JANUARY–FEBRUARY 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 services

Gene expression profiling for cutaneous melanoma

- **New policy**
- **Effective date: Jan. 1, 2019**
- **Procedure codes: *81479, *81599, *84999,**

Cutaneous melanoma accounts for more than 90 percent of cases of melanoma. For many decades, melanoma incidence was rapidly increasing in the United States. However, recent estimates have suggested the rise may be slowing. In 2018, more than 90,000 new cases of melanoma are expected to be diagnosed, and more than 9000 people are expected to die of melanoma.

Primary care providers evaluate suspicious pigmented lesions to determine who should be referred to dermatology. Factors considered include both a patient's risk for melanoma as well as a visual examination of the lesion. The visual examination assesses whether the lesion has features suggestive of melanoma.

Criteria for features suggestive of melanoma have been developed. One checklist is the ABCDE checklist[11]:

- Asymmetry
- Border irregularities
- Color variegation
- Diameter ≥6 mm
- Evolution

Another criterion commonly used is the "ugly duckling" sign. An ugly duckling is a nevus that is obviously different from others in a given patient. Primary care providers generally have a low threshold for referral to dermatology.

Wide local excision is the definitive surgical treatment of melanoma. Following surgery, patients with American Joint Committee on Cancer stage I or II (node-negative) melanoma do not generally receive adjuvant therapy. Patients with higher risk melanoma receive adjuvant immunotherapy or targeted therapy.

Gene expression profiling measures the activity of thousands of genes simultaneously and creates a snapshot of cellular function. Data for gene expression profiles are generated by several molecular technologies including DNA microarrays that measures activity relative to previously identified genes and RNA-Seq that directly sequences and quantifies RNA molecules. Clinical applications of gene expression profiling may include disease diagnosis, disease classification, prediction of drug response and prognosis. Currently there is not an explicated, evidence-based management pathway for the use of the test. The evidence is insufficient to determine the effects of the technology on health outcomes.

The peer reviewed medical literature has not demonstrated the clinical utility of gene expression profiling for cutaneous melanoma. Therefore, this service is experimental.

Cont.

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Medical policy updates *Cont.*

Lumbar traction devices for the treatment of low back pain

- **New policy**
- **Effective date: Jan. 1, 2019**
- **Procedure codes: *E0830, *E0941, *E1399**

Traction is the use of a pulling force to treat muscle and skeletal disorders. Lumbar traction has historically been used to treat low back pain in conjunction with other treatment modalities in an outpatient setting as part of a directly supervised physical therapy regimen. Typically, these modalities are used short term. Types of traction include continuous/intermittent traction, mechanical traction, manual traction (unspecific or segmental traction), autotraction, gravity-dependent traction and pneumatic traction.

Continuous/intermittent traction

Continuous spinal traction is applied for up to several hours at a time with the use of a small weight. Intermittent traction is similar to continuous traction but alternately applies and releases the traction force at certain intervals.

Manual/mechanical traction

Manual traction is a technique in which a therapist uses his or her hands to perform spinal decompression. The therapist provides a very specific and controlled distraction force to the spine or joint to alleviate pain or compression. Mechanical traction involves a mechanical device with traction alternately applied and withdrawn every few seconds. This is probably the most popular form of traction in use. Some examples of mechanical traction devices include the Chattanooga® New Lumbar Home Traction, Saunders® Lumbar Hometrac and the Enshey™ Traction Bed.

Autotraction

Autotraction is defined as the use of one's own weight to create the traction force (the patient determines the traction force). By utilizing positional and gravity-assisted traction principles, autotraction can provide multi-plane traction. Some of the brand names of these devices include the Spinalator Spinalign® massage intersegmental traction table, the Arthrotonic stabilizer™, the Quantum 400™ intersegmental traction table and the Anatomotor™.

Gravity-dependent traction

Axial spinal unloading devices (gravity-dependent traction (axial spinal unloading devices) are designed to support the upper body's weight and transfer that weight to the hips via a mechanical or pneumatic mechanism. Patient-operated spinal unloading has been suggested as a conservative treatment for pain related to spinal disc disease or joint dysfunction. Several patient-operated spinal unloading devices are currently available on the market, including the Orthotrac Pneumatic Vest™ (manufactured by Kinesis Medical, Minneapolis, MN) and the LTX 3000™ (manufactured by Spinal Designs International, Minneapolis, MN).

Pneumatic traction

Pneumatic home lumbar traction devices have been developed which manufacturers claim can apply up to 200 pounds of traction force. Examples of these pneumatic devices include autotraction devices include the Spinalator Spinalign® massage intersegmental traction table, the Arthrotonic stabilizer™, the Quantum 400™ intersegmental traction table and the Anatomotor™.

These devices are said to mimic the traction offered in a clinical setting by providing a friction-free split surface that actively moves, enabling vertebral separation by inducing a pulling force. It's suggested that when using these devices, the patient can be positioned so that the lumbar curve is in any degree of flexion, neutral or in extension. Each of these devices has both a patient-controlled pressure valve that limits the amount of force transmitted to the user and a hand-held pump for immediate release of pressure.

The use of mechanical, autotraction, gravity-dependent (axial spinal unloading) and pneumatic lumbar traction devices are experimental in any setting. These devices have not been scientifically demonstrated to be safe and effective for the treatment of low back pain, herniated disc or other indications and have not been shown to improve patient outcomes.

Exclusions:

Non-established lumbar traction devices include, but are not limited to:

- Pneumatic lumbar traction devices (for example, Saunders® Lumbar HomeTrac, Saunders® STx, Orthotrac Pneumatic Vest™).
- Autotraction devices (for example, the Spinalator Spinalign® massage intersegmental traction table, the Arthrotonic stabilizer™, the Quantum 400™ intersegmental traction table and the Anatomotor™)
- Axial spinal unloading (gravity-dependent traction) devices (LTX 3000).
- Conventional lumbar traction using a pelvic harness attached to pulleys and weights, now considered to be obsolete
- Mechanical traction devices (Chattanooga® New Lumbar Home Traction, Saunders® Lumbar Hometrac and the Enshey™ Traction Bed)

Cont.

Medical policy updates *Cont.*

Polymerase chain reaction (PCR) testing in the diagnosis of onychomycosis

- **New policy**
- **Effective date: Jan. 1, 2019**
- **Referral required; Plan approval with clinical review; Use appropriate contracted vendor**
- **Procedure codes: *81400, *81401, *81402, *81403, *81404, *81405, *81406, *81407, *81479, * 87798, *87801**

Polymerase chain reaction assays have been developed to detect fungal DNA from infected nails. PCR is a technique that permits the amplification of very short sections of DNA (or RNA) into very large numbers of the same sequence. Thousands to millions of copies of a particular DNA (or RNA) sequence can be generated, allowing for identification of dermatophytes and non-dermatophytes in just a few hours.

Polymerase chain reaction for the diagnosis of onychomycosis is experimental. There is insufficient scientific evidence in the current medical literature to indicate that this technology is as beneficial as the established alternatives.

Covered services

Bone marrow transplant – hematopoietic cell transplantation for acute myeloid leukemia

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **Plan notification; Plan approval with clinical review**
- **Procedure codes: Multiple**

Acute myeloid leukemia refers to leukemias that arise from a myeloid precursor in the bone marrow. There is a high incidence of relapse, which has prompted research into various post-remission strategies using either allogeneic (allo-) or autologous hematopoietic cell transplantation, or HCT. HCT refers to a procedure that infuses hematopoietic stem cells to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of drugs with or without whole-body radiotherapy.

The safety and effectiveness of hematopoietic cell transplantation for acute myeloid leukemia has been established. It may be considered a useful therapeutic option for patients meeting specified guidelines.

Inclusions:

- ***Allogeneic*** hematopoietic cell transplantation (HCT) using a myeloablative conditioning regimen for patients with either:
  - Poor- to intermediate-risk AML in first complete remission (CR1) (see Policy Guidelines for information on risk stratification)
  - AML that is refractory to standard induction chemotherapy but can be brought into CR with intensified chemotherapy (Note: Primary refractory acute myeloid leukemia [AML] is defined as leukemia that does not achieve a complete remission after conventionally dosed [non-marrow ablative] chemotherapy)
  - AML that relapses following chemotherapy-induced CR1 but can be brought into CR2 or beyond with intensified induction chemotherapy
  - AML in patients who have relapsed following a prior autologous HCT but can be brought into CR with intensified induction chemotherapy and are medically able to tolerate the procedure
  - AML in patients who have relapsed more than six months post allogeneic hematopoietic cell transplantation
  - AML in patient when the first allogeneic hematopoietic cell transplantation was unsuccessful due to primary graft failure
- ***Allogeneic*** hematopoietic cell transplantation (HCT) using a *reduced-intensity conditioning* regimen in patients with:
  - AML who are in complete marrow and extramedullary remission (CR1 or beyond), and who for medical reasons would be unable to tolerate a myeloablative conditioning regimen (See Policy Guidelines section.)
  - AML in patients who have relapsed more than six months post allogeneic hematopoietic cell transplantation
  - AML in patient when the first allogeneic hematopoietic cell transplantation was unsuccessful due to primary graft failure
- ***Autologous*** hematopoietic stem-cell transplantation (HCT) in patients with either:
  - AML in CR1 or beyond
  - Relapsed AML if responsive to intensified induction chemotherapy

Exclusions:

All other indications not specified under the inclusions.

Cont.

Medical policy updates *Cont.*

Coronary computed tomography angiography with selective noninvasive fractional flow reserve (FFRCT)

- **New policy**
- **Effective date: Jan. 1, 2019**
- **Use appropriate contracted vendor**
- **Procedure codes: *75574, *0501T, *0502T, *0503T, *0504T**

Invasive coronary angiography, or ICA, is clinically useful in stable ischemic heart disease, or SIHD, when there is coronary artery obstruction that may benefit from revascularization. However, many individuals currently undergoing ICA will not benefit from revascularization. Therefore, if there are noninvasive alternatives to guide decisions about the use of ICA to spare individuals from undergoing unnecessary ICA, there is potential to improve health outcomes. Using noninvasive measurement of fractional flow reserve as part of a noninvasive imaging strategy prior to ICA may be beneficial to avoid the need for ICA.

For individuals with stable chest pain at intermediate risk of coronary artery disease (for example, suspected or presumed stable ischemic heart disease) being considered for ICA who receive noninvasive fractional flow reserve (or, FFR) measurement following coronary computed tomography angiography, the evidence includes both direct and indirect evidence. The available evidence provides support that use of CCTA with selective FFR-CT is likely to reduce the use of ICA in individuals with stable chest pain who are unlikely to benefit from revascularization by demonstrating the absence of functionally significant obstructive CAD. In addition, the benefits are likely to outweigh potential harms because rates of revascularization for functionally significant obstructive CAD appear to be similar and treatment-related adverse events do not appear to increase following CCTA with a selective FFR-CT strategy. In aggregate, the evidence provides reasonable support that the selective addition of FFR-CT following CCTA results in a meaningful improvement in the net health outcome. The evidence is sufficient to determine that the technology results in meaningful improvements in the net health outcome.

The use of noninvasive fractional flow reserve to guide decisions about the use of invasive coronary angiography in select patients has been established. It is a useful diagnostic option when indicated.

Inclusions:

Patients must meet *both* criteria below:

- Have stable chest pain
- Have intermediate risk of coronary artery disease (suspected or presumed stable ischemic heart disease)

In addition:

- Diagnosis of congestive heart failure/cardiomyopathy/left ventricular dysfunction when all the following are met:
  - Left ventricular ejection fraction < 55%
  - Low to moderate coronary heart disease risk[a]
  - Coronary artery disease has not been excluded as the etiology of the cardiomyopathy ***or***
- Symptomatic[b] or asymptomatic patients undergoing non-coronary surgery (including open and percutaneous valvular procedures or ascending aortic surgery)
  - All the pre-operative information can be obtained using cardiac CT ***and***
  - Moderate coronary heart disease risk[a] ***or***
- Symptomatic[b] patients who are suspected of having coronary artery disease and meet ***one*** of the following:
  - During a planned outpatient exercise stress test (without imaging) ***all*** the following apply:
    - Performed within the past 60 days
    - Patient is symptomatic[b]
    - During the test ***one*** of the following occurred:
      - » Exercise-induced chest pain
      - » ST segment change
      - » Abnormal blood pressure response
      - » Complex ventricular arrhythmias or
  - Have undergone *either* myocardial perfusion imaging or a stress echocardiogram within the past 60 days and imaging is ***one*** of the following:
    - Neither normal or abnormal
    - Abnormal ***or***
  - No coronary artery disease imaging has been performed within the preceding 60 days (Myocardial perfusion imaging, cardiac PET scan, stress echo or coronary angiogram)

Cont.

Medical policy updates *Cont.*

- Symptomatic[b] patient with abnormal resting EKG
  - Exercise stress test (without imaging) would be uninterpretable related to one of the following:
    - Left bundle branch block
    - Paced ventricular rhythm
    - Left ventricular hypertrophy with repolarization abnormalities
    - Resting ST segment depression
      - » ≥ 1 mm
    - Digoxin effects as evidence by one of the following:
      - » ST depression in a concave shape
      - » Flattened, inverted, or biphasic T waves
      - » Shortened QT interval
    - Pre-excitation syndrome (for example, Lown-Ganong-Levine Syndrome, Wolff-Parkinson-White Syndrome)
      - » Short PR interval (< 0.12 sec)

Note: Fractional flow reserve using coronary tomography angiography requires at least 64-slice coronary computed tomography angiography and cannot be calculated when images lack sufficient quality

[a] Risk factor is determined using standard assessment methods (SCORE risk chart)

[b] Symptomatic is defined by one or more of the following:

- Chest pain with low probability of coronary artery disease, but high risk
- Moderate to high risk of coronary artery disease and one of the following:
  - Chest, jaw, neck, shoulder, arm, hand, epigastric or back pain
  - Diaphoresis
  - Syncope
  - Shortness of breath
- High risk of coronary artery disease and one of the following:
  - Palpitations
  - Lightheadedness
  - Near syncope
  - Nausea/vomiting
  - Anxiety
  - Weakness
  - Fatigue
- Patients with any cardiac symptom who have any of the following diseases associated with coronary artery disease
  - Abdominal aortic aneurysm
  - Chronic renal insufficiency or renal failure
  - Diabetes mellitus
  - Established and symptomatic peripheral vascular disease
  - History of:
    - Cerebrovascular accident
    - Transient ischemic attack
    - Carotid endarterectomy
    - High grade carotid stenosis (>70%)

Exclusions:

- Assessment of coronary arteries for suspected congenital anomalies
- Patients who have:
  - BMI > 35% kg/m^2
  - Presence of uncontrolled rapid heart rate or arrhythmia
  - Suspicion of acute coronary syndrome when acute myocardial infarction or unstable angina have not been ruled out
  - History of:
    - Myocardial infarction within the last 30 days
    - Coronary artery bypass graft surgery
    - Presence of dense arterial calcification or intracoronary stent
    - Evidence of clinical instability (unstable blood pressure – Systolic < 90 mmHg, severe congestive heart failure, acute pulmonary edema, cardiogenic shock)
- Patients who require emergent procedures
- Patients not meeting inclusionary guidelines

Cont.

Medical policy updates *Cont.*

Intensity-modulated radiation therapy (IMRT) of the abdomen and pelvis

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **No referral required; Use appropriate contracted vendor**
- **Procedure codes: *77301, *77338, *77385, *77386, *77387, G0615, G0616**

External beam radiotherapy has evolved to permit precise targeting of tumors with complex geometries. EBRT includes three-dimensional conformal radiotherapy and intensity-modulated radiotherapy. IMRT offer better conformality than 3D-CRT because it modulates that intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment filed. Treatment planning and delivery are more complex, time consuming and labor intensive for IMRT.

Intensity-modulated radiation therapy may be considered established as an approach to delivering radiation therapy for patients with cancer of the anus and anal canal.

Intensity-modulated radiation therapy may be considered established for the treatment of cancers of the abdomen and pelvis based on analysis of dosimetric data including comparative models if necessary.

Intensity-modulated radiation therapy (IMRT) of the breast and lung

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **No referral required-Use appropriate contracted vendor**
- **Procedure codes: *77301, *77338, *77385, *77386, *77387, G0615, G0616**

External beam radiotherapy has evolved to permit precise targeting of tumors with complex geometries. EBRT includes three-dimensional conformal radiotherapy and intensity-modulated radiotherapy. IMRT offer better conformality than 3D-CRT because it modulates that intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment filed. Treatment planning and delivery are more complex, time consuming and labor intensive for IMRT.

Intensity-modulated radiation therapy may be considered established for the treatment of breast cancer based on analysis of dosimetric data including comparative models if necessary.

Intensity-modulated radiation therapy may be considered established for the treatment of lung cancer based on analysis of dosimetric data including comparative models if necessary.

Intensity-modulated radiation therapy (IMRT): Cancer of the head and neck or thyroid

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **No referral required; Use appropriate contracted vendor**
- **Procedure codes: *77301, *77338, *77385, *77386, *77387, G0615, G0616**

External beam radiotherapy has evolved to permit precise targeting of tumors with complex geometries. EBRT includes 3-dimensional conformal radiotherapy and intensity-modulated radiotherapy. IMRT offer better conformality than 3D-CRT because it modulates that intensity of the overlapping radiation beams projected on the target and uses multiple-shaped treatment filed. Treatment planning and delivery are more complex, time consuming and labor intensive for IMRT.

Intensity-modulated radiation therapy may be considered established for the treatment of head and neck cancers based on analysis of dosimetric data including comparative models if necessary.

Intensity-modulated radiation therapy may be considered established for the treatment of thyroid cancer when it is:

- Unresectable
- Residual or persistent following surgery
- A locoregional recurrence
- An area that has been previously irradiated

Intensity-modulated radiation therapy (IMRT): Central nervous system tumors

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **No referral required-Use appropriate contracted vendor**
- **Procedure codes: *77301, *77338, *77385, *77386, *77387, G0615, G0616**

External beam radiotherapy has evolved to permit precise targeting of tumors with complex geometries. EBRT includes 3-dimensional conformal radiotherapy and intensity-modulated radiotherapy. IMRT offers better conformality than 3D-CRT because it modulates that intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment filed. Treatment planning and delivery are more complex, time consuming and labor intensive for IMRT.

Intensity-modulated radiation therapy may be considered established for the treatment of tumors of the central nervous system based on the analysis of dosimetric data including comparative models if necessary.

Cont.

Medical policy updates *Cont.*

Intensity-modulated radiation therapy of the prostate

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **No referral required; Use appropriate contracted vendor**
- **Procedure codes: *77301, *77338, *77385, *77386, *77387, G0615, G0616**

External beam radiotherapy has evolved to permit precise targeting of tumors with complex geometries. EBRT includes 3-dimensional conformal radiotherapy and intensity-modulated radiotherapy. IMRT offer better conformality than 3D-CRT because it modulates that intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment filed. Treatment planning and delivery are more complex, time consuming and labor intensive for IMRT.

Intensity-modulated radiation therapy may be considered established for the treatment of prostate cancer based on the analysis of dosimetric data including comparative models if necessary.

Sleep disorders, diagnosis and medical management

- **Revised policy**
- **Effective date: Jan. 1, 2019**
- **Procedure codes: *95782, *95783, *95800, *95805-*95811, E0486, G0398, G0399**

Due to the length of this medical policy, only recent updates to the policy are included in this article. Please reference the medical policy for complete information.

Obstructive sleep apnea syndrome results in repetitive episodes of upper airway obstruction. The most common symptoms in adults are snoring, excessive daytime sleepiness and hypertension.

Diagnosis

The diagnostic test to determine obstructive sleep apnea is a polysomnogram performed in a sleep laboratory.

Home sleep studies (unattended or unsupervised) may be appropriate if criteria are met.

Unattended (unsupervised) home sleep study, with a minimum of four recording channels (including oxygen saturation, respiratory movements, airflow and ECG or heart rate) is contraindicated if the patient has history of a stroke, severe insomnia or chronic opioid use.

Attended (supervised) sleep study performed in a sleep lab is considered established when the initial unattended study was negative, inadequate, equivocal or non-diagnostic and clinical suspicion for obstructive sleep apnea remains.

A repeated sleep study performed in a sleep lab is considered established when the initial polysomnogram is negative and a clinical suspicion of obstructive sleep apnea remains.

Medical management

Intraoral appliances may be considered established in adult patients with clinically significant obstructive sleep apnea. (Verify coverage of intraoral appliances under the DME benefit.)

Inclusions:

- OSA as defined by either of these:
  - An AHI, RDI or REI of at least 15 events per hour
  - An AHI, RDI or REI of at least five events per hour in a patient with excessive daytime sleepiness or unexplained hypertension

In addition, these criteria must be met:

- A trial of CPAP has failed or is contraindicated.
- The device is prescribed by a treating physician.
- The device is custom-fitted by qualified dental personnel.
- There is absence of temporomandibular dysfunction or periodontal disease.

Exclusions:

- Prefabricated (not custom-fit) devices

Cont.

Medical policy updates *Cont.*

Policy Guidelines

Facility / Provider Requirements

An attended sleep study in a non-hospital-based sleep laboratory must be accredited by the American Academy of Sleep Medicine (AASM).

An attended sleep study in a hospital-based sleep testing center must be accredited by AASM or an accreditation organization accepted under the *Participating Hospital Agreement*.

To perform and receive reimbursement for in-center and out-of-center sleep testing, a physician must be board-certified in sleep medicine by the American Board of Medical Specialties or the American Board of Sleep Medicine. Any M.D. or D.O. may order a sleep test; however, it must be performed and interpreted by a physician who is board-certified in sleep medicine. Follow our pre-authorization program for in-lab sleep testing.

The technician performing the sleep testing must have one of the following certifications:

- American Board of Sleep Medicine, registered sleep technologist
- Board of Registered Polysomnographic Technologists, registered polysomnographic technologist
- National Board for Respiratory Care (any of the following):
  - Certified pulmonary function technologist
  - Registered pulmonary function technologist
  - Certified respiratory therapist
  - Registered respiratory therapist

