MARCH – APRIL 2020

BCN Provider News

Medical policy updates

The following applies to Blue Care Network members:

- Noncovered services appear first; covered services follow.
- The effective date is indicated for the service, technology or procedure.

Noncovered services

Surface electromyography (SEMG)

- **Revised policy**
- **Effective date: March 1, 2020**
- **Procedure codes: S3900, *95999**

TMJ, also known as temporomandibular joint syndrome, refers to a cluster of problems associated with the temporomandibular joint and musculoskeletal structures. Craniomandibular disorders are often called temporomandibular joint disorders. The etiology of TMJ remains unclear and is believed to be multifactorial. TMJ is often divided into two main categories: articular disorders (for example, ankylosis, congenital or developmental disorders, disc derangement disorders, fractures, inflammatory disorders, osteoarthritis, joint dislocation) and masticatory muscle disorders (myofascial pain, myofibrotic contracture, myospasm, neoplasia).

In the clinical setting, TMJ is often a diagnosis of exclusion and involves physical examination, patient interview and a review of dental records. Diagnostic testing and radiologic imaging are generally only recommended for patients with severe and chronic symptoms. Diagnostic criteria for TMJ have been developed and validated for use in both clinical and research settings. Symptoms attributed to TMJ vary and include, but are not limited to, clicking sounds in the jaw; headaches; closing or locking of the jaw due to muscle spasms (trismus) or displaced disc; pain in the ears, neck, arms and spine; tinnitus; and bruxism (clenching or grinding of the teeth).

For many patients, symptoms of TMJ are short-term and self-limiting. Conservative treatments (eating soft foods, rest, heat, ice, avoiding extreme jaw movements) and anti-inflammatory medication are recommended before considering more invasive or permanent therapies, such as surgery.

Surface electromyography is an office-based procedure that is most commonly used by physiatrists or chiropractors. The following clinical applications of SEMG have been proposed:

- Clarification of a diagnosis (for example, muscle, joint or disc disease)
- Selection of a course of medical therapy
- Selection of a type of physical therapy
- Preoperative evaluation
- Postoperative rehabilitation
- Follow-up of acute low back pain
- Evaluation of exacerbation of chronic low back pain
- Evaluation of pain management treatment techniques

Surface electromyography is considered experimental to diagnose or monitor temporomandibular joint and craniomandibular disorders. There's insufficient evidence demonstrating how findings from SEMG alter patient management and how use of this test improves health outcomes.

Surgery for groin pain in athletes

- **New policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *27299, *49659, *49999**

Sports-related groin pain, commonly known as athletic pubalgia or sports hernia, is characterized by disabling activity-dependent lower abdominal and groin pain not attributable to any other cause. Athletic pubalgia is most frequently diagnosed in high-performance male athletes, particularly those who participate in sports that involve rapid twisting and turning such as soccer, hockey and football. For patients who fail conservative therapy, surgical repair of any defects identified in the muscles, tendons, or nerves has been proposed.

Surgical treatment of groin pain** in athletes who present with the absence of a preoperative anatomical defect is considered experimental.

**Also known as athletic pubalgia, Gilmore groin, osteitis pubis, pubic inguinal pain syndrome, inguinal disruption, slap shot gut, sportsmen groin, footballer's groin injury complex, hockey groin syndrome, athletic hernia, sports hernia or core muscle injury

Cont.

Medical policy updates *Cont.*

Covered services

Ground ambulance services

- **New policy**
- **Effective date: March 1, 2020**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: A0225, A0398, A0426, A0427, A0428, A0429, A0433, A0434, A0998**

An ambulance is a specially designed and equipped vehicle to transport ill or injured individuals. These services may involve ground, air or sea transport in both emergency and non-emergency situations.

Ambulance services are transportation and life-support services furnished to sick, injured or incapacitated patients by a licensed ambulance company. There are three major categories of ambulance services:

- Basic life-support services provide for the initial stabilization and transport of a patient and must include at least two professionals licensed to provide emergency services present during the trip. One of the emergency medical services personnel must ride in the patient compartment of the ambulance.
- Limited advanced life-support services include all basic life support services as well as endotracheal intubation, intravenous therapy and establishment and maintenance of airway.
- Advanced life-support services include all basic and limited advanced life-support services as well as drug administration, cardiac monitoring and use of appropriate telemetry and defibrillation equipment.

Occasionally, a hospitalized patient may need to be transported to another hospital or facility for treatment and the ambulance service may include waiting time. Waiting time is defined as the time between the delivery of the patient to a treatment site and the time the same patient is loaded in the ambulance for the return trip to the originating hospital or facility.

Ambulance services include mileage for the distance traveled by an ambulance vehicle transporting patients. Transportation is covered to the nearest facility that is qualified to treat the patient.

The safety and effectiveness of ground ambulance service has been established. It may be considered a useful option when indicated for transporting patients when medical circumstances could endanger the patient's health or life.

Patients must be transported in a state-licensed vehicle designated as an ambulance and the ambulance must carry personnel qualified to treat the patient. Ambulance transport is medically necessary for:

- Transporting a patient to a hospital
- Transferring a patient from a hospital to another treatment location, such as another hospital, a skilled nursing facility, a medical clinic or the patient's home. (The attending physician must order the transfer.)
- Ambulance providers to respond and treat the patient without transport

Ambulance services must meet the following criteria:

- Services must be **medically necessary**. Medically necessary means that transportation other than by ambulance could endanger the patient's health or life.
- Emergency ambulance services are considered medically necessary as a result of an accidental injury or medical emergency when requested by an employer, school or public safety official.
- Non-emergency ambulance services are covered when medically necessary and authorized by the patient's physician.
- The services must be provided by an approved, state-licensed ambulance provider.
- If the services were not ordered by the attending physician, extenuating circumstances may warrant individual consideration for the service.
- The patient must be transported to the nearest facility equipped to provide the necessary treatment.
- Transportation coordination to airfield or helipad.

Deceased patients:

- Ambulance services are medically appropriate only to the place where the patient is found (one-way) if the patient is pronounced dead after the ambulance is called but before it arrives at the scene.
- Ambulance services are medically appropriate for the entire ambulance trip (round-trip) if the patient was pronounced dead while on route to or upon arrival at the hospital

Cont.

Medical policy updates *Cont.*

The following services do not meet the definition of medically necessary ambulance services:

- Use of vehicles not certified by the state as an ambulance
- Ambulance trips when a patient is not transported
- Ambulance services for the convenience of the patient, family or physician
- Coverage is only provided to the place where the patient was found (one-way) if the patient was pronounced dead after the ambulance was called but before it arrives at the scene.

- Ambulance services are not medically appropriate when the patient was pronounced dead by an authorized individual before the ambulance was called.
- Ambulance services are not medically appropriate when the patient was found deceased and pronounced at home with ground ambulance transport to morgue for post-mortem care.

Coverage limitations

Travel and transportation expenses for clinical trials are excluded from coverage. These include, but are not limited to, the following examples:

- Fees for all types of transportation (for example, personal vehicle, taxi, medical van, ambulance)
- Rental car expenses
- Mileage reimbursement for driving a personal vehicle

Genetic testing-molecular analysis for targeted therapy of non-small cell lung cancer

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *81235, *81275, *81404, *81405, *81479, *81406**

Treatment options for non-small cell lung cancer depend on disease stage and include various combinations of surgery, radiation therapy, chemotherapy and best supportive care. Unfortunately, in up to 85% of cases, the cancer has spread locally beyond the lungs at diagnosis, precluding surgical eradication. In addition, up to 40% of patients with non-small cell lung cancer present with metastatic disease. When treated with standard platinum-based chemotherapy, patients with advanced non-small cell lung cancer have a median survival rate of 8 to 11 months and a one-year survival rate of 30% to 45%. More recently, the identification of specific, targetable oncogenic "driver" mutations in a subset of non-small cell lung cancers have resulted in a reclassification of lung tumors to include molecular subtypes, which are predominantly of adenocarcinoma histology.

NTRK gene fusions encode tropomyosin receptor kinase fusion proteins that act as oncogenic drivers for solid tumors including lung, salivary gland, thyroid and sarcoma. It is estimated that NTRK gene fusions occur in 0.2% of patients with non-small cell lung cancer and do not typically overlap with other oncogenic drivers.

Tumor mutational burden is an emerging biomarker of outcomes with immunotherapy in multiple tumor types, including lung cancer.

NTRK gene fusion testing

Analysis of gene fusions is established to predict treatment response to larotrectinib in patients with advanced lung adenocarcinoma or in whom an adenocarcinoma component cannot be excluded.

Tumor mutational burden testing

Analysis of tumor mutational burden for targeted therapy in patients with non-small cell lung cancer is considered experimental.

Cochlear implant

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *Multiple**

A cochlear implant is a device for treatment of severe to profound hearing loss in individuals who only receive limited benefit from amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

The safety and effectiveness of U.S. Food and Drug Administration-approved bilateral and unilateral cochlear implants and associated hybrid cochlear implant devices have been established. The implants may be considered useful therapeutic options when indicated.

Cont.

Medical policy updates *Cont.*

Inclusions

Bilateral or unilateral cochlear implantation is considered an established, safe and effective therapy if all the following criteria are met:

- FDA-approved cochlear implant
- 12 months of age or older
- Bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss
  - Defined as a hearing threshold of pure-tone average of 70 dB hearing loss or greater at 500, 1000, 2000 Hz

Unilateral cochlear implantation is considered established, safe and effective therapy in single sided deafness (SSD)[a,b] when all the following are met:

- FDA-approved cochlear implant
- Age 5 and older
- Profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear
  - Profound hearing loss is defined as having a pure-tone average of 90dB hearing loss or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
    a. Individuals with single sided deafness or asymmetrical hearing loss must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals age 18 and older, limited benefit from unilateral amplification is defined by test scores of 5% correct or less on monosyllabic consonant-nucleus-consonant words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years old, insufficient functional access to sound in the ear to be implanted.
    b. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Replacement of internal and external components in a small subset of members may be considered established when all the following are met:

- There is an inadequate response to existing components to the point of:
  - Interfering with the individual's activities of daily living **or**
  - The components are no longer functional and cannot be repaired
- Copies of original medical records must be submitted either hard copy or electronically to support medical necessity.

Cochlear implant with a hybrid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (for example, the Nucleus® Hybrid L24 Cochlear Implant System) may be considered established for patients age 18 and older who meet all the following criteria:

- Bilateral severe-to-profound high frequency sensorineural hearing loss with residual low-frequency hearing sensitivity
- Receive limited benefit from appropriately fit bilateral hearing aids
- Have the following hearing thresholds:
  - Low frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation
  - Severe to profound mid-to-high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥75 dB hearing level) in the ear to be implanted
  - Moderately severe to profound mid-to-high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≤ 60 dB hearing level) in the contralateral ear
  - Aided consonant-nucleus-consonant word recognition score from 10% to 60% in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct

In certain situations, implantation may be considered before 12 months of age. One scenario includes post meningitis when cochlear ossification may preclude implantation. Another is in cases with a strong family history, because establishing a precise diagnosis is less uncertain.

Cont.

Medical policy updates *Cont.*

Contraindications to cochlear implantation may include deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem; active or chronic infections of the external or middle ear; and mastoid cavity or tympanic membrane perforation. Cochlear ossification may prevent electrode insertion, and the absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication.

Exclusions:

- Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model
- Replacement of internal or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device
- Non-FDA-approved devices

Implantable bone-conduction and bone-anchored hearing devices

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *69710, *69711, *69714, *69715, *69717, *69718, L8625, L8690, L8691, L8692, L8693, L8694**

External bone-conduction hearing devices function by transmitting sound waves through the bone to the ossicles of the middle ear. The external devices must be applied close to the temporal bone, with either a steel spring over the top of the head or a spring-loaded arm on a pair of spectacles.

The safety and effectiveness of unilateral or bilateral fully- or partially-implanted bone-conduction (bone-anchored) hearing aids have been established. They may be considered a useful therapeutic option when indicated.

The use of a Baha® Softband may be considered established in children age 5 and younger meeting criteria for bone-anchored hearing aid, or BAHA, treatment, but who are determined to have inadequate skeletal maturity to sustain osteointegration of the device.

Inclusions

Conductive hearing loss

Unilateral or bilateral fully- or partially-implantable bone-conduction (bone-anchored) hearing aids may be necessary as an alternative to an air-conduction hearing aid in patients age 5 and older with conductive or mixed hearing loss who also meet at least one of the following criteria:

- Congenital or surgically-induced malformations (atresia) of the external ear canal or middle ear
- Chronic external otitis or otitis media
- Tumors of the external canal or tympanic cavity
- Chronic dermatitis of the external canal prohibiting the usage of an air conduction hearing aid

In addition, the patient must meet the following audiologic criteria:

- A pure-tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz or better than or equal to 45 dB (Otomag Bone Conduction [OBC] and Baha BP100, Baha 4 and Baha 5 devices), 55 dB (Intenso device), or 65 dB (Cordele II and Baha 5 SuperPower devices).

For bilateral implantation, patients should meet the above audiologic criteria in both ears and have symmetrically conductive or mixed hearing loss as defined by a difference between left and right side bone-conduction threshold of less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz (4 kHz for OBC and Ponto Pro), or less than 15 dB at individual frequencies.

Sensorineural hearing loss**:

A unilateral implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction contralateral routing of signal hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. The pure-tone average air-conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz.

**The Audiant® bone conductor is a bone-conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.

Cont.

Medical policy updates *Cont.*

In patients being considered for implantable bone-conduction (bone-anchored) hearing aids, skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, patients (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

Exclusions:

Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered experimental.

Charged-particle (proton or helium ion) radiotherapy for neoplastic conditions

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *32701, *77300, *77520, *77523, *77522, *77525**

Charged-particle beams consisting of protons or helium ions are a type of particulate radiotherapy. They have several unique properties that distinguish them from conventional electromagnetic (photon) radiotherapy, including minimal scatter as particulate beams pass through tissue and deposition of ionizing energy at precise depths (for example, the Bragg peak). Thus, radiation exposure of surrounding normal tissues is minimized. The theoretical advantages of protons and other charged-particle beams may improve outcomes when the following conditions apply:

- Conventional treatment modalities do not provide adequate local tumor control.
- Evidence shows that local tumor response depends on the dose of radiation delivered.
- Delivery of adequate radiation doses to the tumor is limited by the proximity of vital radiosensitive tissues or structures.

Charged-particle irradiation with proton or helium ion beams may be considered established for specific patient populations. It's a useful therapeutic option when indicated.

If safe and effective, charged-particle irradiation with proton or helium ion beams may be open for consideration in the treatment of cancer based on the analysis of dosimetric data including comparative models if necessary.

Other applications of charged-particle irradiation with proton beams are considered experimental.

There's insufficient evidence to show that proton beam radiation therapy provides an incremental benefit in the treatment of localized prostate cancer when compared with lower cost alternative procedures.

Inclusions**:

Charged-particle irradiation with proton or helium ion beams is established for the following indications:

- In the treatment of intracranial arteriovenous malformation not amenable to surgical excision or other conventional forms of treatment or adjacent to critical structures such as the optic nerve, brain stem or spinal cord
- Primary or metastatic central nervous system malignancies, such as gliomas, when adjacent to critical structures such as the optic nerve, brain stem, or spinal cord and when other standard radiation techniques such as intensity-modulated radiation therapy or standard stereotactic modalities would not reduce the risk of radiation damage to the critical structure
- Post-operative therapy (with or without conventional high-energy X-rays) in patients who have undergone biopsy or partial resection of chordoma or low-grade (I or II), chondrosarcoma of the basisphenoid region (skull-base chordoma or chondrosarcoma), cervical spine, or sacral/lower spine. Patients eligible for this treatment have residual localized tumor without evidence of metastasis.
- Primary therapy for melanoma of the uveal tract (iris, choroid or ciliary body), with no evidence of metastasis or extrascleral extension and with tumors up to 24 mm in largest diameter and 14 mm in height, and particularly when plaque brachytherapy is not a feasible option
- In the treatment of all pediatric tumor types (through age 21)
- Repeat irradiation of previously treated fields where the dose tolerance of surrounding normal structures would be exceeded with 3D conformal radiation or IMRT

**Use of proton beam therapy may require prior authorization to verify that Blue Cross Blue Shield of Michigan and Blue Care Network criteria are met and, where appropriate, to explore the appropriateness of using alternative therapeutic modalities (for example, IMRT, 3-Dimensional Conformal Radiation Therapy).

Medical policy updates *Cont.*

Exclusions:

- All other applications of charged-particle irradiation including, but not limited to, clinically localized prostate cancer, non-small cell lung cancer at any stage or for recurrence, breast cancer, pancreatic cancer and hepatocellular carcinoma are experimental.
- Proton beam therapy for the treatment of macular degeneration or choroidal neovascularization and hemangiomas is excluded.

Skin and tissue substitutes

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *Multiple**

Bioengineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials.

The safety and effectiveness of skin and tissue substitutes approved by the U.S. Food and Drug Administration and the Centers for Medicare & Medicaid Services have been established for patients meeting specified selection criteria. They may be useful therapeutic options when indicated.

Human tissue products are subject to the rules and regulations of banked human tissue by the American Association of Tissue Banks. EpiFix is an amniotic membrane allograft that is established for the treatment of neuropathic diabetic foot ulcers and venous stasis ulcers that have failed to respond to conservative measures.

Inclusions

The following skin and tissue substitutes are considered established as they have been approved by the FDA. This list may not be all-inclusive:

- Apligraft®
- Biobrane®
- Cytal® Burn Matrix
- Cytal® MicroMatrix™
- Cytal® Wound Sheet
- Derma-Gide
- Dermagraft®
- Endoform Dermal Template™
- Epicel® has FDA Humanitarian Device Approval
- E-Z Derm™
- Hyalomatrix®
- Integra® Bilayer Matrix
- Integra® Dermal Regeneration Template
- Integra® Flowable Wound Matrix
- MediSkin®
- Oasis® Burn Matrix
- Oasis® Ultra Tri-Layer Wound Matrix
- Oasis® Wound Matrix
- OrCel®
- Permacol™ (Covidien)
- PriMatrix™
- PuraPly Wound Matrix (PuraPly)
- PuraPly Antimicrobial Wound Matrix (PuraPly AM)
- Strattice™
- Suprathel®
- SurgiMend®
- Talymed™
- TenoGlide™
- TheraSkin®
- TransCyte®

Breast reconstructive surgery using allogeneic acellular dermal matrix productsa (including each of the following: AlloDerm®, AlloMend®, Cortiva®, [AlloMax™], DermACELL™, DermaMatrix™, FlexHD®, FlexHD® Pliable™, Graftjacket®) are considered established when **one** of the following is met:

- There is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required.
- There is viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis.
- The inframammary fold and lateral mammary folds have been undermined during mastectomy and reestablishment of these landmarks is needed.

Various acellular dermal matrix products used in breast reconstruction have similar efficacy. The products listed are those that have been identified for use in breast

Cont.

Medical policy updates *Cont.*

reconstruction. Additional acellular dermal matrix products may become available for this indication.

Treatment of chronic, noninfected, full-thickness diabetic lower extremity ulcers is established when using the following tissue engineered skin substitutes:

- AlloPatch®[a]
- Apligraft®[b]
- Dermagraft®[b]
- GraftJacket® Regenerative Tissue Matrix-Ulcer Repair
- Integra®, Omnigraft™ Dermal Regeneration Matrix (also known as Omnigraft™) and Integra Flowable Wound Matrix
- Theraskin®

Treatment of chronic, noninfected, partial- or full-thickness lower-extremity skin ulcers due to venous insufficiency, which have not adequately responded following a one-month period of conventional user therapy is established when using the following tissue-engineered skin substitutes:

- Aplifraf®[b]
- Oasis™ Wound Matrix[c]
- Theraskin®

OrCel™ is considered established when all the following criteria are met:

- Used for the treatment of dystrophic epidermolysis bullosa
- Used for the treatment of mitten-hand deformity
- Standard wound therapy has failed
- Provided in accordance with the humanitarian device exemption specifications of the U.S. Food and Drug Administration

The following skin and tissue products and substitutes are considered established for use in the treatment of second- and third-degree burns:

- Alloderm
- Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30% when provided in accordance with the HDE specifications of the FDA)[d]
- Integra® Dermal Regeneration Template[b].

[a] Banked human tissue
[b] FDA premarket approval
[c] FDA 510(k) clearance
[d] FDA-approved under an HDE

Exclusions:

All other uses of bioengineered skin and soft tissue substitutes listed above unless they meet the following criteria:

- FDA approval and provided in accordance with the FDA guidelines
- Covered by Centers for Medicare & Medicaid Services

All other skin and soft tissue substitutes, including, but not limited to:

- ACel® UBM Hydrated/Lyophilized Wound Dressing
- AlloSkin™
- AlloSkin™ RT
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX
- ArthroFlex™ (Flex Graft)
- Atlas Wound Matrix
- Avagen Wound Dressing
- AxoGuard® Nerve Protector (AxoGen)
- BellaCell HD or SureDerm®
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Coll-e-Derm
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- Cymetra™ (Micronized AlloDerm™)
- Dermadapt™ Wound Dressing
- DermaPure™
- DermaSpan™
- DressSkin
- Durepair Regeneration Matrix®
- ENDURAGen™

Cont.

Medical policy updates *Cont.*

- Excellagen
- ExpressGraft™
- FlexiGraft®
- GammaGraft
- Graftjacket® Xpress, injectable
- Helicoll™
- hMatrix®
- Keramatrix®
- Kerecis™
- MariGen™/Kerecis™ Omega3™
- MatriDerm®
- Matrix HD™
- MemoDerm™
- Microderm® biologic wound matrix
- MyOwn Skin™
- NeoForm™
- NuCel
- Pelvicol®/PelviSoft®
- Progenamatrix™
- PuraPly XT
- Puros® Dermis
- RegenePro™
- Repliform®
- Repriza™
- SkinTE™
- StrataGraft®
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- TruSkin™
- Veritas® Collagen Matrix
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB.

Closure devices for patent foramen ovale and atrial septal devices

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan notification**
- **Procedure codes: *93580, *93799, *33999**

Patent foramen ovale, or PFO, and atrial septal defects are relatively common congenital heart defects that can be associated with a range of symptoms. PFOs may be asymptomatic but have been associated with higher rates of cryptogenic stroke. PFOs have also been investigated for a variety of other conditions, such as a migraine. Depending on their size, atrial septal defects may lead to left-to-right shunting and signs and symptoms of pulmonary overload. Repair of atrial septal defects is indicated for patients with a significant degree of left-to-right shunting. Transcatheter closure devices have been developed to repair PFO and atrial septal defects. These devices are alternatives to open surgical repair for ASDs or treatment with antiplatelet and/or anticoagulant medications in patients with cryptogenic stroke and PFO.

Closure of patent foramen ovale, using an FDA-approved device according to the labeled instructions, for a percutaneous transcatheter approach, may be considered established when specified criteria are met.

Transcatheter closure of secundum atrial septal defects may be considered established when using a device that has been FDA approved for that purpose and used according to the labeled indications.

Inclusions:

Closure of patent foramen ovale using a percutaneous transcatheter approach, with an FDA approved device per labeled instructions, when all of the following are met:

- It's used to reduce the risk of recurrent ischemic stroke
- Patient is predominantly between ages 18 and 60
- Echocardiography confirms diagnosis of patent foramen ovale with a right-to-left interatrial shunt
- Documented history of cryptogenic ischemic stroke or TIA due to presumed paradoxical embolism as determined by a neurologist **and** cardiologist

Cont.

Medical policy updates *Cont.*

- Any other identifiable cause of stroke has been excluded including:
  - Large vessel atherosclerotic disease
  - Small vessel occlusive disease
- **None** of the following are present:
- Uncontrolled vascular risk factors including:
  - Uncontrolled diabetes mellitus
  - Uncontrolled hypertension
- Other sources of right-to-left shunts including:
  - Atrial septal defect
  - Fenestrated septum
- Active endocarditis or other untreated infections
- Inferior vena cava filter

Closure of atrial septal defects with an FDA-approved device, per labeled instructions, when **both** of the following are met:

- There is echocardiographic evidence of ostium secundum atrial septal defect.
- There is evidence of right ventricular volume overload or paradoxical embolism.

Exclusions:

- Patent foramen ovale with recurrent cryptogenic migraine
- Closure of a septal defect when performed using the transmyocardial approach
- Open surgery is needed to repair multiple congenital defects or other cardiac defects
- Multiple cardiac defects that cannot be covered by the device

Magnetic resonance-guided focused ultrasound

- **Revised policy**
- **Effective date: March 1, 2020**
- **Plan approval with clinical review**
- **Procedure codes: *76999, *0398T**

MRgFUS is a noninvasive treatment that combines two technologies, focused ultrasound and magnetic resonance imaging. The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures.

The safety and effectiveness of magnetic resonance-guided high-intensity ultrasound ablation has been established. It may be a considered a useful therapeutic option in specified situations.

Inclusions:

- Pain palliation in adult patients with metastatic bone cancer who fail or are not candidates for radiotherapy
- Treatment of medicine-refractory essential tremors (for example, a failure, intolerance or contraindication to at least two trials of medication therapy)

Exclusions:

All other situations including but not limited to:

- Treatment of uterine fibroids
- Treatment of other tumors (for example, brain cancer, prostate cancer, breast cancer, desmoid)

Drug testing in pain management and substance use disorders treatment

- **Revised policy**
- **Effective date: March 1, 2020**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *80305 -*80307, *80320 - *80377, *83992 (for reporting purposes), G0480 - G0483, G0659**

Various strategies are available to monitor pain and patients with substance use disorders; multicomponent interventions are often used. One such strategy for monitoring patients is testing of biologic specimens for the presence or absence of drugs.

Testing guidelines

How clinicians order urine drug tests will vary depending on the clinical scenario of the individual and the purpose for the testing. National provider organizations have discouraged establishing limits on the frequency of testing and the number of tests allowed in a benefit year out of concern that such limits will potentially undermine physician management and be a barrier to medically necessary testing. Most guidelines suggest that testing in the initial phase of substance use disorder treatment be performed weekly. And as the

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Medical policy updates *Cont.*

individual's circumstances stabilize, testing may progress to monthly and then less frequently. Based on plan data, it's extremely unlikely that an individual would require more than a combined total of 25 presumptive and definitive tests in a year.

A definitive drug test is medically necessary and clinically justified when the results of *presumptive* testing have been evaluated and support that follow-up *definitive* testing will contribute to clinical decision-making. Routine definitive drug testing that is ordered automatically, independent of an analysis of presumptive testing, is not medically necessary. A definitive drug test that is performed without consideration of a patient's specific circumstances is not medically necessary. The medical record should support the rationale for testing; this record may be assessed as part of a retrospective review or audit.

Presumptive and definitive drug testing in the outpatient setting may be considered established when criteria are met.

Inclusionary and exclusionary guidelines (clinically based guidelines that may support individual consideration and prior authorization decisions)

This policy addresses drug testing in an outpatient setting.

The policy does not apply to drug testing in emergency department, acute inpatient medical or behavioral health facility settings, or testing ordered by or on behalf of a provider or facility that receives per-diem reimbursement which includes clinical diagnostic laboratory testing (skilled nursing facility).

Inclusions:

A. Presumptive drug testing

- For outpatient pain management, presumptive drug testing is considered established in:
  - Baseline screening at the initiation of treatment
  - Subsequent monitoring of treatment at an appropriate frequency based on the risk level of the individual, including assessment of aberrant behavior
- For outpatient substance use disorder treatment, presumptive drug testing is considered established in:
  - Baseline screening at the initiation of treatment
  - Subsequent screening, based on the risk level of the individual and the substance being used
- For an individual not participating in outpatient pain management or outpatient substance use disorder treatment:
  - When a clinical evaluation suggests use of non-prescribed medications, illegal or other substances

B. Definitive / Confirmatory drug testing

- Definitive drug testing is considered established:
  - When immunoassays for the relevant drugs are not commercially available
  - In situations where definitive drug levels are required for clinical decision-making (for example, unexpected positive test that is inadequately explained by the patient, unexpected negative test, quantitative levels are needed to determine clinical treatment)

Exclusions:

- Drug testing as a third-party requirement (for example, for employment, licensing, court order)
- Simultaneously testing for the same drug with two specimens from different sources (for example, blood and urine)

Policy guidelines

One presumptive and one definitive test code may be billed per date of service.

Billing guidelines — Definitive drug testing

Bill G0480-G0483, G0659 as appropriate, for the number of drug classes tested.

Bill *80XXX and *83992 to report the appropriate drug or metabolite testing. The codes are no longer individually reimbursed for the purpose of this policy; however, we request that they're reported with the appropriate G code.

Contracted laboratories

Providers should select contracted laboratories for the processing of drug tests. Referring a member to a non-participating laboratory may result in unnecessary services (such as processing tests not originally ordered) and greater financial liability for the member. The referring provider may be held accountable for any inappropriate behavior on the part of the non-participating laboratory.

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