JULY–AUGUST 2019

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 service

Breast elastography – Ultrasound or magnetic resonance

- **New policy**
- **Effective date: July 1, 2019**
- **Procedure codes: *76391, *76981, *76982, *76983**

Elasticity is the property of a substance to be deformed in response to an external force and to resume its original size and shape when the force is removed. In evaluation of superficial tissue such as skin, breast or prostate, manual palpation can distinguish normal tissue from stiffer tissue. Elastography is a noninvasive technique that evaluates the elastic properties or stiffness of tissues. Its application for diagnosing breast cancer is based on the principle that malignant tissue is less elastic than normal, healthy breast tissue. Elastography has been investigated as an additive technique to increase the specificity of ultrasound and magnetic resonance imaging.

Breast elastography by ultrasound or magnetic resonance is considered experimental. There is insufficient evidence that elastography is effective in the screening or diagnosis of breast cancer.

Covered services

Closure devices for patent foramen ovale and atrial septal defects

- **Revised policy**
- **Effective date: July 1, 2019**
- **Plan notification, Plan approval with clinical review**
- **Procedure codes: *93580, *33999, *93799**

Patent foramen ovale

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Before birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over a course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in the permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale, or PFO, is a common finding in normal adults, detected in up to 25% of asymptomatic adults.

In some epidemiologic studies, PFO has been associated with cryptogenic stroke, a type of stroke defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular or neurologic sources. Studies also show an association of PFO and migraine headache. There has been interest in either open surgery or transcatheter approaches to close the PFO in patients with a history of cryptogenic stroke to prevent recurrent stroke.

Cont.

 R089640

Medical policy updates *Cont.*

Atrial septal defect

Unlike PFO, which represents the postnatal persistence of normal fetal cardiovascular physiology, atrial septal defects, or ASDs, represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized by their anatomy. Ostium secundum describes defects located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and are within the spectrum of atrioventricular septal defects. Primum defects occur commonly in patients with Down syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins.

Closure of patent foramen ovale using 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 using AMPLATZER™ PFO Occluder when **all** of the following are met:

- Used to reduce the risk of recurrent ischemic stroke
- Patient is between 18 and 60 years of age
- Echocardiography confirms diagnosis of patent foramen ovale with a right-to-left interatrial shunt
- Documented history of cryptogenic ischemic stroke due to presumed paradoxical embolism as determined by a neurologist and cardiologist:
  - 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 when all of the following are met:

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

Exclusions:

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

* Available evidence does not support that PFO closure definitively improves outcomes in patients at risk of cryptogenic stroke. However, in selected PFO cases where a patient has suffered a stroke while on maximum recommended anticoagulant therapy and the attending physician feels the PFO represents a continuing risk of paradoxical embolization, individual consideration for PFO closure may be extended.

Cont.

Medical policy updates *Cont.*

Gait analysis

- **Revised policy**
- **Effective date: July 1, 2019**
- **Referral required**
- **Procedure codes: *96000 - 96004**

Comprehensive gait analysis, also known as motion analysis, is the quantitative assessment of coordinated muscle function. Evaluation is conducted in a laboratory and typically involves a dedicated facility and staff. A visual assessment of walking is supplemented by video recording. Joint angles and various time-distance variables, including step length, stride length, cadence, and cycle time, can be measured. Electromyography, assessed during walking, measures timing and intensity of muscle contractions. The combined calculations are used to determine whether a certain muscle's activity is normal, out of phase, continuous or clonic.

The safety and effectiveness of comprehensive gait analysis (the use of sophisticated quantitative and video capture devices) have been established. It may be considered a useful diagnostic option in specified situations.

Inclusions:

- As an aid in surgical planning in patients with gait disorders associated with cerebral palsy

Exclusions:

- Surgical planning for conditions other than gait disorders associated with cerebral palsy
- Postoperative evaluation of surgical outcomes
- Rehabilitation evaluation or planning for all conditions
- Gait analysis that is not comprehensive

Genetic testing for the diagnosis of inherited peripheral neuropathies

- **Revised policy**
- **Effective date: July 1, 2019**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *81324-81326, *81403-80406, *81448, *81479**

Inherited peripheral neuropathies are the most common inherited neuromuscular disease. They are divided into the hereditary motor and sensory neuropathies, hereditary neuropathy with liability to pressure palsies (HNPP), and other miscellaneous, rare types (for example, hereditary brachial plexopathy, hereditary sensory autonomic neuropathies).

A genetic etiology of a peripheral neuropathy is typically suggested by generalized polyneuropathy, family history, lack of positive sensory symptoms, early age of onset, symmetry, associated skeletal abnormalities, and a very slow, progressive clinical course.

The safety and effectiveness of genetic testing for inherited peripheral neuropathies have been established. It may be considered a useful diagnostic option for patients meeting the specified selection criteria.

Inclusions:

Genetic testing for an inherited peripheral neuropathy is considered established under both the following conditions:

- The diagnosis of an inherited peripheral motor or sensory neuropathy is suspected due to clinical signs and symptoms, but a definitive diagnosis cannot be made
- The following testing strategy is utilized:
  - Initial genetic testing of *PMP22* (duplications or deletions), *GJB1* (Cx32) and *MFN2*.
    - If *PMP22* or *GJB1* or *MFN2* is **positive**, no further testing is indicated.
    - If *PMP22*, *GJB1* and *MFN2* are **negative**, test for the genomic sequence analysis panel that includes at least five peripheral neuropathy-related genes (for example, *BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1*).

Exclusions:

- Genetic testing for an inherited peripheral neuropathy is excluded for all other indications.

Cont.

Medical policy updates *Cont.*

Genetic testing-expanded molecular panel testing of cancers to identify targeted therapies

- **Revised policy**
- **Effective date: July 1, 2019**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *81445, *81450**

Tumor location, grade, stage and the patient's underlying physical condition have traditionally been used in clinical oncology to determine the therapeutic approach to a specific cancer. However, this traditional approach to cancer treatment does not reflect the wide diversity of cancer at the molecular level. Some individual genetic markers and variants have established utility, and there are medical policies addressing their utility. This policy addresses expanded panels of five to 50 genes for potential variants.

Molecular panel testing may be considered established as a useful diagnostic option when specific criteria are met.

Inclusions:

Testing for appropriate actionable genomic alterations that influence therapy may be performed through a panel test for the following conditions:

- Non-small-cell lung cancer
- Colorectal cancer
- Cutaneous melanoma
- Gastrointestinal stromal tumor
- Glioma
- Thyroid cancer
- Acute myeloid leukemia

Exclusions:

Molecular panel testing for conditions other than those listed in the Inclusions section is considered experimental.

Drug testing of urine, oral fluids and hair

- **New policy**
- **Effective date: May 1, 2019**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *80305 – 80307, *80320 – 80377, *83992 (for reporting purposes), G0480 – G0483, G0659**

The American Society of Interventional Pain Physicians reports that approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them. Substance use disorder is defined as the recurrent use of alcohol or drugs that causes clinically and functionally significant physical or mental impairment, disability, or failure to meet major responsibilities at work, school or home. A diagnosis of substance use disorder is made when there is evidence of impaired control, social impairment, risky use and pharmacological criteria.

Various strategies are available to monitor pain management and substance use disorder treatment in patients, and multicomponent interventions are often used. One such strategy for monitoring patients is testing of biologic specimens for the presence or absence of drugs. Currently, urine is the most commonly used biologic substance.

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

Cont.

Medical policy updates *Cont.*

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; and, this record may be assessed as part of a retrospective review or audit.

Inclusionary and exclusionary guidelines (Clinically-based guidelines that may support individual consideration and pre-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 (for example, skilled nursing facility).

Inclusions:

A. Presumptive urine drug testing
   - For **outpatient pain management**, presumptive urine 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 urine drug testing is considered established in:
     - Baseline screening at the initiation of treatment, one time per program entry
     - Weekly screening during the first four weeks of treatment
     - Subsequent targeted screening once every one to three months
   - 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 or illegal substances

B. Definitive/ confirmatory urine drug testing
   - Definitive urine 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:

- Urine drug testing as a third-party requirement (for example, for employment, licensing, court order)
- Simultaneously testing for the same drug with both a blood and a urine specimen

Oral fluid drug testing and hair drug testing are considered experimental.

Policy guidelines

Contracted laboratories

Providers should select contracted laboratories for the processing of urine 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.

Genetic testing for myotonic dystrophy

- **Revised policy**
- **Effective date: July 1, 2019**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *81187, *81234, *81239, *S3853**

Muscular dystrophy refers to a group of more than 30 inherited diseases that cause progressive muscle weakness and muscle loss. Myotonic dystrophy, or DM, is a type of muscular dystrophy and has two forms, Type 1 (DM1) and Type 2 (DM2). It is the most common form of adult-onset muscular dystrophy.

Genetic testing for the presence of myotonic dystrophy Type I (DM1) and Type 2 (DM2) has been established. It may be considered a useful diagnostic option when indicated.

Cont.

Medical policy updates *Cont.*

Inclusions:

Genetic testing for DM1 (*DMPK* gene) and DM2 (*CNBP* / *ZNF9* gene) is considered established when the following are met:

- The member displays clinical features suggestive of myotonic dystrophy Type 1 (DM1) or Type 2 (DM2); and:
  - The result of the test will directly impact the treatment being delivered; or
  - The member is at risk of inheriting the mutation; or
- For prenatal diagnosis or preimplantation genetic diagnosis of DM1 or DM2

Growing rods for scoliosis (for example, MAGEC® spinal bracing and distraction system)

- **New policy**
- **Effective date: July 1, 2019**
- **Plan approval with clinical review**
- **Procedure code: *22899**

Spinal deformities result from an abnormal formation or alignment of the vertebral column. Scoliosis is a common musculoskeletal disorder characterized by abnormal lateral curvature of the spine measuring more than 10° in the coronal plane. The spinal curvature may develop in a single curve or as two curves. The several types of scoliosis are characterized by age of onset, etiology, severity and type of spinal curve. Adolescent idiopathic scoliosis, or AIS, is the most prevalent form of scoliosis, affecting approximately 0.5% to 5% of children in the United States, accounting for 80% to 85% of all scoliosis cases. In children and teens, scoliosis often doesn't cause any noticeable symptoms and may not be apparent until it has progressed significantly.

Treatment depends on a variety factors including, but not limited to, etiology, severity of the spinal curve, curve pattern and remaining growth of the patient. Traditional conservative treatment for scoliosis involves observation or use of a supportive brace, which is recommended when a child's bones are still growing or in cases of moderate scoliosis. Surgery may be recommended in patients that exhibit progressive deformity and in adolescents with a Cobb angle more than 45° to 50°. Scoliosis of this severity may be associated with heart and lung problems in childhood, which may become increasingly problematic in adulthood. However, surgery is not without its risks. Not only is there a high risk for neurological impairment arising from surgery; it also leads to frequent hospitalizations, increase costs and negatively affects quality of life.

The MAGEC® Spinal Bracing and Distraction System is comprised of a sterile single use spinal rod that can be surgically implanted. The implanted MAGEC rod is used to brace the spine during growth to minimize the progression of scoliosis. The system includes a non-sterile hand-held external remote controller (ERC or ERC 2) that is used periodically after implantation to non-invasively distract the implanted spinal rod. The titanium MAGEC rod includes an actuator portion that holds a small internal magnet. The magnet in the actuator can be turned non-invasively by use of the ERC, which is electrically powered. The hand-held non-invasive ERC is placed over the patient's spine and then manually activated, which causes the magnet within the implanted MAGEC rod to rotate and distract. Once the physician determines that the implant has achieved its intended use and is no longer required, the device is explanted.

The safety and effectiveness of FDA-approved growing rods in the treatment of early onset scoliosis have been established. It may be considered a useful therapeutic option when indicated.

Inclusions:

Use of FDA-approved growing rods in the treatment of early onset scoliosis may be a therapeutic option when:

- Skeletally immature patients less than 10 years of age
- Severe progressive spinal abnormalities (for example, Cobb angle of 30° or more)
- Thoracic spine height less than 22 cm
- Associated with or at risk of Thoracic Insufficiency Syndrome (TIS)*

*TIS is defined as the inability of the thorax to support normal respiration or lung growth.

Exclusions:

When the above criteria are not met.