>
<tr>
<td>June 23, 2022</td>
<td>CGRP antagonists added as a class of prophylactic medication as suggested by clinician reviewer due to FDA approval of a CGRP antagonist for migraine prevention in 2021; policy amended to permit up to 5 treatments in a 12-month period as suggested by clinician reviewer based on clinical experience; literature and guideline updates with no substantive changes.</td>
</tr>
</tbody>
</table>
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

See the Evidence of Coverage (EOC) as definitions of Cosmetic Services may vary within the Exclusions section of the EOC documents (this exclusion does not apply to ‘Reconstructive Surgical Services’ or services that are medically necessary).

POLICY AND 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 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 (e.g. oncoplastic reduction)
  - Capsule revision (capsulotomy, capsulectomy, capsulorrhaphy)
  - Dermal rearrangement (i.e. “Goldilocks” flaps)
• 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.
  o 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.
  o 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 procedures are considered medically necessary when performed either at the time of mastectomy (immediate reconstruction) or in a staged manner following mastectomy (delayed reconstruction). Contraindications to immediate reconstruction are:
  ▪ Severe obesity (BMI >40)
  ▪ Uncontrolled diabetes (HbA1c >8.0)
  ▪ Inflammatory breast cancer
  ▪ Members who decline or are non-compliant with standard of care cancer treatment
  ▪ Active or recent use of tobacco and/or tobacco products* (members with a history of tobacco products* use must have a documented “quit” date >6 months prior to referral for consultation OR a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation. *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff))

• Reconstructive surgical revisions may be performed as deemed necessary by a physician board-certified in plastic surgery.
  o 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.
  o Once the initial sequence of tattoo sessions has been completed, further touch-ups will be considered cosmetic (see Special Group Considerations).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)
1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.
*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)

**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher. Members with a HbA1c in the 7-8 range may be assessed for relative contraindications on a case-by-case basis.

3. 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.

4. Any other surgical contraindications will be determined by the surgeon.

**SPECIAL GROUP CONSIDERATIONS**

**Medicare**- This policy does not apply to Medicare. See NCD 140.2: Breast Reconstruction Following Mastectomy and LCD 37020: Plastic Surgery.

**Senior Advantage EOC states:**

- We cover reconstructive surgery to correct or repair abnormal structures of the body caused by congenital defect, developmental abnormalities, accidental injury, trauma, infection, tumors, or disease, if a network physician determines that it is necessary to improve function, or create a normal appearance, to the extent possible. However, reconstructive surgery that offers only a minimal improvement in appearance or is performed to alter or reshape normal structures of the body in order to improve appearance are not covered.
- Cosmetic Surgery or Procedures are covered in cases of an accidental injury or for improvement of the functioning of a malformed body member; and for all stages of reconstruction for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.

Tattooing is covered when performed in conjunction with breast reconstruction. If the tattooing is done by the operating surgeon and within the 90-days after the reconstruction surgery, it is included in the global fee for breast reconstruction CPT codes (19350, 19357-19369) and not separately reported. If the tattooing is not done by the operating surgeon and/or not done within the 90-days after the reconstruction surgery, it may be billed separately.

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)).

**RATIONALE**

**EVIDENCE BASIS**

A 2021 Agency for Healthcare Research and Quality (AHRQ) systematic review of surgical breast reconstruction options after mastectomy for breast cancer compared implant-based reconstruction (IBR) vs. autologous reconstruction (AR), assessed evidence about the timing of IBR and AR in relation to chemotherapy and radiation therapy, compared implant materials for IBR, compared anatomic planes of implant placement during IBR, evaluated the used of acellular dermal matrices (ADMs) during IBR, and compared flap types for AR.¹ The overall conclusions of this review are as follows:

“Our analysis of all surgical choices examined as KQs in this review finds no clear winners when all outcomes are considered. We encourage clinicians to inform patients about the limitations of existing research and to help patients make decisions regarding options for breast reconstruction based on their values and preferences, together with the clinician’s expertise and experience. Research is needed to address various
questions related to breast reconstruction, particularly the timing of IBR and AR in relation to chemotherapy and radiation therapy, and the choices of implant materials, anatomic planes of implant placement during IBR, and flaps used for AR. Future studies should either randomize patients or adequately account for important confounders and evaluate key outcomes, especially those in the existing core outcome set for breast reconstruction after mastectomy.¹

Tobacco Use:

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following breast reconstruction.² These complications include donor site complications, infection, and fat necrosis, all of which were significantly more common among smokers compared to non-smokers.² A 2015 systematic review of the association between smoking status and outcomes of plastic surgery reports significantly increased odds of surgical site infections, delayed wound healing, and cutaneous necrosis among patients who were smokers compared to non-smokers.³

REFERENCES

4. WHCRA (Women’s Health and Cancer Rights Act)
5. ORS 743A.110 Mastectomy-related Services
6. Oregon House Bill 3616 amending ORS 743A.110- defines "mastectomy" for purposes of statute requiring health benefit plan coverage
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.

POLICY AND CRITERIA

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:

a. coronary artery bypass surgery
b. stable, chronic heart failure with left ventricular ejection fraction of ≤35% and New York Heart Association Class II to IV symptoms (including patients with a ventricular assist device). Stable patients are defined as those who have not had recent (<6 weeks) major cardiovascular hospitalizations or procedures AND do not have signs or symptoms of volume overload on examination or by history (no orthopnea, paroxysmal nocturnal dyspnea, lower extremity edema) AND the diuretic dose has not been increased within the last 4 weeks (the only relevant diuretics are: furosemide (lasix), torsemide (demadex), bumetanide (bumex), chlorthalidone, metolazone (zaroxolyn, mykrox)). Placement of automated implantable cardioverter defibrillators (AICD), pacemakers (all kinds), loop recorders, left or right heart catheterizations with or without a percutaneous transluminal coronary angioplasty (PTCA), cardioversions and cardiovascular hospitalizations of less than 24 hours duration should not be considered a major cardiovascular hospitalization or procedure.

c. acute myocardial infarction (MI) within the preceding 12 months
d. current stable angina pectoris
e. heart valve repair or replacement
f. percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting  
g. heart or heart-lung transplant  
h. left ventricular assist device (LVAD)

OTHER REQUIREMENTS

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

a. Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;  
b. Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to patients’ individual needs;  
c. Psychosocial assessment;  
d. Outcomes assessment; and  
e. 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 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 cannot 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):

f. percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting  
g. heart or heart-lung transplant  
h. left ventricular assist device (LVAD)
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 with 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 130 beats per minute at rest, lasting more than 36 hours, 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 30 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 30 days.
   The exception is if patients undergoing angiogram or PCI who have ventricular arrhythmias at the time of the intervention; if no other ventricular rhythms, then patient may enroll in cardiac rehab.

g. 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.

h. third degree atrioventricular block (without a functioning pacemaker)

i. active pericarditis or myocarditis

SPECIAL GROUP CONSIDERATIONS

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

Medicare: These criteria apply to Medicare adult patients as well as Medicare pediatric patients. See Medical Policy 0014 Pediatric Cardiac Rehabilitation for non-Medicare pediatric criteria.

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.
Several recent Cochrane systematic reviews have assessed the evidence for the use of exercise-based cardiac rehabilitation for adult patients, including: following heart valve surgery, in heart transplant recipients, in those with stable angina, in those with heart failure, and in those with an implantable cardioverter defibrillator. Overall, the findings of these reviews are mixed and summarized individually below:

Heart Failure

A 2019 review to determine the effects of exercise-based cardiac rehabilitation in people with heart failure (k=44 trials) reports that compared to no exercise control conditions, cardiac rehabilitation had no impact on mortality in the short term (<12 months follow-up), likely reduces the risk of all-cause hospital admissions and may reduce heart failure-specific hospital admissions in the short term (up to 12 months), and some evidence suggests that cardiac rehabilitation may yield a clinically important improvement in health-related quality of life.¹

Stable Angina

A 2018 review to assess the effects of exercise-based cardiac rehabilitation in adults with stable angina (k=7 trials) determined that the effects of this therapy compared to control were uncertain for mortality, morbidity, cardiovascular hospital admissions, adverse events, and health-related quality of life. This is due to the small number of available trials and the overall low quality of the evidence for these outcomes.² The report indicates that exercise-based cardiac rehabilitation may result in a small increase in exercise capacity compared to usual care.²

Heart Valve Surgery

A 2021 review to assess the benefits and harms of exercise-based cardiac rehabilitation compared to no exercise training in adults following heart valve surgery or repair (k=6 trials) reports that the impact of exercise-based cardiac rehabilitation on mortality, hospitalization, and health-related quality of life is unclear in this population.³ The overall body of evidence is of very low quality and available trials are heterogeneous in terms of the outcomes reported, outcome measurement, and length of follow-up, making it difficult to draw firm conclusions about the effect of the intervention.³

Heart Transplant

A 2017 review to determine the effectiveness and safety of exercise-based cardiac rehabilitation for people after heart transplantation (k=10 RCTs) reports that exercise-based cardiac rehabilitation increased exercise capacity in this population compared to no exercise.⁴ The review reports inconclusive results for health-related quality of life in the short-term (median 12 weeks of follow-up) following interventions, due primarily to the variation in outcomes and methods of reporting across studies examining HRQoL.⁴

Implantable Cardioverter Defibrillator
A 2019 review to assess the benefits and harms of exercise-based cardiac rehabilitation programs compared to control in people with an implantable cardioverter defibrillator (ICD) (k=8 RCTS) reports that exercise capacity was higher among those in exercised-based cardiac rehabilitation programs compared to those in control conditions.\textsuperscript{5} The review indicates a lack of evidence to adequately assess the impact of exercise-based cardiac rehabilitation on mortality, serious adverse events, or health-related quality of life.\textsuperscript{5}

**Implantable Ventricular Assist Devices**

A 2018 review to determine the benefits and harms of exercise-based cardiac rehabilitation programs for people with implantable ventricular assist devices (VADs) (k=2) reports improvements in scored assessments of quality of life in participants in exercise-based cardiac rehabilitation groups compared to usual care groups.\textsuperscript{6} The review notes a lack of evidence for the effectiveness of exercised-based cardiac rehabilitation because of small sample sizes in the included studies, wide confidence intervals, high risk of performance bias, and young age of participants. Additionally, it was not possible to determine the effect of exercise-based cardiac rehabilitation on mortality, rehospitalization, heart transplantation, or cost as these outcomes were not reported in the included studies.\textsuperscript{6}

**REFERENCES**


7. Pub 100-04, Medicare Claims Processing Manual; Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Programs Furnished On or After January 1, 2010.

8. MCG Medicare Compliance module: NCD Cardiac Rehabilitation Programs for Chronic Heart Failure (20.10.1) Version 1; NCD: N20101v1

LVEF threshold of $\leq 45\%$ is based on the *Heart Failure Reduced Ejection Fraction* used by the American College of Cardiology and the American Heart Association (clarification: while this is accurate, current Medicare guidelines for cardiac rehab cover EF $\leq 35\%$).
PEDIATRIC CARDIAC REHABILITATION
(NON-MEDICARE MEMBERS ONLY)

Policy Number: 0014
Effective Date: September 2020
Reviewed Date: August 2022
Next Review: August/September 2023
Clinical Reviewer: Jeanne A. Mowry, MD

BACKGROUND

CLINICAL BACKGROUND

Pediatric cardiac rehabilitation is aimed to improve a child’s functional capacity, improve quality of life, increase lean mass relative to fat mass, increase overall physical activity, educate a family to adopt a healthy lifestyle, and ultimately decrease risk of future cardiovascular disease. Cardiac rehabilitation typically is composed of three separate components, including aerobic training, resistance training, and flexibility training.

POLICY AND CRITERIA

Pediatric cardiac rehabilitation may be medically indicated for patients aged 8 to 17 years when ONE of the following are true:

1. Patient has at least one of the following diagnoses:
   a. Cardiomyopathy; OR
   b. Single ventricle; OR
   c. Coronary artery anomalies

   OR

2. Patient is status post valve repair or replacement

Pediatric cardiac rehabilitation is not considered to be medically indicated for pulmonary hypertension, atrial septal defect, or ventricular septal defect.

For patients meeting criteria for pediatric cardiac rehabilitation, treatment is limited to 15 visits over 6 months, to include initial consult (with cardiopulmonary exercise testing and 6-minute walk tests). Twelve weekly visits may also be authorized.

NOTE: These criteria do NOT apply to Medicare members. See UR 12.1 for Medicare members.

RATIONALE

EVIDENCE BASIS

Wittekind (2018) reported outcomes among 8 young patients with nonischemic dilated cardiomyopathy who underwent cardiac rehabilitation. Patients ranged in age from 10 years to 31 years, and half of patients were male. Average BMI was 38.2 kg/m2 at baseline, with a mean waist circumference of 46.8 inches. Of the 8 subjects included in this study, 3 were under age 18 (a 10-year old boy, a 14-year old boy, and a 17-year old girl). Subjects attended two 45-minute sessions per week for up to 16 weeks. Authors reported that patients attended, on average, 85% of possible sessions. Overall, there were no statistically significant differences in mean left ventricular ejection fraction or in body mass index.
However, waist circumference was significantly decreased by approximately 1.4 inches at one-year follow-up, and 6-minute walk distance increased by roughly 111 meters. Findings from this study are limited by the extremely small sample size, and the failure to control for medications used.

Rhodes (2005) reported on 19 children with serious congenital heart disease who were referred for cardiac rehabilitation. Of the patients who completed the study (n=16), 11 were Fontan patients and 5 had other congenital heart disease. Patients were only eligible if they were between ages 8 and 17 years, had nontrivial congenital heart disease of severity sufficient to have activity restriction, had undergone at least 1 surgical or interventional procedure and/or had significant residual hemodynamic defect, have abnormal exercise function (peak VO$_2$ less than 80%) measured within the prior 6 months, and a commitment to attend and participate in rehabilitation. The treatment program consisted of 1-hour sessions twice weekly for 12 weeks. On average, patients attended 18 of 24 sessions. Authors reported that 15 of 16 patients had statistically significant improvements in at least one measure. On average, peak VO$_2$ increased from 26.4 to 30.7 mL/kg, and peak work rate increased from 93 to 106 W. There were no statistically significant changes in body mass index, resting oxygen saturation, FEV1/FVC, or blood pressure. No adverse events were reported, and authors concluded that the study was inadequately powered to identify adverse events due to small sample size.

While findings from the initial Rhodes study support use of cardiac rehabilitation in this highly selected population, the duration of treatment effect remains unclear. The same authors published a follow-up study of the same population, reporting outcomes on average 7 months after completion of the rehabilitation program (Rhodes 2006). In that analysis, authors reported that exercise function did not significantly decrease from completion of the program to follow-up and remained significantly elevated relative to baseline. Authors also reported improved quality of life measures, such as self-esteem, behavior, and emotional state. A group of 18 control subjects with similar diagnoses who had not undergone cardiac rehabilitation were found to have no statistically significant changes in exercise function over the same period.

Dulfer (2014) evaluated the effects of an exercise program in terms of health-related quality of life among children and adolescents with congenital heart disease. Patients included those who had undergone surgical repair for tetralogy of Fallot or those with a Fontan circulation for single-ventricle defects. Authors randomized subjects to a control group or to a cardiac rehabilitation program consisting of 3 weekly visits for 12 weeks. Authors reported that the younger patients (aged 10-15) had significantly improved cognitive functioning (self-reported) and social functioning (parent-reported). Subjects who were older (16 to 25 years) had no significant changes in health-related quality of life.

Kroll (2021) examined the impacts of a multidisciplinary cardiac rehabilitation program on exercise capacity, patient functioning (social, emotional, school, psychological), and quality of life in 25 patients with CHD between the ages of 7 and 24 years old. The program was a home-based year-long program based out of a children’s hospital that included 4 in-person visits with multiple providers (e.g., cardiologist, physical therapist, occupational therapist, psychologist, registered nutritionist) every 3 to 6 months. Participants were provided an activity monitor and personalized physical activity prescription and had the option of being paired with a mentor who would contact them between in-person visits to assess progress with the physical activity recommendations. Between baseline and the final session, a significant improvement in exercise capacity was observed. Parents of participants reported improvements in the patients’ emotional, social, school, psychosocial, cognitive functioning, communication, and overall QoL, whereas patients did not report improvements in these areas. Patients reported improvements in perceived cardiac-related QoL and self-concept.

Ferrer-Sargues (2021) reported on the effect of a cardiopulmonary rehabilitation program on peripheral musculature function of 15 children (ages 12-16 years) with CHD. The intervention consisted of twice weekly exercise sessions of 70 minutes each, including both endurance and resistance training components, for a total of 24 sessions. Peripheral muscle function was measured at baseline, upon completion of the 24 sessions, and 6 months after program completion via hand grip strength, biceps brachii strength, quadriceps femoris strength, and single heel-rise tests. Improvements in peripheral muscle function were observed across all measures of strength from baseline and were maintained at 6
months post-intervention. Findings from this study are limited by the small sample size, lack of comparison group, and lack of data collection about physical activity during the 6-month follow-up period.

Balfour (1991) reported on 16 patients who participated in a pediatric/young adult cardiac rehabilitation program. Less than half of patients completed the program (7 of 16), and outcome data were only available for 6 patients. The treatment program included 3 supervised sessions of 30-40 minutes each week for 3-6 months. Diagnoses among the patients included: dilated cardiomyopathy, aortic stenosis, tetralogy of Fallot, idiopathic hypertrophic subaortic stenosis, aortic valve replacement, ventricular septal defect, mitral valve prolapse, Fontan circulation, premature ventricular contractions, and pulmonary stenosis. Overall, there were statistically significant decreases in resting blood pressure, as well as significant increases in peak oxygen consumption and exercise treadmill time. The study was limited by very small sample size and high loss to follow-up.

**EXPLANATION AND RATIONALE**

There is very low strength of evidence that pediatric cardiac rehabilitation may yield short-term improvements in VO$_2$ among patients with severe congenital heart disease. There is insufficient evidence to determine whether cardiac rehabilitation is effective among other pediatric populations. Additionally, there is insufficient evidence regarding long-term outcomes following pediatric cardiac rehabilitation, as the longest follow-up was roughly nine months after program completion. However, Northwest Permanente clinical expert consensus supports pediatric cardiac rehabilitation as being valuable for select populations despite the limited evidence base.

**REFERENCES**


Northwest Region Utilization Review

UR 71 Carotid Endarterectomy
Medical Necessity Criteria

Department: Non-Behavioral Health
Number: UR 71
Section: KPNW Region
Effective: 10/19
Applies to: KPNW Region
Reviewed: 10/19, 10/22
Review Responsibility: UR Oversight Committee
Revised: 10/20, 11/21
Reviewer: Yanina Benikova, MD

DEFINITIONS
Carotid stenosis- Narrowing of the blood vessels (carotid arteries) in the neck restricting the blood flow to brain and head.

POLICY AND CRITERIA

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. ipsilateral carotid-related transient ischemic event or stroke) and the procedure is judged appropriate as indicated by ALL of the following:
  o 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)
  o Patient at low perioperative risk for complications or death

• Patient is asymptomatic but procedure is judged appropriate as indicated by ALL of the following:
  o 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)
  o Patient at low perioperative risk for complications or death
  o Medical management and risk factor modification (e.g. antiplatelet therapy, diabetes control, smoking cessation, treatment of hypertension and hyperlipidemia) are not preferred

NOTE: Carotid revascularization, whether by carotid endarterectomy or stenting, is not considered medically necessary for treatment of chronic total (100%) occlusion.

SPECIAL GROUP CONSIDERATIONS
These criteria do not apply to OR/WA Medicaid
EVIDENCE BASIS

MCG reviewed the evidence on carotid endarterectomy (CEA) for essential tremor in 2021. Their findings are provided below:

The benefits of carotid endarterectomy (CEA) beyond that of contemporary, best medical therapy (i.e., antiplatelet agent, antihypertensive treatment, statin therapy, risk factor modification) in patients with carotid artery stenosis is unclear.\(^1\)\(^-\)\(^5\) Randomized trials comparing CEA to medical therapy that showed lower stroke recurrence following CEA were performed decades ago, when medical treatment was less comprehensive and likely less effective.\(^1\)\(^-\)\(^7\) An attempt to compare CEA with more modern medical therapy was performed in a propensity-matched study of 5221 patients (mean age 73.6 years) with asymptomatic carotid stenosis 70% or greater treated with either CEA or medical management which found, after adjusting for competing mortality risks, that the absolute reduction in the 5-year risk of fatal and nonfatal strokes associated with CEA was less than half the risk difference in trials from 20 years ago and was not statistically significant (5.4% CEA vs 6.2% medical).\(^8\)

The evidence base concerning carotid artery stenting (CAS) as an alternative to CEA is limited by relatively short follow-up periods (e.g., less than 5 years) in the few randomized trials performed.\(^2\)\(^-\)\(^5\) Similar to CEA, whether CAS offers benefit above and beyond that of contemporary, best medical therapy is unknown.\(^1\)\(^-\)\(^5\) A meta-analysis and systematic review for a specialty guideline of 9 randomized controlled trials, encompassing 5486 low surgical risk patients (mean age 69 years) with symptomatic carotid artery stenosis treated with CEA or transfemoral CAS found that patients treated with CEA had a lower risk of stroke at 30 days.\(^6\) In the same review, analysis of pooled data from 4 of these studies (4754 patients with greater than 50% carotid stenosis) showed that CEA also had a lower composite outcome of mortality or stroke at 120 days (5.5% vs 8.7%) and at 5 years (8.3% vs 11.4%).\(^6\) Due to evidence of higher perioperative stroke risk, and no evidence of improved long-term outcomes compared to CEA, CAS is generally recommended as an option for patients at increased surgical risk (severe comorbidities such as CHF, CAD, COPD, renal disease) or who present with anatomic or clinical findings that render CEA more difficult or less suitable.\(^2\)\(^-\)\(^5\)

Even when presuming a potential benefit to carotid revascularization over medical therapy, due to the narrow risk-benefit ratio, any advantage to CEA or CAS is contingent upon proper patient selection and low operator perioperative morbidity and mortality (e.g., 30-day postoperative stroke or mortality).\(^2\)\(^-\)\(^5\) Specifically, patients should not be at high estimated risk of perioperative (30-day) morbidity and mortality, and the procedure should be performed in settings (surgeon, institution) with documented perioperative outcomes indicating low risk. For symptomatic patients (e.g., ipsilateral transient ischemic attack or stroke within past 6 months), the recommended level of risk is less than 6% (based on patient risk factors and tracked operator and facility track record).\(^2\)\(^-\)\(^5\) For asymptomatic patients, the risk-benefit ratio is even narrower. To this end, screening asymptomatic patients is not recommended.\(^9\) In incidentally found asymptomatic carotid artery stenosis, any potential benefit to intervention (CEA or CAS) is contingent upon a life expectancy of at least 5 years and perioperative risks of less than 3% (based on patient risk factors and tracked operator and facility track record).\(^2\)\(^-\)\(^5\)
CLINICAL REFERENCES: The MCG Solutions’s evidence summary was used in conjunction with the judgement of a qualified health care provider in the development of this policy.

REFERENCES


**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.

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. (Chiropractic maintenance therapy is not considered to be medically reasonable...
POLICY AND 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 (see definition above) 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:

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

SPECIAL GROUP CONSIDERATIONS:

Medicare: 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" and "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 affect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time.
Medicare does not make separate payment for any device used during spinal manipulation.

RATIONAL

EVIDENCE BASIS

In 2020, the Agency for Healthcare Research and Quality (AHRQ) published an updated report on noninvasive nonpharmacologic treatment for selected chronic pain conditions that includes an assessment of the effectiveness of spinal manipulation for these conditions.¹ For patients with chronic back pain, evidence from 3 RCTs was pooled and showed that spinal manipulation resulted in function improvement over the short and/or intermediate term and improved pain at intermediate term.¹ AHRQ produced surveillance reports to identify more recent evidence published between December 2021 and March 2022 and assess how any more recent evidence impacts the findings of the 2020 report.² One additional RCT examining spinal manipulation for chronic low back pain was identified that did not impact the overall conclusions from the 2020 report.²

In 2017, the Evidence-based Synthesis Program of the Department of Veterans Affairs (VA) published a systematic review on the effectiveness and harms of spinal manipulative therapy for acute neck and lower back pain compared to usual care or other forms of acute pain management.³ The review reports overall statistically significant evidence of clinical benefit of spinal manipulation treatments for acute lower back pain (moderate quality of evidence), with improvement to the outcomes of pain and function. The review found very few studies examining spinal manipulation therapy for acute neck pain and rated the evidence as “low” that this form of therapy improves outcomes in patients with acute neck pain. The review found insufficient evidence to determine the relationship between spinal manipulation therapy and the use of opiate medication for either acute low back pain or acute neck pain. There was a high degree of heterogeneity across the results of the included studies which is unexplained and suggests a need for more research to better understand what contributes to patient selection and intervention to improve the consistency of results across studies.³

REFERENCES


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
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 or 2 below in addition to 3 through 5:
   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. Single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in the ear to be implanted and normal hearing or mild to moderate sensorineural hearing loss in the other ear.
   3. For single sided deafness, cochlear implant is not recommended if profound hearing loss for over 10 years.
   4. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
   5. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.

B. Children (age 9 months through 17 years) with 1 or 2 below in addition to 3 through 9:
   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 patients 5 years and older with single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in the ear to be implanted and normal hearing or mild to moderate sensorineural hearing loss in the other ear.
   3. For single sided deafness, cochlear implant is not recommended if profound hearing loss for over 10 years.
   4. For children age 12-24 months, profound sensorineural hearing loss: thresholds of 90dB or greater at 1000Hz.
   5. For children age 24 months to 17 years, pure tone average of 70dB or greater at 500Hz, 1000Hz, and 2000Hz.
   6. 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.
   7. A three to six-month hearing aid trial is required for children without previous experience with hearing aids. Radiographic evidence of labyrinthine fibrosis that would lead to ossification will justify implantation without a trial of amplification.
   8. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.
   9. 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
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

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

RATIONALE

EVIDENCE BASIS

MCG reviewed the evidence on cochlear implants in 2022. Their findings are provided below:

For adults with hearing loss, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review and meta-analysis of 14 studies (679 adult patients) evaluating quality of life improvement after cochlear implantation found that cochlear implantation was associated with significant improvement in quality of life measured by hearing-specific or cochlear implant-specific quality of life patient-reported outcomes.1 A systematic review of 3 randomized controlled trials and 7 observational studies (308 adult patients) with severe to profound sensorineural hearing loss found that compared with unilateral cochlear implantation, bilateral cochlear implantation was associated with improved speech perception in noise, sound localization, and subjective improvements in speech and spatial hearing.2 A systematic review of unilateral vs bilateral cochlear implantation in adults concluded that unilateral implantation with or without the use of hearing aids was effective for improving speech perception in adults with severe to profound sensorineural hearing loss; both simultaneous and sequential bilateral cochlear implantation provided additional improvement in speech perception.3 A systematic review of 14 studies comparing unilateral cochlear implant with or without hearing aid
on the non-implant ear vs bilateral cochlear implant found benefit for bilateral implants in noise conditions and in several self-reported outcome measures.\(^4\) A systematic review of sequential cochlear implants in adults and children found that although the quality of the studies was poor, the evidence suggested that a second implant can be beneficial even if there is a substantial interval between implants.\(^5\) An industry-sponsored randomized controlled trial of 38 adults with postlingual, severe to profound hearing loss compared simultaneous and sequential (2 years between procedures) bilateral cochlear implants and found, 1 year after both implants were in place, comparable results between the groups in terms of speech intelligibility in noise from straight ahead, from spatially separated sources, and in silence. The authors concluded that patients who receive sequential implants derive the same benefit as those who receive them simultaneously.\(^6\) A national guideline recommends simultaneous bilateral cochlear implantation only for adults with severe to profound deafness who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism of spatial awareness.\(^7\) Most adult patients who receive a cochlear implant have improvement in both hearing threshold and ability to lip-read. Postlingual deaf adults attain scores of 90% to 100% for speech-reading capabilities on everyday sentence material and above 80% for high-content sentences after cochlear implant. Over half of postlingual deaf adults can achieve some degree of telephone conversational ability after cochlear implant.\(^8\) A prospective study of 94 postlingual deaf patients (65 to 85 years of age) who were treated with cochlear implants for sensorineural hearing loss found a mean improvement in speech perception scores of 52% at 6 months, with continued improvement at 12 months; there was also significant improvement in quality of life. Patients with depression, as assessed by the Geriatric Depression Scale-4 (GDS-4), decreased from 41% to 24% at 12 months after implantation.\(^9\) A literature review of patients 65 years and older who were treated with cochlear implants found that patients showed improvement in speech outcomes and quality of life and had similar device complication rates as compared with younger patients. The authors concluded that elderly age should not exclude appropriate candidates for a cochlear implant.\(^10\) A prospective study of 20 patients with asymmetric hearing loss found, at 1-month follow-up, that cochlear implantation in the affected ear was associated with decreased tinnitus severity and improved sound localization and hearing-specific quality of life, as compared with preoperative measurements; the improvements were sustained at 12-month follow-up.\(^11\) A technology assessment found moderate-quality evidence that cochlear implants improve sound localization, speech perception in noise, tinnitus symptoms, and quality of life in adults and children with single-sided deafness or asymmetric hearing loss.\(^12\) For infants or children with hearing loss, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review of prognostic factors for cochlear implant in children found that improved outcomes were associated with early implant, congenital deafness due to GJB-2 gene mutation, less severe inner ear malformations, and early implant of postmeningitic or congenitally deaf children.\(^13\) Multiple studies of unilateral cochlear implant in children demonstrate that functional outcomes are improved when the surgery is performed at a younger age. Eligible children should receive a cochlear implant as soon as bilateral profound hearing impairment is diagnosed to maximize speech and language achievement and integration into an oral communication environment. Children who are implanted when younger than 2 years can experience normal or near-normal rates of auditory skill and oral language development. However, even in older children, the oral language and speech benefits of implant are substantial for those who have some residual hearing because they are able to hear more speech and sound information with the cochlear implant than with a hearing aid.\(^14-18\) A systematic review of 14 studies evaluating the effect of early (before 12 months) cochlear implantation found better scores on speech production, auditory performance, and some receptive language tests in children
implanted before 12 months compared with those implanted later. However, the authors noted that the available evidence consisted of cohort studies with moderate to high risk of bias, and recommended long-term follow-up studies.\textsuperscript{19} A systematic review of 4 studies with a total of 103 pediatric patients found that simultaneous bilateral implantation, as compared with sequential bilateral implantation, resulted in statistically significant higher speech and language development scores 3 years after the first cochlear implantation.\textsuperscript{20} Children with bilateral cochlear implants that are activated at earlier ages and with shorter gaps between surgeries appear to receive greater benefit than those implanted later and with longer gaps between surgeries.\textsuperscript{21} Other systematic reviews that compared bilateral cochlear implant with unilateral implant in children found that, although the data are limited, bilateral cochlear implant appeared to be more effective in terms of sound localization and improved speech perception in quiet and noise.\textsuperscript{22-24} A systematic review and meta-analysis of 12 observational studies with 119 pediatric patients (mean age 6.6 years) with single-sided deafness (unaided pure-tone average of 90 dB or greater in one ear) found that cochlear implants improved speech perception in noise in 79.6% of patients and speech perception in quiet in 81% of patients; cochlear implants were also associated with improved sound localization.\textsuperscript{25} A technology assessment found moderate-quality evidence that cochlear implants improve sound localization, speech perception in noise, tinnitus symptoms, speech and language development, and quality of life in children with single-sided deafness or asymmetric hearing loss.\textsuperscript{12} A systematic review of 13 studies with a total of 1073 pediatric patients compared the outcome of cochlear implantation in children with normal development to those with mild to severe developmental disability; children with mild developmental delay had similar receptive and expressive language outcomes as compared with children without developmental delay, but children with severe developmental delay had worse outcomes. Careful preoperative and postoperative counseling may be particularly important in this patient population.\textsuperscript{26} A retrospective study of factors associated with limited use and nonuse of cochlear implants in children found that disabilities (eg, cerebral palsy, autism, moderate mental retardation, attention-deficit hyperactivity disorder, learning disability) and lack of family interest were factors that required more support to ensure adequate use.\textsuperscript{27}

REFERENCES


CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) TITRATION IN A SLEEP CENTER MEDICAL NECESSITY CRITERIA

POLICY AND CRITERIA

CPAP sleep center titration may be indicated for 1 or more of the following:

1) Adult with central sleep apnea syndrome due to congestive heart failure

2) Adult with obesity hypoventilation (shallow breathing) syndrome, as indicated by ALL of the following:
   A. BMI (body mass index) greater than 30
   B. Daytime hypercapnia (excess carbon dioxide in the blood) with PaCO₂ (partial pressure of carbon dioxide) greater than 45 mm Hg/ 6.0 kPa (kPa is a unit of pressure) without other etiology (eg, kyphoscoliosis, lung parenchymal disease, myopathy, severe hypothyroidism)
   C. Sleep-disordered breathing or hypoventilation on polysomnography (sleep study), as indicated by 1 or more of the following:
      i. Apnea-hypopnea index of 5 or greater
      ii. Increase in PaCO₂ during sleep by more than 10 mm Hg/ 1.3 kPa above value while awake
      iii. Significant oxygen desaturation (ie, less than 90%) not explained by obstructive apneas or hypopneas
   D. TSH level does not demonstrate hypothyroidism.

3) Adult with obstructive sleep apnea, as indicated by ALL of the following:
   A. Obstructive sleep apnea, as indicated by 1 or more of the following:
      i. Mild obstructive sleep apnea (ie, apnea-hypopnea index or respiratory disturbance index between 5 and 15, determined with polysomnography) and 1 or more of the following:
         a. Cardiovascular disease documented (eg, hypertension, ischemic heart disease, heart failure, stroke)
         b. Excessive daytime sleepiness (eg, Epworth Sleepiness Scale score of 10 or greater in adult patient)
         c. Fibromyalgia-like symptoms
         d. Headaches upon awakening
         e. Heartburn and reflux
         f. Impaired cognition
         g. Mood disorder
         h. Night sweats
      ii. Severe obstructive sleep apnea (ie, apnea-hypopnea index or respiratory disturbance index greater than 15, determined with polysomnography) and 1 or more of the following:
         a. Cardiovascular disease documented (eg, hypertension, ischemic heart disease, heart failure, stroke)
         b. Excessive daytime sleepiness (eg, Epworth Sleepiness Scale score of 10 or greater in adult patient)
         c. Fibromyalgia-like symptoms
         d. Headaches upon awakening
         e. Heartburn and reflux
         f. Impaired cognition
         g. Mood disorder
         h. Night sweats
i. Nocturia or nocturnal enuresis
j. Observed apnea or choking episodes
k. Patient is commercial vehicle driver
l. Snoring

ii. Moderate or severe obstructive sleep apnea (ie, apnea-hypopnea index or respiratory disturbance index 15 or greater, determined with polysomnography)

iii. Upper airway resistance syndrome associated with unexplained excessive daytime sleepiness

B. Performed as full-night CPAP titration study or split-night study (ie, polysomnography with CPAP titration)

4) Child, infant, or adolescent with obstructive sleep apnea and ALL of the following:

A. Polysomnography demonstrates obstructive sleep apnea (ie, apnea-hypopnea index of 1 or greater in child younger than 18 years)
B. Signs and symptoms consistent with obstructive sleep apnea, including 1 or more of the following:
   i. Daytime sleepiness
   ii. Enuresis
   iii. Failure to thrive (weight less than fifth percentile for age)
   iv. Hyponasal speech
   v. Mouth breathing
   vi. Nocturnal pauses in breathing
   vii. Nonspecific behavioral problems (eg, hyperactivity, developmental delay, aggression, poor school performance)
   viii. Pulmonary hypertension
   ix. Signs of increased respiratory effort (ie, nasal flaring)
   x. Snoring

C. No tonsillar or adenoid enlargement (or tonsillar or adenoid enlargement and contraindication to surgical intervention), or failure of tonsil or adenoid removal to change symptoms

D. Performed as full-night CPAP titration study, or split-night study (ie, polysomnography with CPAP titration) if patient is 12 years or older

**RATIONALE**

**EVIDENCE BASIS**

MCG reviewed the evidence on CPAP in 2022.\(^1\) Their findings are provided below:

“For adults with central sleep apnea due to congestive heart failure, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review identified 16 articles that studied treatment of central sleep apnea syndromes related to congestive heart failure and concluded that CPAP therapy can normalize the apnea-hypopnea index and improve left ventricular ejection fraction.\(^2\)

For adults with obesity hypoventilation syndrome, evidence demonstrates at least moderate certainty of at least moderate net benefit. CPAP has been shown to be effective for the treatment of the majority of
patients with obesity hypoventilation syndrome, particularly in the subgroup with severe obstructive sleep apnea.³

For adults with obstructive sleep apnea, evidence demonstrates at least moderate certainty of at least moderate net benefit. In adults, mild obstructive sleep apnea is defined as an apnea-hypopnea index or respiratory disturbance index of 5 to 15, moderate as 15 to 30, and severe as greater than 30.⁴ Systematic reviews, prospective cohort studies, and randomized trials have concluded that CPAP is an effective treatment, with improvement in objective and subjective sleepiness, quality of life, and clinical measures such as blood pressure (in patients who are hypertensive) and cardiovascular mortality.⁵⁻⁹ A randomized trial evaluating the effects of CPAP on prehypertension and masked hypertension in males with severe obstructive sleep apnea found that the use of CPAP promotes significant reductions in blood pressure.¹⁰ Another randomized trial of male and female patients with resistant hypertension and obstructive sleep apnea found that the use of CPAP for greater than 5.8 hours at a time resulted in significant blood pressure reductions.¹¹ For patients with obstructive sleep apnea and heart failure, studies have demonstrated improved left ventricular ejection fraction and cardiac remodeling, and a trend toward decreased mortality when treatment consists of CPAP in addition to optimal medical therapy for heart failure.¹²⁻¹⁴ A study of nocturnal CPAP in obese patients with obstructive sleep apnea found that the use of CPAP increased exercise tolerance and improved dyspnea in these patients.¹⁵ With appropriate titration, positive airway pressure devices resolve most sleep-disordered breathing regardless of the disease severity level;¹⁶ goals of CPAP titration include achieving a respiratory disturbance index less than 5, a pulse oximetry greater than 90%, and tolerable air leak at the mask.¹⁷ Performance of a split-night study may be indicated if the diagnosis of moderate or severe obstructive sleep apnea can be made within the first 2 hours of recorded sleep, and at least 3 hours of CPAP titration is demonstrated, including the ability of CPAP to eliminate respiratory events during both rapid eye movement sleep and non-rapid eye movement sleep.¹⁸⁻¹⁹ Specialty society practice parameters note that a repeat CPAP titration study may be appropriate when the initial CPAP titration fails to resolve obstructive sleep apnea findings sufficiently, when the response to therapy is inadequate despite good adherence and adequate interface fit, when symptoms return after a period of adequate response to CPAP therapy, or when greater than 10% body weight gain or loss necessitates adjustment of pressure settings.²⁰⁻²¹

For children, infants, or adolescents with obstructive sleep apnea, evidence demonstrates at least moderate certainty of at least moderate net benefit. The criteria for interpreting pediatric polysomnograms typically define mild obstructive sleep apnea as an apnea-hypopnea index of 1 to 5, moderate as 6 to 10, and severe as greater than 10.²²⁻²⁴ A specialty society recommended using the pediatric scoring rules for children younger than 18 years of age; however, studies indicated that some of the adult scoring rules may be used in adolescents 13 to 18 years of age.²⁵⁻²⁹ Specialty society clinical guidelines recommend that pediatric patients with symptoms of obstructive sleep apnea who are not candidates for adenotonsillectomy or who have persistent obstructive sleep apnea after adenotonsillectomy should be referred for CPAP management.²⁴,³⁰,³¹ Although there is limited evidence for its use, a specialty society recommends using polysomnography when titrating CPAP in infants.³² Performance of a split-night study may be indicated if the diagnosis of moderate or severe obstructive sleep apnea can be made within the first 2 hours of recorded sleep, and at least 3 hours of
CPAP titration is demonstrated, including the ability of CPAP to eliminate respiratory events during both rapid eye movement sleep and non-rapid eye movement sleep.\textsuperscript{18, 19} An evidence-based specialty society guideline is unable to recommend split-night CPAP titration for children younger than 12 years due to a lack of data.\textsuperscript{20} A review article noted that obstructive sleep apnea in children may manifest as hyperactivity, emotional difficulties, decreased academic performance, and difficulty concentrating; in contrast, daytime sleepiness, morning headache, memory impairment, and daytime fatigue are more common symptoms in adults.\textsuperscript{33} Specialty society guidelines note that repeat CPAP titration testing may be appropriate when the initial CPAP titration study fails to achieve optimal results, when symptoms return after an initial adequate CPAP therapy response, after 10\% body weight gain or loss, and with growth in children using CPAP therapy for obstructive sleep apnea.\textsuperscript{20, 24, 31}\textsuperscript{1}

The United States Preventive Services Task Force (USPSTF) issued updated recommendations on screening for obstructive sleep apnea in asymptomatic adults in November 2022.\textsuperscript{34} The supporting evidence review examined the benefits, effectiveness, and harms of treatment with positive airway pressure in adults with obstructive sleep apnea and reports that, compared to inactive control, positive airway pressure was associated with a significant improvement in Epworth Sleepiness Scale score from baseline, sleep-related quality of life, and general health-related quality of life.\textsuperscript{34} Additionally, the review summarizes evidence from other systematic reviews that show a small but statistically significant association of positive airway pressure with reduced blood pressure.\textsuperscript{34} No included trials in this review found significant benefits of treatment with positive airway pressure on mortality, cardiovascular events, or motor vehicle crashes.\textsuperscript{34}

\begin{center}
\textbf{REFERENCES}
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1. MCG. CPAP Titration, Sleep Center. MCG. Accessed December 5, 2022.


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 facial configuration or 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 (see Special Group Considerations for Added Choice members and members in Lane County) will be authorized for the member’s condition to be assessed. The Kaiser Permanente (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 facial configuration or function.

1) A congenital anomaly exists affecting the bony structures of the face or head which disrupts facial configuration and/or 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 facial configuration or function.

SPECIAL GROUP CONSIDERATIONS

OR/WA Commercial: Mandate applies to all commercial groups. For HMO members in Lane County, a referral to KP’s Craniofacial Clinic in Portland is highly recommended but cannot be required due to the distance required to access services in Portland.

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

Added Choice/POS: A referral to KP’s Craniofacial Clinic in Portland is highly recommended but not required. 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. Most procedures (e.g. advanced imaging and some DME) and levels of care other than office visits require prior-authorization (please refer to members’ benefits but examples of exceptions to the above include outpatient labs, x-rays, and preventive services).

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

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

- Congenital facial asymmetry Q67.0
- Congenital compression facies Q67.1
- Depressions in skull
- Deviation of nasal septum, congenital
- Dolichocephaly Q67.2
- Plagiocephaly Q67.3
- Other congenital deformities of skull, face and jaw Q67.4
- Potter's facies
- Squashed or bent nose, congenital
PURPOSE

Describe the policy and medical necessity criteria for the provision of general anesthesia (GA) in an operating room (OR) of a hospital or ambulatory surgery center (ASC) or a surgical suite of a dental clinic when GA is required to safely provide necessary dental treatment.

POLICY

It is an accepted community standard to provide necessary dental care under GA when the dental procedures cannot be safely performed in a traditional dental office setting because the member has special needs or because the member is 12 years of age or younger.

The eligibility criteria described herein are NOT intended to be used for patients who require GA in the OR for oral surgery services that are covered under medical benefit and provided by an Oral Surgeon.

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 room or a surgery suite within a hospital or ambulatory surgery center or dental clinic 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 or younger
- **Special Needs:** Medical, developmental, or mental condition that may impair member’s ability to receive dental care in a traditional dental office setting. These conditions may include:
  - Alzheimer’s disease
  - Parkinson’s disease
  - Autism spectrum disorder
  - Cerebral palsy
  - Down syndrome
  - Intellectual disability
  - Paralysis
  - Seizure disorder
  - Sensory disorder
  - Developmental delay
  - Allergy to all conventional local anesthetics (confirmed by documented evaluation by allergist)
NOTE: Dental Phobia in members older than 12 years is not considered to be a special need and does NOT meet the criteria for Medical Necessity of general anesthesia for dental procedures.

MEDICAL NECESSITY CRITERIA

Provision of general anesthesia in operating room of a hospital or ambulatory surgery center or a surgical suite of a dental clinic for dentally necessary dental services may be considered medically necessary when BOTH of the following criteria are met:

**Criterion 1:**
The pediatric dentist or general dentist or oral surgeon has documented that the member requires dentally necessary care AND clinically appropriate alternatives which can be provided in a traditional dental office setting are not available.

**Criterion 2:**
The member of any age has a special needs diagnosis which significantly impairs their ability to safely cooperate with dental care in a traditional dental office setting;

OR

The member is 12 years of age or younger and the pediatric dentist or general dentist or oral surgeon has documented that the member’s dental care cannot be safely provided in a traditional dental office setting due to factors that include but are not limited to:

- age;
- physical, medical or mental status;
- extent of treatment planned / degree of difficulty of the procedure;
- member’s inability to cooperate due to acute situational anxiety /dental phobia;
- exaggerated gag reflex;
- need for immediate comprehensive dental treatment prior to medical treatment;
- allergy to local anesthetic/ inability to achieve local anesthesia;
- protecting the developing psyche of patient and/ or reduce medical risk;
- failed attempt of dental treatment in dental office.

SPECIAL GROUP CONSIDERATIONS

**Commercial:** This policy applies to all commercial groups

**Medicare:** This policy does NOT apply to Medicare

**Washington Medicaid:** This policy does not apply, see references below

**Oregon Medicaid:** This policy does not apply, see references below.

REFERENCES

American Academy of Pediatric Dentistry Oral Health Policy 2020, Policy on Hospitalization and Operating Room Access for Oral Care of Infants, Children, Adolescents, and Individuals with Special Health Care Needs

Policy Number: NW.DENTAL.BENEFITS.022.0 - Request for Extra Contractual Services in Operating Room
The purpose of hospital dentistry is to provide safe, efficient dental care when providing routine (non-emergency) dental services for Division of Medical Assistance Programs (Division) 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 the following Division clients:

a. Children (18 or younger) who:
   (A) Through age (3): Have extensive dental needs;
   (B) (4) years of age or older: 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 conscious 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;
      ii. A physically compromising condition.

b. 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;
      ii. A physically compromising condition.
   (B) Have sustained extensive orofacial or dental trauma; or
   (C) Are medically fragile, with a medical or physical condition which requires monitoring during dental procedures (i.e. coronary disease, asthma, or chronic obstructive pulmonary disease (COPD), heart failure, serious blood or bleeding disorder, or unstable diabetes or hypertension), have complex medical needs, contractures or other significant medical conditions potentially making the dental office setting unsafe for the client.

Washington Medicaid:

RCW 48.43.185 - General anesthesia services for dental procedures.

RCW 48.43.185: General anesthesia services for dental procedures. (wa.gov)

(1) Each group health benefit plan that provides coverage for hospital, medical, or ambulatory surgery center services must cover general anesthesia services and related facility charges in conjunction with any dental procedure performed in a hospital or ambulatory surgical center if such anesthesia services and related facility charges are medically necessary because the covered person:
(a) Is under the age of seven, or physically or developmentally disabled, with a dental condition that cannot be safely and effectively treated in a dental office; or

(b) Has a medical condition that the person's physician determines would place the person at undue risk if the dental procedure were performed in a dental office. The procedure must be approved by the person's physician.

(2) Each group health benefit plan or group dental plan that provides coverage for dental services must cover medically necessary general anesthesia services in conjunction with any covered dental procedure performed in a dental office if the general anesthesia services are medically necessary because the covered person is under the age of seven or physically or developmentally disabled.

(3) This section does not prohibit a group health benefit plan or group dental plan from:

(a) Applying cost-sharing requirements, maximum annual benefit limitations, and prior authorization requirements to the services required under this section; or

(b) Covering only those services performed by a health care provider, or in a health care facility, that is part of its provider network; nor does it limit the health carrier in negotiating rates and contracts with specific providers.

(4) This section does not apply to Medicare supplement policies, or supplemental contracts covering a specified disease or other limited benefits.

(5) For the purpose of this section, "general anesthesia services" means services to induce a state of unconsciousness accompanied by a loss of protective reflexes, including the ability to maintain an airway independently and respond purposefully to physical stimulation or verbal command.

(6) This section applies to group health benefit plans and group dental plans issued or renewed on or after January 1, 2002.

WAC 182-531-0300 - Anesthesia providers and covered physician-related services. The Medicaid agency bases coverage of anesthesia services on Medicare policies and the following rules:

(1) The agency reimburses providers for covered anesthesia services performed by:

(a) Anesthesiologists;

(b) Certified registered nurse anesthetists (CRNAs);

(c) Oral surgeons with a special agreement with the agency to provide anesthesia services; and

(d) Other providers who have a special agreement with the agency to provide anesthesia services.

(2) The agency covers and reimburses anesthesia services for children and noncooperative clients in those situations where the medically necessary procedure cannot be performed if the client is not anesthetized. A statement of the client-specific reasons why the procedure could not be performed without specific anesthesia services must be kept in the client's medical record. Examples of such procedures include:

(a) Computerized tomography (CT);

(b) Dental procedures;

(c) Electroconvulsive therapy; and

(d) Magnetic resonance imaging (MRI).

(3) The agency covers anesthesia services provided for any of the following:

(a) Dental restorations and/or extractions:

(b) Maternity per subsection (9) of this section. See WAC 182-531-1550 for information about sterilization/hysterectomy anesthesia;

(c) Pain management per subsection (5) of this section;

(d) Radiological services as listed in WAC 182-531-1450; and

(e) Surgical procedures.

(4) For each client, the anesthesiologist provider must do all of the following:

(a) Perform a preanesthetic examination and evaluation;

(b) Prescribe the anesthesia plan;
(c) Personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence;
(d) Ensure that any procedures in the anesthesia plan that the provider does not perform, are performed by a qualified individual as defined in the program operating instructions;
(e) At frequent intervals, monitor the course of anesthesia during administration;
(f) Remain physically present and available for immediate diagnosis and treatment of emergencies; and
(g) Provide indicated post anesthesia care.

(5) The agency does not allow the anesthesiologist provider to:
(a) Direct more than four anesthesia services concurrently; and
(b) Perform any other services while directing the single or concurrent services, other than attending to medical emergencies and other limited services as allowed by Medicare instructions.

(6) The agency requires the anesthesiologist provider to document in the client’s medical record that the medical direction requirements were met.

(7) **General anesthesia:**
(a) When a provider performs multiple operative procedures for the same client at the same time, the agency reimburses the base anesthesia units (BAU) for the major procedure only.

Certified on 10/25/2019 WAC 182-531-0300 Page 1

WAC 182-500-0070 - Definitions:

"Medically necessary" is a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service. For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

Molina: 2021Redline_Medicaid_MHWFinalDraft2_forRRD_R (molinahealthcare.com)

“Medically Necessary” or “Medical Necessity” means a requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the Enrollee that endanger life, or cause suffering of pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity, or malfunction. There is no other equally effective, more conservative, or substantially less costly course of treatment available or suitable for the Enrollee requesting the service. For the purpose of this Contract, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all (WAC 182-500-0070).

This is for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms. Those services must be deemed by Molina to be:
1. In accordance with generally accepted standards of medical practice:
2. Clinically appropriate and clinically significant, in terms of type, frequency, extent, site and duration. They are considered effective for the patient’s illness, injury or disease; and, 3. Not primarily for the convenience of the patient, physician, or other health care Provider. The services must not be more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease. For these purposes, “generally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature. This literature is generally recognized by the relevant medical community, physician specialty society recommendations, the views of physicians practicing in relevant clinical areas and any other relevant factors. The fact that a Provider has prescribed,
recommended or approved medical or allied goods or services does not, in itself, make such care, goods or services medically necessary, a medical necessity or a covered service/benefit.
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.
Burns
Cardiac
Critical Illness
Gastrointestinal Bleeding
General Surgery
Neurology, including stroke
Neurosurgery, adult
Neurosurgery, pediatric
Orthopedics
Plastic Surgery
Pediatrics
Psychiatry
Renal
Respiratory
Trauma
  - Blunt
  - Head and spine
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 Randall Children’s 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
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 fibrinolytics 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.
5. Patient has a Swan-Ganz catheter inserted but otherwise stable (as defined here) is appropriate for transfer.

**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 / AORTIC ANEURYSM**

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.

**NOTE:** if transferring for higher level of care and on IABP (intra-aortic balloon pump), ensure IABP compatibility with pump at SMC.
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
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 10 mcg/kg/min
• 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 PaO\textsubscript{2} < 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
• 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

*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 +/- or 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 ≥15 years of age. If age <15, transport to DCH.
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
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 Randall Children’s Hospital 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;
GENERAL

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.
**GENERAL**

**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 screening.

**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).

NOTE: Doernbecher Children’s Hospital Inpatient Pediatric Ward does not accept medically stable/cleared psychiatric patients who are awaiting inpatient or residential psychiatric treatment.
Hemodialysis patients exhibiting volume overload or electrolyte imbalance and are often in need of urgent or emergent dialysis.

Patients on sustained low-efficiency dialysis (SLED) can be repatriated at Sunnyside Medical Center whereas patients on continuous renal replacement therapy (CRRT) cannot be repatriated. Patients need to be able to be on intermittent not continuous dialysis. They can only move when able to be off CRRT for 15 hours and then transferred to SLED.

**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

**RENA TRANSPLANT 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.
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 weights the overall risks and benefits of transfer.
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
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.
EPIDURAL STEROID INJECTIONS

Policy Number: 0001
Effective Date: Jan 20, 2015
Reviewed Date: Jan 18, 2022, July 19, 2022
Next Review: July 2023
Clinical Reviewer: John Borgoy, MD

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 one or two injections are not medically necessary.

Subsequent injections

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.

NOTE: A particular patient will often exhibit a fair amount of variability in terms of response from one injection to another. If a patient has an established pattern of responsiveness to ESI prior to an ineffective ESI, subsequent injections may still be beneficial.

1. There are different techniques for ESI.
   a. No individual technique has been proven consistently superior across patients.
   b. Individual patients may respond better to a particular technique.
2. At different points in time, the same patient may have different generator(s) of similar symptoms, that could benefit from injection(s) at different location and/ or with different technique.
3. ESI often has significant advantage over other interventions in terms of cost, access, and potential risk.

**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)

A 2019 Health Technology Assessment of epidural steroid injections for cervical radiculopathy identified 6 RCTs evaluating ESI for treatment of cervical radiculopathy and determined that the overall quality of the evidence was low due to individual study limitations and a small quantity of evidence for each comparison of ESI to alternate treatment options. This report concluded that the evidence on ESI for cervical radiculopathy failed to demonstrate beneficial effects of ESI on pain or disability associated with cervical radiculopathy compared with an epidural injection of anesthetic alone. No available studies included a placebo group, thus it is unclear whether and to what extent any observed improvements after ESI are attributable to the anesthetic, the injection itself, placebo effects, or other factors. Based on the available evidence reviewed in the report, ESI appeared safe and well-tolerated, with reported AEs generally mild and transient. ESI does have potential for serious AEs, including paralysis. The report notes a need for additional information to determine whether effectiveness of ESI varies by patient characteristics, type of ESI, and how ESI compares to well-defined controls as well as evidence for long-term outcomes in those treated with ESI. (Hayes 2019)

**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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REFERENCES


Magnetic Resonance-guided Focused Ultrasound (MRgFUS) for Essential Tremor

Policy Number: 0018  
Effective Date: February 2020  
Reviewed Date: June 2023  
Next Review: June 2024  
Specialist Reviewer: Branaven Mahadeva, MD

BACKGROUND

CLINICAL BACKGROUND (excerpted from INTC 2019)

Essential Tremor (ET) is a progressive, mainly symmetric, rhythmic, involuntary oscillation movement disorder of the forearms and hands that is usually absent at rest and present during posture and intentional movements. Compared with a rest tremor where the affected body part is completely supported against gravity (e.g., hands resting in the lap), a posture tremor occurs when the affected body part maintains position against gravity (e.g., extending arms in front of body), but is not actively moving. ET, one of the most common movement disorders and the most common action tremor, affects up to 10 million people in the United States.6 Prevalence and incidence increases with age, but data suggests bimodal peaks—second and sixth decade—in age of onset.

MRgFUS is a noninvasive therapeutic procedure involving high-intensity ultrasound energy (or sonication), guided by MRI, that targets tissue deep in the body. A FUS device was first developed in 1942, proposed in combination with MRI in 1992, and used together with MRI for a bloodbrain barrier application in 1996. The FDA’s earliest approval of any MRgFUS device was the Exablate 2000 system (INSIGHTEC Ltd.; Tirat Carmel, Israel) for treating uterine fibroids in 2004. The FDA then approved Exablate 2000 and 2001 for pain palliation of metastatic bone cancer in 2012 and Exablate Neuro (also called Exablate 4000) for ET in 2016. Exablate Neuro has been used to treat more than 2,000 patients worldwide and is currently offered at 16 U.S. sites, including Cleveland Clinic, Stanford University, and the University of California, Los Angeles.16 Outside the United States, the Exablate system for ET has been approved in Russia (2004), European Economic Area (2012), Israel (2013), Korea (2015), Canada (2016), and Taiwan (2017).

POLICY AND CRITERIA

Magnetic-resonance-guided focused ultrasound (MRgFUS) may be considered medically necessary when ALL of the following criteria are met:

1. Member has essential tremor refractory to at least two trials of medical therapy;
2. There is moderate to severe postural or intention tremor of the dominant hand or another nationally accepted clinical measure of tremor severity;
3. The tremor is disabling (defined by a score of ≥2 on any of the eight items in the disability subsection of the CRST or another nationally accepted clinical measure of tremor severity)
4. Member is not a candidate for DBS (e.g., advanced age, anticoagulant therapy, surgical comorbidities, or has failed Deep Brain Stimulation (DBS), but has no retained cranial implants)
5. Neurocognitive testing
6. Brain MRI ruling out brain tumor or prior intracranial hemorrhage

MRgFUS is considered NOT medically necessary in any of the following situations:

- Treatment of head or voice tremor
- Bilateral thalamotomy
- Among members with ANY of the following contraindications:
A neurodegenerative condition
- Unstable cardiac disease
- Coagulopathy
- Risk factors for deep-vein thrombosis
- Severe depression (i.e., a score greater than 20 on the PHQ-9)
- Cognitive impairment (i.e., a score <24 on the mini-mental state examination)
- Previous brain procedure (transcranial magnetic stimulation, DBS, stereotactic lesioning, or electroconvulsive therapy)
- A skull density ratio of cortical to cancellous bone < 0.45
- Any contraindication to MRI

SPECIAL GROUP CONSIDERATIONS
These criteria apply to Commercial group/individual members. They do not apply to Medicare members. For Medicare, see LCD L37738 – "Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor".

RATIONALE

EVIDENCE BASIS

Essential Tremor

The Kaiser Permanente Interregional New Technologies committee reviewed the evidence on MRgFUS for essential tremor in 2019. Their findings are provided below:

"The clinical evidence on MRgFUS for ET, fulfilling PICOTS criteria, consists of 10 clinical series—eight prospective (with a randomized controlled portion in Elias 2016 and retrospective comparisons in Huss 2015 and Jung 2018) and two retrospective—involving the following patients evaluable at one- or 1.5-year followup: 343 to 387 patients who underwent MRgFUS, 89 who had DBS, and 17 with RF. Table 3 outlines the studies’ patient populations, accounting for potential overlap. Details of these studies can be found in the evidence tables at the end of this report.

Reported MRgFUS protocols varied: 15 to 20 mean sonications (five studies), 10 to 16 kilojoules for mean maximum energy (four studies), and roughly 50°C to 66°C for maximum temperature (seven studies). At follow-up, CRST and QUEST scores improved from baseline, statistically significantly in all studies except D’Souza 2019 that did not report p values for baseline-to-follow-up change. All nine studies reporting CRST for the treated hand showed partial to significant improvement (using Meng 2018’s definitions of 10% to 50% for partial improvement and at least 50% for significant improvement). Using the software application Comprehensive Meta-Analysis (version 3.3.070), four meta-analyses based on random effects models were created, presented in Table 5. Pooled estimates of percentage improvement in scores from baseline to one-year follow-up were 52% for CRST total, 67% for CRST part C, 57% for CRST treated hand tremor score, and 57% for QUEST total. (For comparison, the meta-analysis Mohammed 2018,24 which included eight VIM MRgFUS studies and one non-VIM MRgFUS study, reported pooled estimates of percentage improvement based on four or eight studies each: 62% for CRST total, 69% for CRST part C, and 47% for QUEST total.)

"Three studies had results for at least 15 patients with two-year follow-up, demonstrating that one-year improvements were sustained at two-year follow-up. However, less than half of the patients remained in two studies (Meng 2018 and Sinai 2019), whereas the third study used last observation carried forward for 88% of patients (Elias 2016).

At three-month follow-up, before crossover from sham to active treatment, the RCT portion of Elias 2016 noted that MRgFUS had statistically significantly better CRST and QUEST results than sham MRgFUS. In retrospective comparisons at one year follow-up, Huss 2015 demonstrated that MRgFUS was equally effective as unilateral and bilateral DBS for the CRST treated hand tremor score, but was not as effective
in treating overall tremor as bilateral DBS (as expected, since MRgFUS only treats one side of the body), and Jung 2018 found no difference in efficacy among MRgFUS, RF, and unilateral DBS, but significantly fewer adverse events after MRgFUS. The meta-analysis Schreglmann 2018,25 which included three studies of MRgFUS for ET targeting VIM (Elias 2016, Huss 2015, and an 11-patient clinical series not discussed in this report), noted similar mean tremor reductions compared with GK or RF.

At one-year after MRgFUS, three studies (Jung 2018, Pineda-Pardo 2019, and Sinai 2019) reported no severe adverse events, but three other studies (Huss 2015, Elias 2016, and D’Souza 2019) noted a total of five patients with severe complications still remaining. Five studies (Huss 2015, Elias 2016, Meng 2018, Pineda-Pardo 2019, and Sinai 2019) identified several patients with ongoing, presumably non-severe adverse events, such as ataxia, paresthesias, taste disturbance, and weakness.

In summary, MRgFUS is an effective and safe procedure that provides tremor relief and quality of life improvement at one-year follow-up in patients with medication-refractory ET. Retrospective comparisons in two studies showed MRgFUS to be equally effective for treated hand tremor as DBS and RF, with fewer adverse events.

*Parkinson’s Disease*

Overall, there are few studies examining the effect of MRgFUS on tremor-dominant Parkinson’s disease. Studies are small (across all studies, N < 150 patients), observational in design, and with short follow-up periods. A beneficial effect of the intervention on tremor is observed in these studies, but the duration of this benefit is unclear given the short follow-up times in most studies. Given the limitations associated with the size, design, and duration of follow-up in the current body of evidence, larger studies with more robust study methods are needed to strengthen this evidence base.\(^1-3\)

### CODES

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<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>0398T</td>
<td>Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed</td>
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<table>
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<tr>
<th>ICD-10 Code and Description</th>
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<td>G25.0 Essential tremor</td>
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### REFERENCES


Extracorporeal Shockwave Therapy

Policy Number: 0020
Effective Date: February 2020
Reviewed Date: June 2023
Next Review: June 2024
Specialist Reviewer: Ryan Downey, DPM

BACKGROUND

CLINICAL BACKGROUND (excerpted from INTC 2017)

Extracorporeal shockwave therapy (ESWT) is based on the same mechanism of action as conventional shock wave treatment used to break kidney stones. Although the exact physiologic mechanism of effect for ESWT is unclear, it is thought that the shock waves work through direct and/or indirect effects that help to reduce pain transmission, break down calcium deposits and scarring, cause a temporary inflammatory response, and/or simulate healing of tissues. Therapy with ESWT usually consists of 1 to 3 sessions, during which 1000 to 3000 pulses of low- or high-energy shock waves are administered to the pain site. It is theorized that once the deposits are ablated, the associated pain subsides, and new blood vessel formation and tissue development follows.

POLICY AND CRITERIA

Extracorporeal shockwave therapy (ESWT) is considered experimental and investigational for all indications including (but not limited to) musculoskeletal conditions such as Achilles’ tendonitis, plantar fasciitis, epicondylitis, as well as soft tissue indications, such as wounds and burns. There is insufficient evidence to determine whether ESWT is medically appropriate for any indication.

NOTE: This policy does not pertain to extracorporeal shock wave lithotripsy for treatment of kidney stones.

RATIONALE

EVIDENCE BASIS

The Kaiser Permanente Interregional New Technologies Committee (INTC) reviewed the evidence for extracorporeal shockwave therapy in 2017. Their findings include the following:

“Findings from existing systematic reviews and HTAs were mixed, with some authors concluding that the evidence base is conflicting, insufficient, limited, and/or weak, and others concluding that ESWT is an effective treatment for plantar fasciitis and is based on moderate- or high-quality evidence. Reviews with more positive results tended to focus on relatively high-energy ESWT and/or avoidance of anesthesia during ESWT treatment. ESWT for treatment of plantar fasciitis appears to be reasonably safe, although few studies evaluated adverse events as outcomes.

In addition to existing systematic reviews and HTAs, evidence from randomized trials of patients with chronic plantar fasciitis that enrolled at least 100 patients were included. Based on these criteria, the body of evidence on ESWT for treatment of chronic plantar fasciitis includes 10 RCTs that evaluated ~2000 patients. In these RCTs, treatment with ESWT resulted in significantly improved overall pain, pain with daily activity, and pain with applied pressure compared to sham ESWT. However, findings were less consistent for other outcomes, including measures of function and pain with the first steps of the day. Although 10 randomized trials with more than 2000 patients were identified, the overall quality of evidence is low-to-moderate given the relatively small sample size, variations in treatment protocols, and inconsistencies in findings across outcomes.
Most of the studies used a double-blind, sham-controlled study design. Most studies used focused ESWT (as opposed to radial ESWT), although specific treatment parameters varied considerably across studies (e.g., energy flux density [EFD], number of pulses, number of ESWT sessions). Despite limiting enrollment to patients with treatment-refractory, chronic plantar fasciitis, several studies noted that sham patients had substantial improvements compared to baseline. Seven of the 10 studies had some industry affiliation, including 1 or more co-authors currently or formerly employed by a device manufacturer and/or manufacturer-supposed equipment or funding.

The overall body of evidence on ESWT for treatment of wounds, ulcers, or burns includes 10 comparative studies of 473 wounds, ulcers, or burns. In these controlled studies, treatment with ESWT plus standard wound care resulted in significantly improved wound healing compared to either standard wound care alone or hyperbaric oxygen therapy (HBOT) plus standard wound care. Despite clinically heterogeneous study populations and treatment protocols, results were consistent across studies. ESWT for ulcers, wounds, and burns appears to be reasonably safe, although few studies evaluated adverse events as outcomes.

Although many of the studies found statistically significant differences in wound healing outcomes for ESWT versus standard wound care, the overall precision is poor due to the small total sample size (473 wounds, ulcers, or burns). There was notable clinical heterogeneity across studies and the findings for any single indication and treatment protocol are even more limited. Two studies had poor results reporting in which results were not clearly presented and/or data discrepancies were observed for text, tables, and figures. Two studies had inadequate randomization (e.g., based on odd vs. even days of week). Three studies excluded randomized patients with poor compliance or incomplete follow-up data. One study was terminated early due to apparent benefit of ESWT and the published results were from an unscheduled interim analysis. Nine of the 10 studies had some industry affiliation, including 1 or more co-authors currently or formerly employed by a device manufacturer and/or manufacturer-supposed equipment or funding.

Overall, these promising but preliminary findings suggest that ESWT plus standard wound care may result in improved wound healing compared to either standard wound care alone or HBOT plus standard wound care. Although 9 randomized trials were identified, the overall quality of evidence is low given the limitations of the included studies. Additional randomized, double-blind trials are needed to confirm these findings. Clinical input gathered on this topic was consistent with this review. SCPMG is considering an IRB-approved study as some clinicians have some experience with the technology and consider ESWT as a potential alternative to surgery in some patients with chronic plantar fasciitis.

### CODES

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<td>0102T</td>
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### REFERENCES

**Northwest Region Utilization Review**

**UR 57: Facial Dermal Fillers Policy and Medical Necessity Criteria**

<table>
<thead>
<tr>
<th>Departments: Plastic Surgery</th>
<th>Number: UR 57</th>
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<tbody>
<tr>
<td>Section: KPNW Region</td>
<td>Effective: 08/10</td>
</tr>
<tr>
<td>Applies to: KPNW Region</td>
<td>Last Reviewed: 2/19, 2/20, 6/23</td>
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<tr>
<td>SME: Jennifer Murphy, MD - Plastic Surgery</td>
<td>Last Revised: 2/21, 2/22, 6/22</td>
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</table>

**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 antiretroviral therapy (ART).

**Filler:** an injectable substance that fills in hollowed areas created by lipoatrophy.

**CRITERIA**

Filler injections are covered when the following criteria are met:

1) The member has the following conditions:
   a) diagnosis of human immunodeficiency virus (HIV),

   **AND**

   b) diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4, related to HIV or antiretroviral therapy (ART).
AND

2) The filler is FDA approved for the treatment of facial lipodystrophy/lipoatrophy or otherwise approved by the KPNW Plastic Surgery Department (e.g., autologous fat transplantation).

CONTRAINDICATIONS

Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function.

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, the treating specialist will need to reevaluate the patient or repeat photos of the patient’s face will be required to determine if further treatments are warranted. Re-treatment may be needed long term.

SPECIAL GROUP CONSIDERATIONS

These criteria apply to Medicare and Commercial group/individual members. They do 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)

RATIONALE

BACKGROUND

UpToDate – “Injectable soft tissue fillers: Permanent agents”:

- **Surgical approaches:** Plastic surgery is the main therapy for severe facial lipoatrophy; autologous fat transplantation or, more commonly, injections of biodegradable or nonbiodegradable gel fillers can be performed.

- **Fillers:** Plastic surgeons, dermatologists, and others with specific training have treated facial lipoatrophy with various injectable fillers (19,20). Fillers can be temporary or permanent. Overall, temporary fillers are preferred.

- **Autologous fat transplantation:** Autologous fat transplantation involves harvesting of a small intact lump of fatty tissue from the abdomen, cervicodorsal area, or elsewhere that can be processed into small fat “parcels” that are injected by syringe with local anesthesia (47). Use of autologous fat implantation may be less costly than gel fillers but is often limited by the lack of suitable donor sites in patients with extensive lipoatrophy (48).
EVIDENCE BASIS

The Kaiser Permanente Interregional New Technologies Committee (INTC) reviewed the evidence on dermal injections for the treatment of facial lipodystrophy syndrome in 2010. A summary of their findings is provided below:

“There is sufficient evidence to determine that polylactic acid dermal filler injections are a medically appropriate treatment for select patients with HIV-associated facial lipoatrophy. The current evidence base consists of one RCT, several comparative studies and additional case series studies indicating improvements in skin thickness measurements and subjective ratings of lipoatrophy, including improved quality of life and patient satisfaction.”

The focus of the INTC assessment was on FDA approved dermal fillers (i.e., Sculptra, Radiesse and New-Fill) and did not describe evidence on autologous fat transplantation.

A 2013 systematic review of the durability, safety, and clinical outcomes from autologous fat grafting compared to hyaluronic acid and poly-L-lactic acid injectable fillers included 19 primary studies (12 on hyaluronic/PLLA filler, 7 on autologous fat), none of which made direct comparisons between treatment approaches. All included studies were relatively small in sample size (including fewer than 100 participants) and report a range of outcomes, thus, meta-analysis was not possible. Across studies, there were similar improvements in facial volume and durability of treatment between dermal fillers and fat transfer. However, patients treated with poly-L-lactic acid received more sets of injections than those treated with hyaluronic acid or fat transfer (3 or more sets of injections vs. up to 2 sets of injections, respectively). Studies of autologous fat transfer reported no serious adverse events or papule formation, whereas all reports of papule formation occurred in patients treated with poly-L-lactic acid.

A 2018 prospective study (n=147) comparing Sculptra, Radiesse, Aquamid and autologous fat for treatment of HIV-induced lipoatrophy reports an improvement in self-perceived appearance and impact of lipodystrophy on quality of life in all treatment groups except the Radiesse group.
REFERENCES


GENDER-AFFIRMING FACIAL PROCEDURES MEDICAL NECESSITY CRITERIA

Also see related criteria: UR 65 Gender-Affirming Procedures Medical Necessity Criteria and UR 78 Gender-Affirming Voice Modification Surgery Medical Necessity Criteria.

Gender-affirming facial procedures may be considered medically necessary when ALL of the following criteria are met:

1. With regard to the member:
   a. Member has persistent, well-documented gender dysphoria;
   b. Member is undergoing or has undergone other treatments to transition gender;
   c. Member has the capacity to make a fully informed decision and consent for treatment;
   d. Member is 18 years of age or older;
   e. Any significant medical or mental health concerns are reasonably well-controlled; AND

2. With regard to the requested procedure(s):
   a. For each requested procedure, documentation from the plastic surgeon that the member experiences dysphoria specifically associated with that facial element is required (e.g., documentation of dysphoria related to a stereotypically masculine nose for a requested rhinoplasty); AND
   b. The goal of each procedure is to alter or reshape the facial feature to an appearance that is within the range of normal for the member’s identified gender, as determined by a board-certified Plastic Surgeon.

To be authorized for consultation / office visits with Plastic Surgery to discuss gender-affirming facial procedures, member needs to meet criteria 1a-e; to be authorized for gender-affirming facial procedures and pre-operative visits, member needs to meet criteria 1a-e and 2a-b. No WPATH letter is required.

Procedures for facial feminization may include (but are not limited to) mandible contouring, rhinoplasty, and forehead reduction, among others.

Procedures intended solely to reduce the appearance of aging and will not result in significant improvement of the condition being treated are considered not medically necessary.

Facial Hair Removal (by laser or electrolysis) is covered when requested by KP GPC provider and the following criteria are met: (see UR 65 for criteria addressing body hair removal)
1. 16+ years old with parental consent or 18+ years old
2. Treatment with antiandrogens for 2-3 years unless contraindicated OR most recent testosterone level < 100 OR history of an orchiectomy

**Surgical Revisions:**

Surgical revisions following gender-affirming facial 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 affirming facial 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-affirming facial surgery will not be covered when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight.

**Surgical Reversals**

Surgery to reverse gender-affirming facial surgery is considered not medically necessary except in the case of a serious medical barrier to completing the surgery or the development of a serious medical condition necessitating reversal.

**SPECIAL GROUP CONSIDERATIONS**

<table>
<thead>
<tr>
<th></th>
<th>Covered per UR 75 criteria</th>
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<tbody>
<tr>
<td>Medicare</td>
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<tr>
<td>OR Medicaid</td>
<td>See OHP Prioritized List, Guideline Note 127 for treatment of Gender Dysphoria and OAR 410-172-0745: Exception Criteria for Facial Gender Confirmation Surgery</td>
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<td>OR Commercial – KPIF, SBG, LBG</td>
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<td>Religious and/or Exempt Organizations</td>
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<tr>
<td>Away from Home (AFH) members</td>
<td>Redirect to their home region for review/authorization</td>
</tr>
</tbody>
</table>

**REFERENCES**

- Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version. The World Professional Association for Transgender Health (WPATH).
Internal & Outside Referral Guidelines:

Kaiser Foundation Health Plan (KFHP) provides Gender-Affirming Procedures for the treatment of gender dysphoria when the medical criteria below are met.

Members whose employer groups do not cover Gender-Affirming Procedures but who wish to access these services out of pocket, will be evaluated according to the same medical criteria.

Also see related criteria: UR 75 Gender-Affirming Facial Procedures Medical Necessity Criteria and UR 78 Gender-Affirming Voice Modification Surgery Medical Necessity Criteria.

Covered Gender-Affirming Procedures under UR 65 are limited to:

**Assigned male at birth:** Clitoroplasty, Intersex Surgery, Labiaplasty, Orchietomy, Penectomy, Vaginoplasty, Breast Augmentation.

Tracheal Shave is covered when directed by a Gender Pathways Clinic (GPC) provider.

Hair removal of genital surgical area and/or graft harvest area by electrolysis or laser is covered when directed by GPC or the operating surgeon.

Body hair removal by electrolysis or laser is covered, subject to health plan benefits, when directed by GPC.

**Assigned female at birth:** Glansplasty, 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 coverage of genital surgery and surgery-related interventions if they meet all of the following criteria:

1. Member is at least 18 years old; and *(this criterion not applicable if for genital surgery consult only)*
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 (Coverage for the treatment of gender dysphoria resulting from a chromosomal disorder is included in the member’s medical coverage); and
   c. Member’s gender dysphoria is not solely the result of a psychiatric disorder (such as schizophrenia) where, in the opinion of the member’s provider(s), resolution of the underlying disorder would resolve the gender dysphoria; 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;
      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. Members assigned female at birth requesting metoidioplasty or phalloplasty and members assigned male at birth 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:

Members assigned female at birth are eligible for Mastectomies with Chest Reconstruction (areola tattooing, including touch-ups, are covered when the areola can’t be salvaged or when hypopigmentation, significant asymmetry, or incorrect areolar size occur (as determined by a plastic surgeon) following a nipple-sparing or grafting procedure and the tattooing is referred to 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 members assigned female at birth 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, who meet criteria 2-6 above and have parental consent or are legally emancipated.

**Breast Augmentation Clinical Review Criteria:**

Members assigned male at birth 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  
4. Age 18 years or older (Note: age requirement will not be applied to augmentation in patients assigned male at birth if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention); 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 to only the initial 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-affirming 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-affirming 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-affirming surgery will not be covered when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight.

**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.

**Body Hair Removal (electrolysis or laser)**

(See UR 75 Gender-Affirming Facial Procedures for facial hair removal criteria)

Body Hair Removal by electrolysis or laser is covered when requested by KP GPC provider and the following criteria are met:

1. 16+ years old with parental consent or 18+ years old
2. Treatment with antiandrogens for 2-3 years unless contraindicated OR testosterone level < 100 OR history of an orchiectomy

Hair removal by electrolysis or laser hair removal (or combination) when requested by KP GPC provider or the operating surgeon in preparation for genital surgery:

1. Referral for electrolysis/laser hair removal from genital area can happen at time of OHSU referral for vaginoplasty when surgical criteria are met, with the exception of OHP which requires a consult with the surgeon first.
2. Electrolysis/laser hair removal from the graft harvest area for phalloplasty requires consult with the surgeon first to determine the skin donor site.

**Definitions:**

- Breast Augmentation: surgical procedure to increase the size of the breasts
- Clitoroplasty: creation of clitoris
- Glansplasty: procedure to give the head of the neophallus the appearance of a genetic male glans
- Hysterectomy: removal of uterus
- Intersex surgery: genital reconstructive surgery including surgery performed for the purpose of transforming genitalia of one sex to that consistent with the member's gender identity (may also be referred to as sexual reassignment surgery)
- Labiaplasty: creation of labia
- Mastectomy: removal of the breasts
- Metoidioplasty: creation of micro-penis using the clitoris
- Mons resection: removal of excess skin to improve access and visibility of the penis
- Orchietomy: removal of testicles
- Penectomy: removal of penis
- Penile implant: implantation of artificial penis
- Phalloplasty: creation of penis, with or w/o urethra
- Salpingo-Oophorectomy: removal of fallopian tubes and ovaries
- Scrotoplasty: creation of scrotum
- Testicular Prosthesis: implantation of artificial testes
- Urethroplasty: creation of urethra w/in the penis
- Vaginectomy: removal of vagina
- Vaginoplasty: creation of vagina

**Special Group Considerations**

These criteria apply to OR/WA Commercial members.

Federal Employees Health Benefits (FEHB) coverage is limited to the following (coverage added 01/2022):

**Assigned male at birth:** Clitoroplasty, Labiaplasty, Orchiectomy, Penectomy, Vaginoplasty, Breast Augmentation, Tracheal Shave, Facial Hair Removal.
**Assigned female at birth:** Hysterectomy, Mastectomy with Chest Reconstruction, Metoidioplasty, Erectile Prosthesis, Phalloplasty, Oophorectomy, Scrotoplasty, Urethroplasty, Vaginectomy.

These criteria apply to Medicare.

These criteria do NOT apply to WA Medicaid/Molina. Molina members may be covered for genital hair removal but need to be redirected to Washington Health Care Authority to manage through the Fee-for-Service process.

OHP (Oregon Medicaid) see OHP Prioritized List, Guideline Note 127 for treatment of Gender Dysphoria. Facial electrolysis is not covered at this time.

Self-Funded (SF) groups must be verified to see if they have a transgender benefit (GRS in CM). If so, the above criteria for facial and genital hair removal applies.

Away from Home (AFH) members should be redirected to their home region for authorization.

**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
MEDICAL NECESSITY CRITERIA GENDER-AFFIRMING VOICE MODIFICATION SURGERY

Also see related criteria: UR 65 Gender-Affirming Procedures Medical Necessity Criteria and UR 75 Gender-Affirming Facial Procedures Medical Necessity Criteria

DEFINITIONS

F₀ or F₀ - the fundamental frequency at which vocal cords vibrate in voiced sounds.

CRITERIA

Unless patient is receiving gender-affirming medical (non-surgical) care outside of KP, the initial referral must be submitted by the Gender Pathways Clinic.

Gender affirming voice modification surgery is considered medically necessary when:

A. Masculinizing surgery (pitch lowering surgery, e.g. Type III thyroplasty) - member has completed 1.5 years of consistent masculinization hormone therapy and voice/speech therapy has been ineffective - member has ongoing voice complaints including inability to reliably maintain speaking F₀ below 150Hz.

OR

B. Feminizing surgery (pitch elevation surgery, e.g. anterior glottal web formation, cricothyroid approximation (CTA)) - voice/speech therapy has been ineffective - member has ongoing voice complaints including inability to reliably maintain speaking F₀ above 150 Hz.

AND

ALL of the following are met:

- Age 18 years or older
- Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria criteria
- Capacity to make a fully informed decision and to consent for treatment
- Single letter of referral from a qualified mental health professional in support of the requested procedure(s)
- Established with a Speech-Language Pathologist (SLP) and there is no documented evidence of non-compliance with voice therapy techniques and recommended follow-up
- There is no documentation that the member is unable or unwilling to follow-up post-operatively with their surgeon and voice therapist/SLP on a regular cadence as recommended (e.g. 1 week, 1 month, 3 months, 6 months, 1 year, 2 years, etc.)
ADDITIONAL CONSIDERATIONS

- It is recommended that patients undergoing gender-affirming voice therapy establish with a Speech-Language Pathologist (SLP) with experience working with transgender patients.
- Contraindications to gender-affirming voice modification surgery to be determined by the surgeon include:
  - **Nicotine** use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.
    - *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)
    - **NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.
  - Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher.

CPTs:
- 31599 Type III thyroplasty for pitch lowering & anterior glottal web formation for pitch elevation, unlisted procedure, larynx;
- 21899 Cricothyroid approximation (CTA) for pitch elevation, unlisted procedure, neck or thorax.

SPECIAL GROUP CONSIDERATIONS

Commercial and Medicare- criteria apply
Does not apply to Oregon Health Plan
Molina- Surgical procedures related to gender affirmation/reassignment are covered on a fee-for-service basis
  (HCA Physician-Related Services/Healthcare Professional Services Medicaid Provider Guide, Transgender Health Services; and WAC 182-531-1675)

REFERENCES

Adopted from KPWA
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 has recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer (as noted by an ICD-10 diagnosis listed in the “Codes” section of this policy); 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.
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.
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 Hortobogyi et al. 2016, Javle et al. 2016, Schweaderle 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.”

### CODES

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### ICD-10 Code and Description

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C02.4 Malignant neoplasm of lingual tonsil
C02.8 Malignant neoplasm of overlapping sites of tongue
C02.9 Malignant neoplasm of tongue, unspecified
C03.0 Malignant neoplasm of upper gum
C03.1 Malignant neoplasm of lower gum
C03.9 Malignant neoplasm of gum, unspecified
C04.0 Malignant neoplasm of anterior floor of mouth
C04.1 Malignant neoplasm of lateral floor of mouth
C04.8 Malignant neoplasm of overlapping sites of floor of mouth
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C05.0 Malignant neoplasm of hard palate
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C05.2 Malignant neoplasm of uvula
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C06.0 Malignant neoplasm of cheek mucosa
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C06.2 Malignant neoplasm of retromolar area
C06.80 Malignant neoplasm of overlapping sites of unspecified parts of mouth
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C07 Malignant neoplasm of parotid gland
C08.0 Malignant neoplasm of submandibular gland
C08.1 Malignant neoplasm of sublingual gland
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C12 Malignant neoplasm of pyriform sinus
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C22.1 Intrahepatic bile duct carcinoma
C22.2 Hepatoblastoma
C22.3 Angiosarcoma of liver
C22.4 Other sarcomas of liver
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C30.0 Malignant neoplasm of nasal cavity
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<td>Malignant neoplasm of connective and soft tissue of thorax</td>
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C49.5 Malignant neoplasm of connective and soft tissue of pelvis
C49.6 Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8 Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9 Malignant neoplasm of connective and soft tissue, unspecified
C49.A0 Gastrointestinal stromal tumor, unspecified site
C49.A1 Gastrointestinal stromal tumor of esophagus
C49.A2 Gastrointestinal stromal tumor of stomach
C49.A3 Gastrointestinal stromal tumor of small intestine
C49.A4 Gastrointestinal stromal tumor of large intestine
C49.A5 Gastrointestinal stromal tumor of rectum
C49.A9 Gastrointestinal stromal tumor of other sites
C4A.0 Merkel cell carcinoma of lip
C4A.10 Merkel cell carcinoma of unspecified eyelid, including canthus
C4A.11 Merkel cell carcinoma of right eyelid, including canthus
C4A.111 Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112 Merkel cell carcinoma of right lower eyelid, including canthus
C4A.12 Merkel cell carcinoma of left eyelid, including canthus
C4A.121 Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122 Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20 Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21 Merkel cell carcinoma of right ear and external auricular canal
C4A.22 Merkel cell carcinoma of left ear and external auricular canal
C4A.30 Merkel cell carcinoma of unspecified part of face
C4A.31 Merkel cell carcinoma of nose
C4A.39 Merkel cell carcinoma of other parts of face
C4A.4 Merkel cell carcinoma of scalp and neck
C4A.51 Merkel cell carcinoma of anal skin
C4A.52 Merkel cell carcinoma of skin of breast
C4A.59 Merkel cell carcinoma of other part of trunk
C4A.60 Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61 Merkel cell carcinoma of right upper limb, including shoulder
C4A.62 Merkel cell carcinoma of left upper limb, including shoulder
C4A.70 Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71 Merkel cell carcinoma of right lower limb, including hip
C4A.72 Merkel cell carcinoma of left lower limb, including hip
C4A.8 Merkel cell carcinoma of overlapping sites
C4A.9 Merkel cell carcinoma, unspecified
C50.011 Malignant neoplasm of nipple and areola, right female breast
C50.012 Malignant neoplasm of nipple and areola, left female breast
C50.019 Malignant neoplasm of nipple and areola, unspecified female breast
C50.021 Malignant neoplasm of nipple and areola, right male breast
C50.022 Malignant neoplasm of nipple and areola, left male breast
C50.029 Malignant neoplasm of nipple and areola, unspecified male breast
C50.111 Malignant neoplasm of central portion of right female breast
C50.112 Malignant neoplasm of central portion of left female breast
C50.119 Malignant neoplasm of central portion of unspecified female breast
C50.121 Malignant neoplasm of central portion of right male breast
C50.122 Malignant neoplasm of central portion of left male breast
C50.129 Malignant neoplasm of central portion of unspecified male breast
C50.211 Malignant neoplasm of upper-inner quadrant of right female breast
C50.212 Malignant neoplasm of upper-inner quadrant of left female breast
C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221 Malignant neoplasm of upper-inner quadrant of right male 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
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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
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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
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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
C57.00 Malignant neoplasm of unspecified fallopian tube
C57.01 Malignant neoplasm of right fallopian tube
C57.02 Malignant neoplasm of left fallopian tube
C57.10 Malignant neoplasm of unspecified broad ligament
C57.11 Malignant neoplasm of right broad ligament
C57.12 Malignant neoplasm of left broad ligament
C57.20 Malignant neoplasm of unspecified round ligament
C57.21 Malignant neoplasm of right round ligament
C57.22 Malignant neoplasm of left round ligament
C57.3 Malignant neoplasm of parametrium
C57.4 Malignant neoplasm of uterine adnexa, unspecified
C57.7 Malignant neoplasm of other specified female genital organs
C57.8 Malignant neoplasm of overlapping sites of female genital organs
C57.9 Malignant neoplasm of female genital organ, unspecified
C58 Malignant neoplasm of placenta
C60.0 Malignant neoplasm of prepuce
C60.1 Malignant neoplasm of glans penis
C60.2 Malignant neoplasm of body of penis
C60.8 Malignant neoplasm of overlapping sites of penis
C60.9 Malignant neoplasm of penis, unspecified
C61 Malignant neoplasm of prostate
C62.00 Malignant neoplasm of unspecified undescended testis
C62.01 Malignant neoplasm of undescended right testis
C62.02 Malignant neoplasm of undescended left testis
C62.10 Malignant neoplasm of unspecified descended testis
C62.11 Malignant neoplasm of descended right testis
C62.12 Malignant neoplasm of descended left testis
C62.90 Malignant neoplasm of unspecified testis, unspecified whether descended or undescended
C62.91 Malignant neoplasm of right testis, unspecified whether descended or undescended
C62.92 Malignant neoplasm of left testis, unspecified whether descended or undescended
C63.00 Malignant neoplasm of unspecified epididymis
C63.01 Malignant neoplasm of right epididymis
C63.02 Malignant neoplasm of left epididymis
C63.10 Malignant neoplasm of unspecified spermatic cord
C63.11 Malignant neoplasm of right spermatic cord
C63.12 Malignant neoplasm of left spermatic cord
C63.2 Malignant neoplasm of scrotum
C63.7 Malignant neoplasm of other specified male genital organs
C63.8 Malignant neoplasm of overlapping sites of male genital organs
C63.9 Malignant neoplasm of male genital organ, unspecified
C64.1 Malignant neoplasm of right kidney, except renal pelvis
C64.2 Malignant neoplasm of left kidney, except renal pelvis
C64.9 Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1 Malignant neoplasm of right renal pelvis
C65.2 Malignant neoplasm of left renal pelvis
C65.9 Malignant neoplasm of unspecified renal pelvis
C66.1 Malignant neoplasm of right ureter
C66.2 Malignant neoplasm of left ureter
C66.9 Malignant neoplasm of unspecified ureter
C67.0 Malignant neoplasm of trigone of bladder
C67.1 Malignant neoplasm of dome of bladder
C67.2 Malignant neoplasm of lateral wall of bladder
C67.3 Malignant neoplasm of anterior wall of bladder
C67.4 Malignant neoplasm of posterior wall of bladder
C67.5 Malignant neoplasm of bladder neck
C67.6 Malignant neoplasm of ureteric orifice
C67.7 Malignant neoplasm of urachus
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<td>Other malignant neuroendocrine tumors</td>
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C80.0 Disseminated malignant neoplasm, unspecified
C80.1 Malignant (primary) neoplasm, unspecified
C80.2 Malignant neoplasm associated with transplanted organ

REFERENCES

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

See the Evidence of Coverage (EOC) as definitions of Cosmetic Services may vary within the Exclusions section of the EOC documents.

POLICY AND CRITERIA

To be considered for consultation and/or surgical intervention for treatment of gynecomastia, all of the following must be met:

1. Presence of moderate or marked true gynecomastia*, diagnosed by clinical examination:
   a. In adolescent patients (15-18 y/o), moderate palpable glandular breast tissue exceeding areolar boundaries, with or without skin redundancy, present for >12 months. ¹
   b. In adult patients (>18 y/o), moderate palpable glandular breast tissue exceeding areolar boundaries, with or without skin redundancy, present for >6 months. ¹

   * In true gynecomastia, breast enlargement is due to proliferation of glandular breast tissue; on physical examination, there is a discrete palpable glandular mass. In pseudogynecomastia (i.e., lipomastia), breast enlargement is secondary to fat accumulation; on physical examination, there is no palpable glandular mass and the fingers will not meet any resistance. ¹

2. Endocrine assessment completed by primary care, with consultation by endocrinology or pediatric endocrinology if appropriate.

3. Physical exam completed including breast and testicular exam within the last 12 months.
4. Documentation indicating no offending medications, including anabolic steroids and/or illicit substances such as marijuana are contributing to the gynecomastia within the last 12 months.  

14, 19

5. 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.  

3, 19

6. 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.  

3, 16

7. Minimum age 15 or completed or nearly completed puberty.  

3, 14

8. BMI less than or equal to 34.  

7, 17, 20

9. Members with a history of tobacco products* use must have:

   a. a documented “quit” date ≥6 months prior to referral for consultation, or
   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher.

3. Obesity (BMI >34).

4. Any other surgical contraindications will be determined by the surgeon.

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

Policy applies to all Commercial members
Policy does not apply to Medicare (see Medicare Plastic Surgery LCD 37020)
Policy does not apply to Washington Medicaid
Oregon Medicaid: subject to eligibility on OHP Linefinder

RATIONALE

GENERAL CLINICAL INFORMATION AND EVIDENCE BASIS

1. Gynecomastia (enlargement of the male breast) is usually benign.  

3

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

3

3. Gynecomastia frequently occurs in a bimodal pattern during puberty (pubertal gynecomastia) and in men 50-80 years old (senescent gynecomastia).  

3
4. Pseudogynecomastia (adipose tissue without glandular proliferation) is common in obese men and needs to be differentiated from true gynecomastia. In true gynecomastia there may be a button of firm subareolar glandular tissue, or there may be a more diffuse collection of fibroglandular tissue.  

5. Absolute estrogen excess which contributes to gynecomastia: Leydig cell tumors, estrogen-producing adrenal tumors, tumors producing chorionic gonadotropin.  

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  

7. Drugs which contribute to gynecomastia include, but are not limited to: histamine H2-receptor blockers, phenytoin, digoxin, spironolactone, nifedipine, reserpine and other cardiovascular drugs, diethylstilbestrol, testosterone antagonists, flutamide, leuprolide, finasteride, diazepam, tricyclic antidepressants, phenothiazine, risperidone, haloperidol, alcohol, amphetamines, marijuana, heroin, methadone, anti-tuberculosis drugs, cytotoxic agents. 

8. Herbal products that can cause gynecomastia include lavender oil or tea tree oil.  

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

10. Glandular tissue of more than 4 cm in diameter is unlikely to regress spontaneously.  

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. 

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. 

REFERENCES


3. 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  


6. Columbo-Benkmann, Mario MD, PhD.; Buse, Benedikt, MD; Stern, Josef MD, Herfarth, Christian MD. “Indications for and Results of Surgical Therapy for Male Gynecomastia”  

12. Lawrence, Sarah E MD; Faught, Arnold, MD, Vethamuthu Md; Lawson, MD “Beneficial Effects of Raloxifene and Tamoxifen in the Treatment of Pubertal Gynecomastia”
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24. 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 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.

**NOTE:** In addition to the list of excluded services provided within a member’s evidence of coverage (EOC), the following will be applied to all lines of business, except for Medicaid under some circumstances:

• **Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Social Security Act** specifically exclude venipuncture (blood draws) as a basis for qualifying for home health services if this is the sole skilled service the beneficiary requires. However, the home health benefit will continue to pay for a blood draw if the beneficiary has a need for another qualified skilled service and meets all home health eligibility criteria.

**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**


HOME-BASED PALLIATIVE CARE MEDICAL NECESSITY CRITERIA

DEFINITIONS

Home-based palliative care approach in the home aimed at optimizing quality of life, diminishing symptoms and mitigating suffering among people with a serious, complex illness. Services include palliative physician, nursing and social work services in the home. Home-based palliative care is supplemental medical care in addition to the patient’s primary and specialty care teams.

CRITERIA

To qualify for Home-Based Palliative Care, patients must meet all of the following criteria:

1) Have a serious, progressive, terminal illness with a life expectancy of greater than 6 months and up to 2 years;

2) Need specialty level assistance with symptom management;

3) Be functionally homebound.

4) Patients with dementia or serious pain without a separate serious, progressive, terminal illness that causes symptoms, are not eligible.

SPECIAL GROUP CONSIDERATIONS

Commercial: None
Washington Medicaid: None
Oregon Medicaid: None
Medicare: HBPC services are not specifically covered by Medicare and are not addressed in an LCD/NCD but are covered by KPNW in the home to diminish symptoms of terminally ill members with a limited life expectancy. Although the current Senior Advantage EOC limits HBPC eligibility to members with a life expectancy of 7–12 months, the less restrictive criteria above will be applied to all requests.
INTRAOPERATIVE NEUROMONITORING

Policy Number: 0013  
Effective Date: March 2019  
Reviewed Date: June 2023  
Next Review: June 2024  
Clinician Reviewer: Kristophe Karami, DO, Neurosurgery

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.
INDICATIONS

Intraoperative neuromonitoring may be indicated for a variety of spinal, intracranial, and vascular procedures. The specific type of monitoring indicated for each procedure varies, as outlined in the below criteria and summarized in the following tables. Pre-procedural baseline testing may be separately reported, but only once per operative session.

Somatosensory-evoked potentials with or without motor-evoked potentials

Intraoperative neuromonitoring using somatosensory-evoked potentials (SSEP), with or without motor-evoked potentials (using electrical stimulation), may be medically necessary during the following procedures:

- **Spinal procedures**
  - Dorsal rhizotomy
  - Correction of scoliosis
  - Correction of deformity involving traction on the spinal cord
  - Spinal cord tumor removal
  - Surgery due to traumatic injury to spinal cord
  - Surgery for arteriovenous (AV) malformation of spinal cord

- **Intracranial procedures**
  - Microvascular decompression of cranial nerves
  - Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
  - Cholesteatoma, including mastoidotomy or mastoidectomy
  - Vestibular neurectomy for Meniere’s
  - Removal of cranial nerve neuromas affecting any of the following nerves:
    - Abducens
    - Facial
    - Glossopharyngeal
    - Hypoglossal
    - Oculomotor
    - Recurrent laryngeal
    - Spinal accessory
    - Superior laryngeal
    - Trochlear
  - Deep brain stimulation
  - Endolymphatic shunting for Meniere’s disease
  - Oval or round window graft
  - Removal of cavernous sinus tumors
  - Resection of brain tissue near primary motor cortex and requiring brain mapping
  - Resection of epileptogenic brain tissue or tumor
  - Other intracranial procedures (e.g., aneurysm repair, intracranial AVM)

- **Non-cranial vascular procedures**
  - Carotid artery surgery
  - Arteriography with test occlusion of carotid artery
  - Deep hypothermic circulatory arrest
  - Distal aortic procedures
  - Surgery of the aortic arch, its branch vessels, or thoracic aorta
Electroencephalographic monitoring

Intraoperative electroencephalographic (EEG) monitoring may be considered medically necessary for any of the following procedures:

- Intracranial procedures
  - Microvascular decompression of cranial nerves
  - Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
  - Cholesteatoma, including mastoidotomy or mastoidectomy
  - Vestibular neurectomy for Meniere’s
  - Removal of cranial nerve neuromas affecting any of the following nerves:
    - Abducens
    - Facial
    - Glossopharyngeal
    - Hypoglossal
    - Oculomotor
    - Recurrent laryngeal
    - Spinal accessory
    - Superior laryngeal
    - Trochlear
  - Deep brain stimulation
  - Endolymphatic shunting for Meniere’s disease
  - Oval or round window graft
  - Removal of cavernous sinus tumors
  - Resection of brain tissue near primary motor cortex and requiring brain mapping
  - Resection of epileptogenic brain tissue or tumor
  - Other intracranial procedures (e.g., aneurysm repair, intracranial AVM)
- Non-cranial vascular procedures
  - Carotid artery surgery
  - Arteriography with test occlusion of carotid artery

Electromyographic monitoring

Intraoperative electromyographic (EMG) monitoring may be considered medically necessary when monitoring is during any of the following procedures:

- Dorsal rhizotomy
- Microvascular decompression of cranial nerves
- Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
- Cholesteatoma, including mastoidotomy or mastoidectomy
- Vestibular neurectomy for Meniere’s
- Removal of cranial nerve neuromas affecting any of the following nerves:
  - Abducens
  - Facial
  - Glossopharyngeal
  - Hypoglossal
  - Oculomotor
- Recurrent laryngeal
- Spinal accessory
- Superior laryngeal
- Trochlear

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<tr>
<th>SPINAL PROCEDURES</th>
<th>SSEP (with or without MEP) 95925, 95926, 95927, 95938</th>
<th>EEG 95822, 95955</th>
<th>EMG 95860, 95861, 95867, 95868, 95870</th>
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<td>Dorsal rhizotomy</td>
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<td>Surgery for AV malformation of spinal cord</td>
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<th>NON-CRANIAL VASCULAR PROCEDURES</th>
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<th>EEG 95822, 95955</th>
<th>EMG 95860, 95861, 95867, 95868, 95870</th>
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<td>Carotid artery surgery</td>
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<td>Arteriography w/ test occlusion of carotid artery</td>
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<td>INTRACRANIAL PROCEDURES*</td>
<td>SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939</td>
<td>EEG 95822 95955</td>
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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 concluded that IONM is sensitive and specific for detecting neurological complications during spinal surgery.¹ 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.¹

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 evaluated 17 studies
comparing thyroid surgery with and without IONM.\textsuperscript{2} 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.\textsuperscript{2} Another systematic review reported a slightly lower incidence of RLNP among those who had thyroid surgery with IONM, but this difference was not statistically significant.\textsuperscript{3}

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) released an updated position statement on IONM in January 2018. The AANS/CNS concluded that IONM is a reliable diagnostic tool for assessment of spinal cord integrity during surgery, but that there is insufficient evidence of a therapeutic benefit of IONM during spinal surgery.\textsuperscript{4} In 2014, an analysis of all spine surgeries performed from 2007-2011 that were included in the Nationwide Inpatient Sample database that included 443,194 spine procedures in which 31,680 cases utilized IONM.\textsuperscript{5} Iatrogenic neurological injury was rare, occurring in less than 1\% with no difference in cases where IONM was used.\textsuperscript{5} A 2015 analysis of a University of Texas Health Science’s Center department’s spine surgeries completed before and after adoption of a departmental policy limiting IONM use to intradural procedures and those for spinal deformity correction found that while utilization of IONM dropped from 38\% of spinal cases to 7\%, there was no change in incidence of neurological injury.\textsuperscript{6} In fact, the only observed cases of injury occurred in cases utilizing IONM where the monitoring did not alert the surgeon to the injury.\textsuperscript{6}

In 2017, “Guidelines for the Use of Electrophysiological Monitoring for Surgery of the Human Spinal Column and Spinal Cord” was approved by both the American Association for Neurological Surgeons and the Congress of Neurological Surgeons.\textsuperscript{7} This Guideline was based on review of relevant published literature from 1966-2017. This 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 spinal surgery has not been correlated with improvements in neurological outcome that its expense does not appear justified.\textsuperscript{7}

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.\textsuperscript{8}

A 2019 Cochrane systematic review performed a comprehensive review and meta-analysis on the use of IONM for adults undergoing thyroid surgery.\textsuperscript{9} In that review, authors found no definitive evidence that IONM was superior to visual identification of the recurrent inferior
laryngeal nerve during thyroid surgery. Measured outcomes included permanent RILN palsy (Relative Risk 0.77, 95% CI 0.33-1.77, p=NS), transient RILN palsy (RR 0.62, 95% CI 0.35-1.08, p=NS), and transient hypoparathyroidism (RR 1.25, 95% CI 0.45-3.47, p=NS). There were no significant differences in operative time.9

A 2021 Hayes Health Technology Assessment on IONM to detect and prevent surgical manipulations that could cause nerve damage during lumbar spinal discectomy alone or discectomy plus fusion identified 5 studies that evaluated IONM for detection of new neurological deficits and 11 studies that evaluated IONM for intraoperative guidance to prevent new neurological studies.10 Hayes concludes that the overall body of evidence is very low in quality and not sufficient to make conclusions about the efficacy and safety of IONM for detection and prevention of new neurological deficits in patients undergoing lumbar discectomy or fusion.10

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>General neuromonitoring</td>
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<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>
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<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>
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<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>
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<tr>
<td>Somatosensory-evoked potentials (SSEP)</td>
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<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>
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<tr>
<td>Motor evoked potentials (MEP)</td>
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<td>Central motor evoked potential study (transcranial motor stimulation); upper limbs</td>
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<td>95929</td>
<td>Central motor evoked potential study (transcranial motor stimulation); lower limbs</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<td>95939</td>
<td>Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs</td>
</tr>
<tr>
<td>92585</td>
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</tr>
<tr>
<td>92586</td>
<td>Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited</td>
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<tr>
<td>95822</td>
<td>Electroencephalogram (EEG); recording in coma or sleep only</td>
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<td>95955</td>
<td>Electroencephalogram (EEG) during non-intracranial surgery (e.g., carotid surgery)</td>
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<td>95860</td>
<td>Needle electromyography; 1 extremity with or without related paraspinal areas</td>
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<tr>
<td>95861</td>
<td>Needle electromyography; 2 extremities with or without related paraspinal areas</td>
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<tr>
<td>95867</td>
<td>Needle electromyography; cranial nerve supplied muscle(s), unilateral</td>
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<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>
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<tr>
<td>95907-95913</td>
<td>Nerve conduction studies</td>
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<tr>
<td>95930</td>
<td>Visual evoked potential (VEP) testing central nervous system, checkerboard or flash</td>
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<tr>
<td>95937</td>
<td>Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method</td>
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**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.

**References**

Northwest Utilization Review

UR 47 Massage (Soft Tissue/Myofascial Manipulation) Medical Necessity Criteria

Department: Utilization Review
Applies to: Kaiser Permanente NW Region
Review Responsibility: UROC
Subject Matter Expert: Lauren Kaplan, DO

Number: UR 47
Effective: 4/99
Last Reviewed: 2/18, 2/19, 3/20, 2/21
Last Revised: 3/17, 3/22, 2/23

MEDICAL NECESSITY CRITERIA FOR MASSAGE (SOFT TISSUE/MYOFASCIAL MANIPULATION) 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 these criteria and policy is to describe the policy and process requirements for massage (soft tissue/myofascial manipulation) and the medical necessity criteria for its coverage as a benefit.

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.

POLICY AND CRITERIA

POLICY
When a member’s contract covers massage as a benefit, soft tissue/myofascial manipulation 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/myofascial manipulation will be included only if determined to be clinically indicated. When included in the plan, soft tissue/myofascial manipulation will be of short duration, and specific to the region being treated.

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/myofascial manipulation 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 the soft tissue/myofascial manipulation.

RATIONALE

EVIDENCE BASIS

A 2020 Agency for Healthcare Research and Quality (AHRQ) systematic review of noninvasive nonpharmacological treatment for chronic pain reports that massage improved function and/or pain for at least 1 month when used for chronic low back pain, neck pain, and fibromyalgia. This review notes that effects across included studies were mostly small and that there was a paucity of long term evidence. Additionally, no evidence suggested serious harms from massage, but data on harms was limited in the included studies. A 2016 Evidence Map of massage for pain produced by the VA Evidence-based Synthesis Program reports that findings from high-quality systematic reviews report a potential benefit for massage for pain indications (including shoulder, neck, and back pain), but that findings were rated as low to very-low strength, limited certainty in the true effect of massage for these pain indications.

Low Back Pain
A 2015 Cochrane systematic review of the effects of massage therapy for people with low-back pain (primarily chronic or sub-acute low back pain) (k=25) reports improvements in pain outcomes and functional outcomes in the short term among those who received massage therapy compared to inactive control. However, the quality of the underlying evidence in this review was judged to be “low” or “very low”, limiting confidence in the true effect of massage therapy for low-back pain.

Neck Pain
A 2012 Cochrane systematic review of the effects of massage on neck pain (k=15) reports that massage may have a more beneficial effect on function and tenderness compared to control. The reviewers rated the underlying evidence as low or very low quality and the majority of included studies did not adequately describe the massage technique and reported outcomes immediately post-treatment, which is too soon to determine clinical change. Additionally, most studies did not report harms from massage and those that reported post-treatment pain, discomfort, and soreness as possible side effects of massage therapy.

REFERENCES


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.
  --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 apply

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.

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. Most procedures (e.g. advanced imaging and some DME) and levels of care other than office visits require prior-authorization (please refer to members’ benefits but examples of exceptions to the above include outpatient labs, xrays, and preventive services).

Washington Medicaid: Criteria apply

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.
Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures

Policy Number: 0008
Effective Date: August 1, 2015
Reviewed Date: June 2023
Next Review: June 2024
Clinician Reviewer: Jarrod Larson, MD; Krishna Kasturi, MD

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 esophagogastroduodenoscopy (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.

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 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 or 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. Age 30 years or younger; OR
E. Pregnancy; OR
F. History of or active drug or alcohol abuse; OR
G. Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); OR
H. Anxiety, defined as a history of excessive nervousness or worry that is difficult to control, causes significant distress and impairment or ICD-10 diagnosis of nervousness or anxiety/anxiety disorder; OR
I. Post-traumatic stress disorder (PTSD); OR
J. History of sexual abuse; OR
K. Hearing impairment; OR
L. Spasticity or movement disorder complicating procedure; OR
M. 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.

### GENERAL CLINICAL INFORMATION

1. Prolonged or therapeutic endoscopic procedures requiring deep sedation include:
   a. Endoscopic ultrasound (EUS)
   b. Double balloon enteroscopy (push endoscopy)
   c. Transanal endoscopic microsurgery (TEM)
   d. Endoscopic retrograde cholangio-pancreatography (ECRP)
2. History of or anticipated intolerance to standard sedatives includes:
a. Patient has allergy to opiates or benzodiazepines
b. Patient on chronic narcotics and/or benzodiazepines (e.g., using these medications consistently most days in a week, long term)
c. Patient has an unstable neuropsychiatric disorder which would prevent cooperation

3. ASA class III physical status definition: A patient with severe systemic disease. Adult examples include, but are not limited to:
   a. Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.

4. History of/or active drug abuse:
   a. Heavy Marijuana use: Daily use
   b. Alcohol abuse:
      i. National Institute on Alcohol Abuse and Alcoholism (NIAAA) definition for heavy alcohol use: For men, consuming more than 4 drinks on any day or more than 14 drinks per week. For women, consuming more than 3 drinks on any day or more than 7 drinks per week.

**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 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-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.”

A 2020 Kaiser Permanente evidence scan for more recent evidence on monitored anesthesia care for gastrointestinal disorders includes the following findings:

A 2018 systematic review (k=5 studies) of trials and observational studies compares patient safety and procedure quality outcomes following non-anesthesiologist-administered propofol vs. anesthesiologist-administered propofol in routine upper or lower gastrointestinal endoscopy and reports no significant differences in rates of airway intervention, hypotension, gastrointestinal bleeding between groups. Rates of bradycardia and cardiopulmonary events were substantially higher in patients who received non-anesthesiologist administered propofol, however. Studies included in this review primarily included patients meeting ASA class I or II criteria, and where patients meeting ASA class III-IV were included, proportions were not balanced between groups. (Daza et al., 2018)

A 2017 systematic review (k=27 studies; n=2,518 patients) evaluating sedation-related adverse events associated with the use of propofol vs. nonpropofol (i.e., midazolam, meperidine, pethidine, remifentanil, and/or fentanyl) for endoscopic procedures reports no significant differences in pooled odds ratios for rates of hypoxia, hypotension, or arrhythmia by sedation type. An analysis of studies of nonadvanced endoscopy procedures indicates that patients who received propofol were 39% less likely to develop any complications compared to those receiving non-propofol sedation (OR: 0.61; 95% CI: 0.38-0.99). No difference in the complication rate for advanced endoscopy procedures was found between sedation groups. A subgroup analysis comparing complication rates by sedation administration (non-gastroenterologist vs. gastroenterologist) showed no differences in rates of cardiopulmonary complications. (Wadhwa et. al, 2017) A 2019 meta-analysis comparing sedation with propofol to traditional sedatives with or without propofol during endoscopic procedures (k=23 trials; n=3,854) reports no statistical difference in rates of hypotension, oxygen desaturation, and post-procedure anesthetic recovery when propofol is used alone or in combination with benzodiazepines and/or opioids. This review reports greater patient satisfaction among patients who were sedated with benzodiazepines and/or opioids compared to those sedated with propofol alone. This review did not include studies with participants groups with specific comorbidities, including obesity, cardiovascular disease, and pulmonary diseases. (Delgado et al., 2019)

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<td>Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum</td>
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<td>Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum</td>
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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.


Surgical Revascularization for Moyamoya Disease

Policy Number: 0016  
Effective Date: February 4, 2020  
Reviewed Date: June 2023  
Next Review: June 2024  
Clinician Reviewer: Kristophe Karami, DO, Neurosurgery

BACKGROUND

CLINICAL BACKGROUND (excerpted from Acker 2018)

“Moyamoya disease (MMD) is a rare cerebrovascular disease which is characterized by bilateral progressive steno-occlusion of basal cerebral arteries with emergence of coexisting abnormal net-like vessels. MMD is most frequent in Asian countries with an incidence ≤0.94/100 000, but an increase in incidence has been reported in non-Asian countries with some ethnic differences in disease characteristics. MMD shows worldwide a bimodal age distribution with a peak each in childhood and adulthood; thus, it is one of the leading causes of stroke in children and young adults. The most frequent initial symptom of MMD adults in Asians and whites is intracranial hemorrhage because of fragile blood vessels and ischemic events, respectively. Children with MMD worldwide frequently experience ischemic events.”

POLICY AND CRITERIA

Members may be eligible for revascularization surgery to treat Moyamoya disease when the following criteria are met:

1. Member has definitive Moyamoya disease as defined by ALL of the following angiographic findings:
   a. Stenosis or occlusion of at least one of the following
      i. the terminal portion of the intracranial internal carotid artery;
      ii. the proximal portions of the anterior cerebral artery;
      iii. the middle cerebral artery;
   b. Development of abnormal vascular networks near the occlusive or stenotic lesions in the arterial phase;
   c. Bilateral cerebral lesioning; AND
2. Fulfillment of at least ONE of the following criteria:
   a. Symptoms of cerebral ischemia (e.g., ischemic stroke, transient ischemic attack, cognitive decline); OR
   b. Asymptomatic children (under 18 years of age) with:
      i. Decreased regional cerebral blood flow of less than 14%; OR
      ii. Inadequate perfusion reserve as evidenced by regional transit time greater than 8.0 seconds.

Revascularization may be direct, indirect, or a combination of both, depending upon the member’s unique characteristics. Examples of indirect bypass procedures include (but are not limited to): encephaloduroarteriosynangiosis (EDAS), encephalomyosynangiosis (EDAMS), encephaloarteriosynangiosis (EAS), encephalodurogaleosynangiosis (EDGS).
RATIONALE

EVIDENCE BASIS
A comprehensive systematic review and meta-analysis (Ravindran 2019) evaluated methods of surgical revascularization among pediatric patients with Moyamoya disease. Their findings included the following:

“Of the indirect studies, a total of 488 patients were treated via encephaloduroarteriosynangiosis (EDAS), 82 via encephaloduroarteriomyosynangiosis (EDAMS), 410 via EDAS + encephalogaleosynangiosis (EGS), 216 via pial synangiosis, and 107 by dural inversion and EDAS. In the combined and direct cohort, all patients were treated with either superficial temporal artery-middle cerebral artery (STA-MCA) bypass, STA-MCA + encephalomyosynangiosis (EMS), or STA-MCA + EDAMS.

Future Stroke Incidence
The frequencies of future stroke events in patients undergoing either direct bypass alone, combined bypass, or indirect bypass alone were 1 per 190.3 patient-years, 1 per 108.9 patient-years, and 1 per 61.1 patient-years, respectively. The estimated stroke rates were 9.0% with indirect revascularization, 4.5% with direct revascularization alone, and 6.0% with combined revascularization. Stroke events most commonly occurred within the acute postoperative period, up to 7 days from surgery.

When pooling comparative studies, the overall RR of future stroke events after indirect versus combined/direct revascularization did not achieve statistical significance (RR 0.99, 95% CI 0.30–3.24, p = 0.112). On assessing the two comparative studies that included a direct bypass only, the overall RR for future stroke events after indirect versus direct bypass alone similarly did not achieve statistical significance (RR 1.84, 95% CI 0.36–9.40, p = 0.50). After pooling single-arm studies, the overall effect sizes (ESs) of the proportion of patients experiencing future stroke events were the same between combined/direct revascularization and indirect revascularization cohorts (0.04, 95% CI 0.00–0.12, and 0.04, 95% CI 0.02–0.06) and comparable with the direct bypass only cohort (0.07, 95% CI 0.03–0.16). In patients with moyamoya syndrome, the pooled postoperative stroke event rate was 6 of 102 patients (5.9%), as compared to 158 of 1864 (8.5%) in patients with idiopathic moyamoya disease.

Angiographic Outcome
The overall ESs of “excellent” angiographic outcome as designated by Matsushima grade A were 0.58 (95% CI 0.48–0.67) for indirect revascularization and 0.70 (95% CI 0.64–0.75) for combined/direct revascularization.

Complications
A total of 220 complications occurred in 1424 patients treated with indirect revascularization and 48 of 533 patients undergoing combined/direct revascularization. The most common complications in both cohorts were transient ischemic attack (TIA) and infarction within the 30-day postoperative period. Among those undergoing indirect revascularization, the 30-day ischemic infarct rate was 6.9%, relative to 2.1% in the combined/direct group. Hemorrhagic complications were similar between both groups, occurring in 1.9% of patients undergoing indirect revascularization and 0.6% of patients undergoing direct revascularization.

CODES

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>61711</td>
<td>Anastomosis, arterial, extracranial-intracranial (e.g., middle cerebral/cortical) arteries</td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
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ICD-10 Code and Description
167.5 Moyamoya disease
REFERENCES


### 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. Symptomatic menopause (limited to hot flushes/night sweats), perimenopause, or premenstrual syndrome
   
   B. Chronic Irritable Bowel Syndrome
   
   C. Headache (episodic or chronic, with symptom onset >3 months ago)
   
   D. Chronic Eczema/Atopic Dermatitis
   
   E. Osteoarthritis
      
      - Only if patient has been evaluated and failed therapy (in clinic, virtual, or telephonic) through KPNW internal Complementary and Integrative Medicine Clinic, and referral is placed by the clinic provider
   
   F. Chronic (lasting >3 months) pain syndromes (other than secondary to osteoarthritis or headache)
      
      - Only if patient has been evaluated and failed therapy (in clinic, virtual, or telephonic) through KPNW internal Complementary and Integrative Medicine Clinic, and referral is placed by the clinic provider
   
   G. Chronic Fatigue Syndrome
      
      - Only if patient has been evaluated and failed therapy (in clinic, virtual, or telephonic) through KPNW internal Complementary and Integrative Medicine Clinic, and referral is placed by the clinic provider

2. 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, perimenopause, or premenstrual syndrome (PMS):**
   
   i. For hot flushes/night sweats associated with menopause:
      
      [Hormone Replacement Therapy (HRT) requirement can be waived if there is documentation of a shared decision making between the appropriate clinician and the patient regarding HRT]
• 1 oral HRT (at least a 2-month trial with at least 1 dose adjustment), AND one or more of the following:
  • 1 selective serotonin reuptake inhibitor (SSRI) or serotonin/norepinephrine reuptake inhibitor (SNRI) (at least a 1-month trial), or
  • oral Clonidine

ii. For PMS symptoms:
  • 3-month trial of SSRI, or
  • 3-month trial of continuous oral contraceptive pill (OCP)

iii. For perimenopause bleeding:
  • 6-month trial of progestin containing intrauterine device (IUD) or OCP

iv. For perimenopause mood disorder or hot flushes:
  • 2-month trial of low dose OCP, or
  • 1 SSRI or SNRI (at least a 1-month trial)

B. For Irritable Bowel Syndrome (IBS):
   i. IBS-Diarrhea:
      • Trials of at least 2 of the following:
        - dairy holiday or lactose-restricted diet
        - loperamide (if bowel movement cluster in the morning, consider a trial of evening dosing)
        - probiotic
        - cholestyramine
   ii. IBS-Constipation predominant:
      • minimize constipating meds (anti-cholinergics, narcotics), AND
      • Trials of at least 2 of the following:
        - 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 at least 2 of the following:
        - dairy holiday
        - dicyclomine 10mg 4x/day (can increase to 20mg 4x/day if tolerated)
        - FODMAP diet (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols)
        - nortriptyline every evening

C. For Headache (episodic or chronic, with symptom onset >3 months ago):
   • Adequate trial of prophylactic treatment:
     - at least 1 antiepileptic medication, or
     - at least 1 medication from another class (tricyclic antidepressant or beta-blocker), or
     - 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 recommended by a dermatologist
E. For Osteoarthritis:
   - at least a 1-month trial of regular (not as needed) use of at least 1 non-steroidal anti-inflammatory drug (unless patient refusal or contraindicated) (prescription or over-the-counter), AND
   - at least 1 corticosteroid injections per affected joint in the last 24 months (for knee osteoarthritis) (unless patient refusal or contraindicated)

F. Chronic pain syndromes (other than secondary to osteoarthritis or headache): exempt from a trial and failure of standard medical therapies (allopathic care) requirement

G. Chronic Fatigue Syndrome (CFS): exempt from a trial and failure of standard medical therapies (allopathic care) requirement

3. 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.

4. After the initial authorization, 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.

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.

2. 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.

3. 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.

4. Procedures, evaluations, and diagnostic testing, including laboratory tests, that are determined by a network provider (MD, DO, NP or PA) to be medically necessary are to be ordered by a network provider.
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


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 a Sleep Medicine specialist. 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 that is not amenable to orthodontic therapy alone with a referral from a cranio-facial specialist (e.g. ENT, Cranio-facial Surgeon, Oromaxillo-facial Surgeon).
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
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.

DEFINITIONS

Panniculectomy: The excision of an apron of abdominal tissue overhanging the inguinal crease (panniculus).

Abdominoplasty: Cosmetic abdominal contouring surgery that includes skin removal.

See the Evidence of Coverage (EOC) as definitions of Cosmetic Services vary within the Exclusions section of the EOC documents.

POLICY AND CRITERIA

CRITERIA FOR ABDOMINAL PANNICULECTOMY CONSULTATION AND/OR SURGERY

Panniculectomy may be considered medically necessary in the following situations:

A. Panniculectomy is being requested by a surgeon because of difficult surgical access, where the panniculus will interfere with surgery,

OR

B. Panniculectomy is being requested by a patient who meets ALL of the following criteria:

1. The panniculus hangs below the level of the mons pubis (hair bearing area) and completely covers the mons pubis on direct (un-angled) frontal view.

2. There is documentation that the panniculus:

   a. interferes with ambulation OR

   b. causes recurrent chronic rashes, infections, cellulitis, or non-healing ulcers under the panniculus with documentation of at least a 3-month trial and failure of treatment with prescribed or over-the-counter topical medications.
3. Patient's weight has reached a plateau for at least the last 6 months (within 10 lbs of current weight), AND 1 of the following:
   a. Pt with no history of bariatric surgery.
   b. For patients with history of bariatric surgery, 18 months or more has elapsed following bariatric surgery (total of 18 months from day of surgery, including stable weight during the last 6 months).

4. Members with a history of tobacco products* use must have:
   a. a documented “quit” date >6 months prior to referral for consultation, or
   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

* tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)

CRITERIA FOR REMOVAL OF EXCESS/REdundant SKIN OR TISSUE CONSULTATION AND/OR SURGERY
(other than abdominal fat/panniculus)

Excess/redundant skin or tissue removal may be considered medically necessary in the following situations:

1. Excess/redundant skin or tissue removal is being requested by a surgeon because of difficult surgical access, where the excess/redundant skin or tissue will interfere with surgery,

OR

2. Excess/redundant skin or tissue removal is being requested by a patient with documented recurrent chronic rashes, infections, cellulitis, or non-healing ulcers under the excess skin or tissue with documentation of at least a 3-month trial and failure of treatment with prescribed or over-the-counter topical medications.

AND

3. Members with a history of tobacco products* use must have:
   a. a documented “quit” date >6 months prior to referral for consultation, or
   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

* tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)

CONTRAINdications (TO BE DETERMINEd BY THE SURGeON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

* tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)
** NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by an HbA1c of 8.0 or higher.

3. Any other surgical contraindications will be determined by the surgeon.
OTHER REQUIREMENTS

Relevant history and physical findings establishing medical necessity must be documented.

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

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

Criteria apply to Commercial members
Criteria do not apply to Medicare for panniculectomy (see Medicare Plastic Surgery LCD 37020)
Oregon Medicaid: subject to eligibility on OHP Linefinder
WA Medicaid/Molina: these criteria do not apply, refer to WA State Health Care Authority Provider Billing Guide

RATIONALE

EVIDENCE BASIS

Panniculectomy:

A 2018 systematic review of the effects of body contouring surgery (including panniculectomy) on post-bariatric patients reports significant improvement in physical functioning, psychological well-being, and global quality of life scores following body contouring surgery.¹

Tobacco Use:

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following abdominoplasty.² These complications include wound healing due to increased incidence of flap necrosis, infection, and wound separation in, all of which were significantly more common among smokers compared to non-smokers.² A 2015 systematic review of the association between smoking status and outcomes of plastic surgery reports significantly increased odds of surgical site infections, delayed wound healing, and cutaneous necrosis among patients who were smokers compared to non-smokers.³

REFERENCES

Pre-implantation Genetic Testing

Policy Number: 0009
Effective Date: August 1, 2015
Reviewed Date: June 2023
Next Review: June 2024
Clinical Reviewer: Brian Pfeiffer, DO

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

“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 emerging 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.” (excerpted verbatim from Dahdouh 2015)

There are multiple types of pre-implantation genetic testing:

- **PGD** is used to identify inherited genetic defects in embryos created through IVF.
- **PGT-M** is used to detect single gene disorders.
- **PGT-SR** is used to detect structural chromosomal abnormalities.
- **PGT-A** is used to detect aneuploidies (presence of extra chromosomes or absence of one or more chromosomes).
Pre-implantation genetic testing (PGT) is considered medically necessary when BOTH of the following criteria are met:

1. There must be documentation confirming that PGT is medically necessary to detect a single gene disorder (via PGT-M) or structural chromosomal abnormality (via PGT-SR) 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
   b. One genetic parent has a single gene autosomal dominant disorder; OR
   c. Both genetic parents are known carriers of the same autosomal recessive disorder; OR
   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 PGT 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).

PGT is considered NOT medically necessary when the above-outlined criteria are not met.

PGT-A is considered NOT medically necessary for any indication.

**RATIONALE**

**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 2020 on preimplantation genetic testing that includes the following recommendations:

- Preimplantation genetic testing comprises a group of genetic assays used to evaluate embryos before transfer to the uterus. Preimplantation genetic testing-monogenic (known as PGT-M) is target to single gene disorders. Preimplantation genetic testing-monogenic uses only a few cells from the early embryo, usually at the blastocyst stage, and misdiagnosis is possible but rare with modern techniques. Confirmation of preimplantation genetic testing-monogenic results with chorionic villus sampling (CVS) or amniocentesis should be offered.

- To detect structural chromosomal abnormalities such as translocations, preimplantation genetic testing-structural rearrangements (known as PGT-SR) is used. Confirmation of preimplantation genetic testing-structural rearrangements results with CVS or amniocentesis should be offered.

- The main purpose of preimplantation genetic testing-aneuploidy (known as PGT-A) is to screen embryos for whole chromosome abnormalities. Traditional diagnostic testing or screening for aneuploidy should be offered to all patients who have had preimplantation genetic testing-aneuploidy, in accordance with recommendations for all pregnant patients.

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 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.”

In March 2017, ACOG issued a committee opinion titled “Carrier Screening in the Age of Genomic Medicine” (ACOG 2017). This Committee Opinion includes the following recommendations relevant to preimplantation genetic testing:
If a carrier couple (ie, carriers for the same condition) is identified before pregnancy, genetic counseling is encouraged so that reproductive options (eg, donor gametes, preimplantation genetic diagnosis, prenatal diagnosis) can be discussed.

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 trophoderm 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. Trophoderm biopsy has no measurable impact on embryo development, as opposed to blastomere biopsy. Therefore, whenever possible, trophoderm 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 trophoderm biopsy whenever available. (II-2B)

6. The use of comprehensive chromosome screening technology coupled with trophoderm 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

<table>
<thead>
<tr>
<th>CPT or HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>88271 – 88299</td>
<td>Molecular cytogenetics</td>
</tr>
<tr>
<td>89290 – 89291</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than, equal or greater than 5 embryos [not covered to enhance delivery rates in advanced reproductive technologies]</td>
</tr>
<tr>
<td>S3800</td>
<td>Genetic testing for amyotrophic lateral sclerosis (ALS)</td>
</tr>
<tr>
<td>S3840</td>
<td>DNA analysis for germline mutations of the ret proto-oncogene for susceptibility to multiple endocrine neoplasia type 2</td>
</tr>
<tr>
<td>S3841</td>
<td>Genetic testing for retinoblastoma</td>
</tr>
<tr>
<td>S3842</td>
<td>Genetic testing for Von Hippel-Lindau disease</td>
</tr>
<tr>
<td>S3844</td>
<td>DNA analysis of the connexin 26 gene (gjb2) for susceptibility to congenital, profound deafness</td>
</tr>
<tr>
<td>S3845</td>
<td>Genetic testing for alpha-thalassemia</td>
</tr>
<tr>
<td>S3846</td>
<td>Genetic testing for hemoglobin E beta-thalassemia</td>
</tr>
<tr>
<td>S3849</td>
<td>Genetic testing for Niemann-Pick disease</td>
</tr>
<tr>
<td>S3850</td>
<td>Genetic testing for sickle cell anemia</td>
</tr>
<tr>
<td>S3852</td>
<td>DNA analysis for APOE epsilon 4 allele for susceptibility to Alzheimer’s disease</td>
</tr>
<tr>
<td>S3853</td>
<td>Genetic testing for myotonic muscular dystrophy</td>
</tr>
<tr>
<td>S3854</td>
<td>Gene expression profiling panel for use in the management of breast cancer treatment</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>D56.0 – D56.9</td>
<td>Thalassemia</td>
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<tr>
<td>D57.0 – D57.819</td>
<td>Sickle-cell disorders</td>
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<tr>
<td>D61.01 – D61.09</td>
<td>Constitutional aplastic anemia</td>
</tr>
<tr>
<td>E75.02</td>
<td>Tay-Sachs disease</td>
</tr>
<tr>
<td>E75.19</td>
<td>Other gangliosidosis</td>
</tr>
<tr>
<td>E75.4</td>
<td>Neuronal ceroid lipofuscinosis</td>
</tr>
<tr>
<td>E72.00 – E72.9</td>
<td>Other disorders of amino-acid metabolism</td>
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<tr>
<td>E84.0 – E84.9</td>
<td>Cystic fibrosis</td>
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<td>G71.0</td>
<td>Muscular dystrophy</td>
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<td>G71.2</td>
<td>Congenital myopathies</td>
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<td>Q05.0 – Q05.9</td>
<td>Spina bifida</td>
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<tr>
<td>Q06.0 – Q06.9</td>
<td>Other congenital malformations of spinal cord</td>
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<tr>
<td>Q87.40 – Q87.89</td>
<td>Marfan’s syndrome</td>
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<tr>
<td>Q90.0 – Q99</td>
<td>Chromosomal abnormalities, not elsewhere classified</td>
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<tr>
<td>Z14.1</td>
<td>Cystic fibrosis carrier</td>
</tr>
<tr>
<td>Z14.8</td>
<td>Genetic carrier of other disease</td>
</tr>
<tr>
<td>Z81.0</td>
<td>Family history of intellectual disabilities</td>
</tr>
<tr>
<td>Z82.0</td>
<td>Family history of epilepsy and other diseases of the nervous system</td>
</tr>
<tr>
<td>Z83.2</td>
<td>Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism</td>
</tr>
<tr>
<td>Z83.31 – Z83.49</td>
<td>Family history of other endocrine, nutritional, and metabolic diseases</td>
</tr>
<tr>
<td>Z82.79</td>
<td>Family history of other congenital malformations, deformations and chromosomal abnormalities</td>
</tr>
<tr>
<td>Z84.89</td>
<td>Family history of other specified conditions</td>
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</tbody>
</table>
REFERENCES


POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>August 1, 2015</td>
<td>New policy</td>
</tr>
<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>
<td>May 31, 2019</td>
<td>Updated literature search; no policy changes.</td>
</tr>
<tr>
<td>May 12, 2020</td>
<td>No policy changes; reviewed literature.</td>
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</table>
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: less than 30 days.

B. Acute exacerbation: A significant increase in frequency, duration, or intensity of symptoms
typically associated with a person’s existing condition.

C. Subacute: 30 to 90 days.

D. Chronic: greater than 90 days.

E. Maintenance Therapy: any treatment program designed to maintain, prevent, or slow further
deterioration of the patient’s functional status.

F. Neurodevelopmental Disorder: A congenital or acquired neurologically based condition in
which a child does not reach developmental milestones at normative times and fails to master
age-appropriate acquired skills such as selfcare, gross and fine motor skills, coordination and
motor planning skills, communication skills (including speech, speech with augmentative and
alternative communication device, language skills, sensory/motor skills, or swallowing and feeding
skills. Residual effects can persist into adulthood.
G. Sustainable: able to be maintained. For purposes of PT, OT, and ST, progress toward goals can be maintained across visits and following discharge.

H. Physicians: for purposes of these criteria, physicians who can refer to PT/OT/ST are (1) a doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a doctor of podiatric medicine; (4) a doctor of optometry; or (5) a chiropractor. See REFERENCES section for entire definition of Physicians, as defined in 1861(r)(1) of the Social Security Act.

MEDICAL NECESSITY CRITERIA FOR PHYSICAL, OCCUPATIONAL and SPEECH THERAPY

Initiation Criteria

Outpatient physical therapy, occupational therapy and speech therapy are considered medically necessary when all of the following criteria are met:

A. For initial evaluation
   1. the member is referred by an examining *physician, physician assistant, or nurse practitioner
      *See REFERENCES section for definition of Physicians, as defined by the Social Security Act
   2. the member’s condition is acute, subacute, neurodevelopmental, an acute exacerbation of a chronic condition or a function-limiting chronic condition,
   3. the member’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

B. For initiation of therapy treatment
   1. the prescribed therapy services are of the complexity and nature to require that they be performed by a licensed PT, OT, or ST provider,
   2. the therapy plan of care includes the member’s diagnosis with planned treatment interventions; frequency and duration; measurable, time-specific, functional goals for therapy; and expected potential for achievement of goals.
   3. Treatment does not duplicate services provided by other types of therapy, or services provided in multiple settings, including but not limited to those provided as part of an individual educational plan (IEP) or an individual service plan (ISP).
   4. For pediatric members (also see Special Group Considerations below):
      a. when the member falls below the 7th percentile (1.5 SD below the mean) on a standardized test that requires clinician-observed member performance and is consistent with professional standard of practice. *
         *Exception: For those members whose deficits negate the validity of a standardized test, they must demonstrate, through clinician-observed member performance, a clinically significant impairment using a norm-referenced developmental assessment (e.g. Rosetti or Vineland-3.)
      b. for Pediatric Speech/Articulation disorder, the evaluating Speech Language Pathologist has determined that the articulation deficits are not expected to improve with normal maturation.
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.

**Continuation Criteria**

Continued outpatient physical therapy, occupational therapy and speech therapy are considered medically necessary when all of the following criteria are met:

1. Member continues to meet initiation criteria
2. Documentation establishes evidence of clinically significant objective measurable improvement AND evidence of observable improvement in functional task performance in at least 75% of established goals, as compared to most recent reporting period.
3. There is documented evidence that the member and/or caregiver are participating in and adhering to a home exercise program (HEP).
4. Member has not yet met discontinuation criteria.

Therapy extension requests require the following documentation to be submitted in order for requests to be reviewed:

1. Progress report that addresses each treatment goal, with inclusion of member’s initial status, last reporting period status and current reporting period status, with specific reference to the parameters outlined in previous status. Objective measure parameters must be consistent across reporting periods.
2. Planned treatment techniques and interventions are detailed including amount frequency and duration required to achieve ongoing progress toward functional, measurable goals.
3. Identification of any health conditions or other factors which could impede the member’s ability to benefit from treatment.
4. Summary of member’s response to therapy, with documentation of any issues which have limited progress
5. Brief prognosis statement with clearly established discharge criteria
6. An explanation of any significant changes to the member’s Plan of care, and the clinical rationale for revising the treatment plan.
7. Revaluation
   a. For pediatric members: Retesting with norm referenced or criterion-reference standardized tools for re-evaluations is required 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 must justify the change.

**Discontinuation of Therapy**

Continued outpatient physical therapy, occupational therapy and speech therapy are considered not medically necessary in the following situations:

- 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 and it cannot be determined whether the progress is due to therapeutic intervention or natural development
• 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
• For Pediatric members, if the member scores equal to, or less than 1.5 standard deviations below the mean on a standardized test that is consistent with professional standard of practice.
• Member does not meet continuation criteria

**Determination for consideration of a new episode of therapy intervention**

The member may be eligible for a new evaluation/reassessment no sooner than 3 months following the end of the prior episode of care unless there has been a significant change in member’s condition that justifies additional consideration for therapy services.

**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 member 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
• Any service, program, or procedure performed in a non-conventional setting (this includes, but is not limited to camps, educational, vocational, or recreational settings.)

There will be no PT/OT/ST visit limits applied when treatment is associated with a mental health diagnosis and is medically necessary. 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-10 Codes
- F84.0 Autistic disorder
- F87.5 Asperger’s syndrome
- F84.8 Other pervasive developmental disorders
- F84.9 Pervasive developmental disorder, unspecified

SPECIAL CONSIDERATIONS:
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:
1. 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.
RESPONSIBILITIES

A. PhysicianReviewer
   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 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 using nonskilled personnel.

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

For Oregon Health Plan pediatric members assigned to Pacific Source: Speech Therapy Initiation criteria, Section B.4. is modified as follows:

- When the member falls below the 16th percentile (1.0 SD below the mean) on a standardized test that requires clinician-observed member performance and is consistent with professional standard of practice.
  **Exception:** For those members whose deficits negate the validity of a standardized test, they must demonstrate, through clinician-observed member performance, a clinically
significant impairment using a norm-referenced developmental assessment (e.g. Rosetti or Vineland-3.)

Oregon Health Plan members (assigned to Health Share of Oregon or Pacific Source): Check LineFinder for members 21 years old and older to determine whether diagnoses are funded and pair with the requested therapy; use UR 43 to determine medical necessity of therapy. For members under 21 years of age, no LineFinder review is needed; use UR 43 to determine medical necessity of therapy.

REFERENCES

Physicians - as defined in 1861(r)(1) of the Social Security Act: The term “physician”, when used in connection with the performance of any function or action, means
(1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)),
(2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions,
(3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(iii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them,
(4) a doctor of optometry, but only for purposes of subsection (p)(1) of this section and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or
(5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided.

For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

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 absences 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 physical structure is normal (e.g. vocal fatigue, muscle dysphonia or aphonia, diplophonia, ventricular phonation. (American Speech-Language Association, overview of voice disorders.)
Northwest Utilization Review
UR 12.2: Pulmonary Rehabilitation
Medical Necessity Criteria

Department: KPNW Utilization Review
Applies to: KPNW Region
Review Responsibility: UROC
SMEs: Dr Susan Mikkelsen (Pulmonology); and Dr Ryan Clay (Pulmonology)
Number: UR 12.2
Issued: 11/03
Last Reviewed: 5/16

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 (e.g. idiopathic pulmonary fibrosis)
D. Bronchiectasis
E. Pulmonary arterial hypertension
F. CT scan determined severe emphysema
G. Confirmed or suspected COVID-19 with persistent symptoms that include respiratory dysfunction for at least 4 weeks
H. 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
e. An individualized treatment plan detailing how components are utilized for each patient.
Pulmonary rehabilitation items and services are typically furnished in a physician’s office or a hospital outpatient setting with 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) unless ordered/approved by a pulmonologist;

f. Presence of unstable pulmonary hypertension.

SPECIAL GROUP CONSIDERATIONS

Medicare: There is currently no National or Local Coverage Determination addressing pulmonary rehabilitation.

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/condition for that beneficiary.

Note: Beneficiaries with moderate to very severe COPD (defined as GOLD classification II, III, and IV) who have completed pulmonary rehab (PR), may participate in PR again if they had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks. Similarly, beneficiaries who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks and complete PR, may participate in PR again if they have moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease.

CLINICAL REFERENCES:

1. Pub 100-02 Medicare Benefit Policy; Pulmonary Rehabilitation Program Services Furnished On or After January 1, 2010 (Chapter 15, section 231).
2. Medicare Billing and Coding: Pulmonary Rehabilitation Services Article A52770
3. MCG; Ambulatory Care- Pulmonary Rehabilitation (contraindications) 25th edition.
4. Noridian Pulmonary Rehab Program Criteria
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.

Note that separate policies/criteria exist, when applicable, for coverage of:

1. Breast Reconstruction (UR 20.6)
2. Gender-Affirming Procedures (UR 65)

DEFINITIONS

See the Evidence of Coverage (EOC) as definitions of Cosmetic Services may vary within the Exclusions section of the EOC documents.

POLICY AND CRITERIA

A. CRITERIA FOR BREAST REDUCTION/PLASTIC SURGERY CONSULTATION

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:13
   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. Must have a normal mammogram within the past year in women 40 years or older.

5. Members with a history of tobacco products* use must have:
   a. a documented “quit” date >6 months prior to referral for consultation, or
   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

B. CRITERIA FOR BREAST REDUCTION SURGERY (POST-CONSULTATION).

In addition to pre-consultation criteria (section A), the following must be met:

1. Predicted removal of the following:
   a. minimum of 200 grams of breast tissue from the larger of the two breasts when BMI is <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 >30.

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

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

4. No diagnosis of diabetes mellitus or diabetes mellitus with A1c <8.0 within the last 3 months.

5. Members with a history of tobacco products* use must have:
   a. a documented “quit” date >6 months prior to consideration for surgery, or
   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit <6 months prior to consideration for surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher. Members with a Hba1c in the 7-8 range may be assessed for relative contraindications on a case-by-case basis.

3. 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.

4. Any other surgical contraindications will be determined by the surgeon.

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 Medicare Plastic Surgery LCD 37020)
**RATIONALE**

**EVIDENCE BASIS**

*Reduction Mammoplasty:*

Recent systematic reviews have investigated the benefits and harms of reduction mammoplasty in individuals with macromastia and consistently report improved outcomes among those who received reduction mammoplasty compared to those who did not. A 2021 systematic review of randomized controlled trials reports a significant improvement in health-related quality of life (HRQoL) at 4-6 months post-procedure among participants with macromastia who had reduction mammoplasty compared to participants who had non-surgical interventions.¹ Another 2021 review of the risks and benefits of reduction mammoplasty to treat breast hypertrophy reports improved HRQoL and a significant reduction in pain after reduction mammoplasty.² A 2020 systematic review reports an overall statistically significant improvement in back pain following reduction mammoplasty among patients with macromastia.³ A 2019 systematic review of the effect of reduction mammoplasty on the spine of patients with breast hypertrophy reports a substantial reduction in pain among those who underwent reduction mammoplasty compared to those who did not.⁴ A 2019 systematic review of patient-reported outcomes following reduction mammoplasty indicates an overall satisfaction rate of 90.3% among patients with macromastia whose satisfaction was directly measured following the procedure.⁵ The underlying body of evidence included in these reviews had some methodological limitations that hinders determinations related to patient selection for reduction mammoplasty. One review noted that studies on reduction mammoplasty for breast hypertrophy don’t report a definition for breast hypertrophy or detail the indications for reduction mammoplasty that were used.²

*Tobacco Use*

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following reduction mammoplasty.⁶ These complications include skin necrosis, infection, wound separation, delayed wound healing and need for reoperation, all of which were significantly more common among smokers compared to non-smokers.⁶

**REFERENCES**


16. Medicare Coverage Database: LCD for Mammoplasty, Reduction (L15600)

17. 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


Routine Foot Care (MEDICARE ONLY)

Policy Number: UR5b
Effective Date: March 31, 2020
Reviewed Date: July 19, 2022
Next Review: July 2023
Clinical Reviewer: Anthony Domenigoni, DPM

BACKGROUND

CLINICAL BACKGROUND

Individuals with compromised circulation or sensation of the lower extremity are at high risk for causing themselves serious injury when performing routine foot care on their own. These individuals may have difficulty sensing or healing an injury to their feet that may result in painful ulcers or ultimately loss of the limb. Provision of routine foot care services by a medical professional can help prevent adverse outcomes. Routine foot care may include services such as cutting or removal of corns and calluses; trimming, cutting, or debriding nails; hygienic and preventive maintenance foot care (e.g., soaking, applying lotion). Services may be performed in a physician’s office, an outpatient setting, or an individual’s home. While diabetes mellitus is a risk factor for foot ulcers, non-diabetic individuals with vascular disease and/or neuropathy are also at increased risk.

POLICY AND CRITERIA

1. Routine foot care services may be considered medically necessary when the following criteria are met:
   a. Presence of a systemic condition* that has resulted in in severe circulatory insufficiency as evidenced by ANY of the following:
      i. absent posterior tibial pulse by palpation;
      ii. absent dorsalis pedis pulse by palpation;
      iii. lower extremity vascular claudication; OR
   b. Presence of a systemic condition* that has resulted in loss of protective sensation in the feet; OR
   c. Previous non-traumatic lower extremity amputation (patients quality for routine foot care of affected or unaffected lower extremity after partial or complete amputation of foot/toes); OR
   d. The member is undergoing other treatment for which the foot care is a necessary component (e.g., treatment of warts, fitting for a cast).

2. Treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.

3. Treatment of mycotic nails is covered when:
   a. There is clinical evidence of mycosis of the toenail as documented by the attending physician; AND
   b. The patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate OR, if patient is typically ambulatory, there is marked limitation of ambulation attributable to toenail mycosis.

*Examples of systemic conditions that may justify coverage include, but are not limited to, peripheral neuropathies such as those associated with traumatic injury or multiple sclerosis, as well as arteriosclerosis obliterans, chronic thrombophlebitis, and others. For individuals with diabetes mellitus,
see NCD (70.2.1) for Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy).

**RATIONALE**

**EVIDENCE BASIS**

In their review on prevention of foot ulcers and other serious foot lesions, CMS evaluated primarily evidence related to diabetic foot ulcers. However, other disease processes resulting in peripheral neuropathy and/or peripheral vascular disease face similar potential for benefit. Findings from the CMS review are provided below:

“Comprehensive, multifaceted approaches incorporating multiple interventions that promote greater attention to foot care have been shown to be effectively reduce foot ulcers and other serious foot lesions. Specifically, Litzelman and colleagues were able to reduce serious foot lesions in a randomized controlled trial by utilizing multiple interventions (see Table 3). The intervention was based on two observations (1) basic efforts on the part of the health care provider or patient can reduce the likelihood of subsequent amputation due to diabetes-associated foot disease; and (2) many of these basic procedures are not being systematically applied by health care providers or patients. Over the course of the 12-month study, patients received foot care education and entered into behavioral contracts for desired self-care, which was reinforced with telephone calls and post card reminders. Practice guidelines and informational flow sheets on amputation risk factors were provided to health care providers. Also, patients who received the intervention had special identifiers on their charts to prompt foot examinations and to provide foot care education.

The intervention group (patients in the group that received education on appropriate foot care and whose providers had chart reminders to prompt foot examinations and referral recommendations) was less likely than the control group to have serious foot lesions [baseline prevalence, 2.9%, OR 0.41 (95% CI=0.16-1.00), P = 0.05]. Intervention patients were also more likely to report appropriate self-foot-care behavior, to have foot examinations during office visits (68% compared with 28%; P < 0.001), and to receive foot care education from health care providers (42% compared with 18%; P < 0.001). Finally, physicians in the intervention group were more likely than their control counterparts to examine patients’ feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to podiatry clinic (10.6% compared with 5.0%; P = 0.04).

In addition, Bild and colleagues noted three studies in which multidisciplinary interventions reduced the frequency of LEAs. In Atlanta, Grady Memorial Hospital instituted an integrated inpatient/outpatient diabetes unit, which included comprehensive podiatry services, nurse clinicians and an extensive education program. The annual number of LEAs in this largely African American and indigent cohort decreased by almost 50%, from 172 in 1973 to an average of 92 per year from 1973 to 1982 among 8000 clinic patients.

In London, England a diabetes foot clinic at Kings College Hospital added podiatrists and shoe fitters to the diabetes foot clinic. Over a two-year period emphasizing podiatric care, antibiotic therapy, and specially constructed shoes, the amputation rate declined 44%. The effect of specially fitted footwear on recurrent ulcers was particularly dramatic. Patients receiving specially fitted footwear had an ulcer recurrence rate of 26%, compared to 83% among those with regular shoes.

Similarly, at the University Hospital of Geneva an 85% reduction in below knee amputations was observed over a 4-year period after the initiation of patient education and training in foot care for people with diabetes. He concluded that the results support the notion that comprehensive foot care, including podiatric care, education and specially fitted shoes, can reduce LEAs in individuals with diabetes. As with the Patout study, the observational nature of each of these studies raises doubts about the true magnitude of any beneficial effect. In addition, it is noteworthy that all of these studies addressed multidisciplinary or multifactorial interventions for diabetic feet. Patient education, for example may be a critical component, and was included in most of these programs.”
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Routine Foot Care (NON-MEDICARE)

Policy Number: UR5a
Effective Date: March 31, 2020
Reviewed Date: July 19, 2022
Next Review: July 2023
Specialist Reviewer: Anthony Domenigoni, DPM

BACKGROUND

CLINICAL BACKGROUND

Individuals with compromised circulation or sensation of the lower extremity are at high risk for causing themselves serious injury when performing routine foot care on their own. These individuals may have difficulty sensing or healing an injury to their feet that may result in painful ulcers or ultimately loss of the limb. Provision of routine foot care services by a medical professional can help prevent adverse outcomes. Routine foot care may include services such as cutting or removal of corns and calluses; trimming, cutting, or debriding nails; hygienic and preventive maintenance foot care (e.g., soaking, applying lotion). Services may be performed in a physician's office, an outpatient setting, or an individual's home. While diabetes mellitus is a risk factor for foot ulcers, non-diabetic individuals with vascular disease and/or neuropathy are also at increased risk.

POLICY AND CRITERIA

1. Routine foot care services may be considered medically necessary when ANY of the following conditions are present:
   a. significant circulatory insufficiency due to a peripheral vascular disease as evidenced by ANY of the following:
      i. absent posterior tibial pulse by palpation;
      ii. absent dorsalis pedis pulse by palpation;
      iii. lower extremity vascular claudication;
   b. peripheral neuropathy resulting in loss of protective sensation in the feet (as indicated by an absence of sensation at two or more sites out of five tested on either foot when tested with a monofilament*);
   c. previous non-traumatic lower extremity amputation (patients qualify for routine foot care of affected or unaffected lower extremity after partial or complete amputation of foot/toes);
   d. The member is undergoing other treatment for which the foot care is a necessary component (e.g., treatment of warts, fitting for a cast).

INFORMATIONAL ONLY: expected/typical frequency for routine foot care services is no more often than every 60 days. Greater frequency report to Regional Referral Center leadership.

*S a standard monofilament is the 5.07 Semmes-Weinstein monofilament

SPECIAL GROUP CONSIDERATIONS

- This policy applies to commercial plans. For Medicare plans, see separate criteria under UR5b.
- Oregon Medicaid: Check LineFinder.
  o for clients under 21 years non-experimental medically necessary services are covered through the early and periodic screening, diagnosis, and treatment (EPSDT) program -
EVIDENCE BASIS

In their review on prevention of foot ulcers and other serious foot lesions, CMS evaluated primarily evidence related to diabetic foot ulcers. However, other disease processes resulting in peripheral neuropathy and/or peripheral vascular disease face similar potential for benefit. Findings from the CMS review are provided below:

“Comprehensive, multifaceted approaches incorporating multiple interventions that promote greater attention to foot care have been shown to be effectively reduce foot ulcers and other serious foot lesions. Specifically, Litzelman and colleagues were able to reduce serious foot lesions in a randomized controlled trial by utilizing multiple interventions (see Table 3). The intervention was based on two observations (1) basic efforts on the part of the health care provider or patient can reduce the likelihood of subsequent amputation due to diabetes-associated foot disease; and (2) many of these basic procedures are not being systematically applied by health care providers or patients. Over the course of the 12-month study, patients received foot care education and entered into behavioral contracts for desired self-care, which was reinforced with telephone calls and post card reminders. Practice guidelines and informational flow sheets on amputation risk factors were provided to health care providers. Also, patients who received the intervention had special identifiers on their charts to prompt foot examinations and to provide foot care education.

The intervention group (patients in the group that received education on appropriate foot care and whose providers had chart reminders to prompt foot examinations and referral recommendations) was less likely than the control group to have serious foot lesions [baseline prevalence, 2.9%, OR 0.41 (95% CI=0.16-1.00), P = 0.05]. Intervention patients were also more likely to report appropriate self-foot-care behavior, to have foot examinations during office visits (68% compared with 28%; P < 0.001), and to receive foot care education from health care providers (42% compared with 18%; P < 0.001). Finally, physicians in the intervention group were more likely than their control counterparts to examine patients’ feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to podiatry clinic (10.6% compared with 5.0%; P = 0.04).

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As with the Patout study, the observational nature of each of these studies raises doubts about the true
magnitude of any beneficial effect. In addition, it is noteworthy that all of these studies addressed
multidisciplinary or multifactorial interventions for diabetic feet. Patient education, for example may be a
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MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SCAR REVISION AND MEDICAL TATTOO

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

See the Evidence of Coverage (EOC) as definitions of Cosmetic Services vary within the Exclusions section of the EOC documents.

CRITERIA FOR SCAR REVISION AND MEDICAL TATTOO

When the criteria below are met for a scar revision or a medical tattoo, these services will be covered as a form of reconstructive surgery.

1. Scar, discoloration or deformity is a result of an injury or medically necessary surgery

2. Scar, discoloration or deformity duration:
   - If scar is not hypertrophic or keloid, scar has been present for 1 year or more
   - If scar is hypertrophic or keloid, any duration is acceptable
   - For medical tattoo referrals, age of scar, discoloration or deformity is not relevant

3. Scar, discoloration or deformity causes signs or symptoms, as indicated by 1 or more of the following:
   - Loss of range of motion of joint
   - Pain
   - Significant disfigurement, distortion of adjacent structures and/or scars or discoloration in a cosmetically sensitive area, i.e. face (the decision regarding the significance of the scar and the eligibility of scar removal will be determined on a case-by-case basis by the plastic surgeon)

OTHER REQUIREMENTS

- Cosmetic services (see member’s EOC for definition) 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.
- See UR 20.6 Breast Reconstructive Surgery Criteria for information regarding surgical services related to breast reconstruction.
- See the EOC for other inpatient and outpatient reconstructive surgery services related to congenital hemangioma (port wine stains on the face), correction of significant disfigurement resulting from an injury or from medically necessary surgery and correction of congenital defects, disease, or anomalies in order to produce significant improvement in physical function.

- See UR 65 Gender-Affirming Procedures Medical Necessity Criteria for more information regarding gender-affirming areola tattooing.

**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

**CLINICAL**

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SKILLED NURSING FACILITY CARE FOR COMMERCIAL, MEDICAID, AND MEDICARE BUSINESS—see Special Group Considerations for Medicare and 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 benefit 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 medical necessity 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.

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 Services in a Skilled Nursing Facility

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 70: Extenuating Circumstances Policy at http://internal.or.kp.org/utilization/.

Pre-Admission Qualifying Criteria (Medicare Part A and Commercial)

A. Entitlement to Part A Medicare or Commercial Kaiser Permanente Health Plan (KPHP) 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 than 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.

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) and 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.
5. The services delivered are reasonable and necessary for the treatment of the patient’s illness or injury. The services must also be reasonable in terms of duration and quantity.

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.

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 Payment (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 17-2921) 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
MEDICARE
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).
Non-Pharmacological Treatments for Tinnitus and Hyperacusis

Policy Number: 0019
Effective Date: March 1, 2021
Reviewed Date: June 2023
Next Review: June 2024
Specialist Reviewer: John Goddard, MD

BACKGROUND

CLINICAL BACKGROUND (excerpted from Fuller 2020)

Tinnitus is defined as the perception of sound in the absence of a corresponding auditory source (Jastreboff 2004). It is typically described by those who experience it as a ringing, hissing, buzzing or whooshing sound and is thought to result from abnormal neural activity and connectivity in auditory and non-auditory pathways, which is interpreted by the brain as sound (Elgoyhen 2015, Shore 2016). Tinnitus can be either objective or subjective. Objective tinnitus is estimated to occur in up to 10% of people with tinnitus seeking help (Kircher 2008) and refers to the perception of sound that can also be heard by the examiner (Roberts 2010). Objective forms include heartbeat synchronous pulsatile tinnitus, and they usually have a detectable cause such as arteriovenous malformation, carotid stenosis or dissections (Langguth 2013).

Specific medication or surgical treatment can lead to the cessation of the objective tinnitus percept (Kleinjung 2016). Most commonly, however, tinnitus is subjective, meaning that the sound is only heard by the person experiencing it and no source of the sound can be identified (Jastreboff 1988). Subjective tinnitus (the focus of this review) is estimated to affect up to 21% of the general adult population, increasing to as many as 30% of adults over 50 years of age (Davis 2000, Gallus 2015, Kim 2015). It can be experienced acutely, recovering spontaneously within minutes to weeks. However, it can become chronic and is unlikely to resolve spontaneously when experienced for three months or more (Hahn 2008, Hall 2011, Rief 2005). In 1% to 3% of the population tinnitus causes severe problems with daily life functioning (Davis 2000, Kim 2015). Although a range of psychological, sound, electrical and electromagnetic therapies have been developed, currently there is no reliable cure for subjective tinnitus.

POLICY AND CRITERIA

Cognitive-behavioral therapy (CBT) for tinnitus may be considered medically necessary for individuals scoring a minimum of 18 on the tinnitus handicap inventory (THI).

All other non-pharmacological treatments for tinnitus are considered experimental and investigational, including (but not limited to) patient education, masking, and biofeedback.

All treatments for hyperacusis in the absence of comorbid tinnitus are considered experimental and investigational.

RATIONALE

EVIDENCE BASIS

A 2020 Cochrane review analyzed the findings of 28 studies relevant to treatment of tinnitus with cognitive-behavioral therapy. That high-quality review reported that CBT may effectively improve quality of life in the short term, but long-term data is lacking. Adverse events were found to be uncommon. Evidence for other outcomes, including anxiety, was insufficient. CBT was more effective than no treatment, based on an average 10 point decrease on the tinnitus handicap inventory (THI), for which a
decrease of 7 or more points is considered to be clinically significant. Compared to other interventions for tinnitus, CBT was more effective than audiological care (5 point greater decrease on THI), tinnitus retraining therapy (15 point greater decrease on THI), and other active controls (including relaxation and support groups). The authors’ conclusions are outlined below:

“The main results of this review indicate that cognitive behavioural therapy (CBT) may be effective in reducing the impact of tinnitus on quality of life at the end of treatment, and that there are few if any adverse effects from receiving CBT (although further research on this is recommended below). These results provide further evidence or justification for recommendations made in two prominent clinical guidelines endorsing the provision of CBT for patients with chronic bothersome tinnitus (Cima 2019; Tunkel 2014). Consequently, policy-makers and service providers should feel confident that CBT for tinnitus is beneficial for patients at least in the short term. This is not to say, however, that CBT is an easy form of treatment to engage in; it is often personally challenging and can require a considerable investment of time and money from the patient (assuming that CBT is even available and/or covered by insurance in a given country).

CBT for tinnitus appears to have some benefit for people who also experience depression, but the effects are small and there are some concerns with regards to the quality of the evidence. Thus, in addition to receiving tinnitus-specific CBT, people with co-morbid depression should also seek depression-specific treatment. Overall, there is either low-certainty evidence, small effects and/or an insufficient amount of evidence currently to recommend CBT for tinnitus if the primary intention is to improve anxiety or general quality of life, or to change negatively biased interpretations of tinnitus.

CBT for tinnitus delivered in person and delivered via the Internet, with some additional email communication from a professional, appear similarly effective, as does CBT delivered individually and group-wise. Alternative modes of delivery should be considered depending on patient preference, accessibility and cost.

There is insufficient evidence to support a recommendation for whom should provide CBT for tinnitus, although it is noted that psychologists and/or psychiatrists were involved in the design, conduct and/or supervision of all CBT treatments.

The results from this review are relevant to tinnitus patients with varying levels of hearing loss and thus they should also be eligible to access treatment. We do not know, however, to what extent the study populations represent the whole patient population.

It is important to keep in mind that approximately half of the included studies in the review only reported group-level data/ analyses. This means that the results represent an average of the outcomes for participants in the study. In other words, on average, people improved receiving CBT compared with waiting for it (tinnitus) to get better, or another available treatment. It is likely that individual patients might respond better or worse than the average treatment effects reported here and that patients should make informed choices aligned with personal preference where possible.”

A 2021 assessment of the effectiveness of Tinnitus Retraining Therapy (TRT) produced for KP Southern California’s Medical Technology Assessment Team (MTAT) identified 7 studies (5 RCTs and 2 quasi-experimental clinical studies) involving 620 patients. The report concludes that these studies suggest a benefit of TRT for improving tinnitus symptoms, severity, and function compared to partial TRT, structured counseling, tinnitus education, or provision of resources as part of standard care. MTAT indicates that the findings should be interpreted with caution because the overall quality of the evidence was rated “low” for all key outcomes. All identified studies were determined to be at serious risk of bias due to lack of well-described random sequence generation, allocation concealment, and/or blinding. Additionally, across the studies there was substantial heterogeneity regarding TRT directive counseling protocols in addition to the magnitude and significance of estimated effects (SCPMG Evidence-Based Medicine Services 2021).
### CODES

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<th>Description</th>
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<tbody>
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<td>90832-90840</td>
<td>Psychotherapy</td>
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### ICD-10 Code and Description

- H93.1 Tinnitus
- H93.11 Tinnitus, right ear
- H93.12 Tinnitus, left ear
- H93.13 Tinnitus, bilateral
- H93.19 Tinnitus, unspecified ear
- H93.A Pulsatile tinnitus
- H93.A1 Pulsatile tinnitus, right ear
- H93.A2 Pulsatile tinnitus, left ear
- H93.A3 Pulsatile tinnitus, bilateral
- H93.A9 Pulsatile tinnitus, unspecified ear
- H93.23 Hyperacusis
- H93.231 Hyperacusis, right ear
- H93.232 Hyperacusis, left ear
- H93.233 Hyperacusis, bilateral
- H93.239 Hyperacusis, unspecified ear

### REFERENCES


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
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
TRIGGER POINT INJECTIONS FOR MYOFASCIAL PAIN

Policy Number: 0003
Effective Date: March 19, 2016
Reviewed Date: July 19, 2022
Next Review: July 2023
Clinical Reviewer: John Borgoy, MD

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 was conducted. 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 measurable 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.

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REFERENCES


