MARCH-APRIL 2022

BCN Provider News

Medical policy updates

- **The following applies to BCN members.**
- **The effective date is indicated for the service, technology or procedure.**

Covered services

Assisted reproductive techniques (title changed from "Reproductive techniques")

- **Revised policy**
- **Effective date: March 1, 2022**
- **Referral required**
- **Procedure codes: *Multiple**

Selected assisted reproductive techniques (ART) are established and may be considered useful therapeutic options in the treatment of infertility.

When infertility (see the medical policy "Infertility services") is due to an underlying medical condition (for example, chronic infection, uterine fibroids), the treatment of that disorder is medically necessary and is covered under basic medical-surgical benefits. When no underlying medical condition is found, other options may be pursued. One option is ART — specific services that may be used to establish pregnancy. Assisted reproductive techniques are only available to members when the employer group has chosen to offer the services as additional benefits, through certificate benefit language or riders.

The focus of this policy is the use of ART in heterosexual couples who are infertile. Eligibility of same sex couples or single individuals for ART is based on benefit coverage (the certificate of coverage or rider) and is beyond the scope of this medical policy.

Inclusions

- Artificial Insemination
- Assisted reproductive technologies
  - in vitro fertilization (IVF)
  - gamete intrafallopian transfer (GIFT)
  - transuterine fallopian transfer (TUFT)
  - natural oocyte retrieval with intravaginal fertilization (NORIF)
  - pronuclear state tubal transfer (PROST)
  - tubal embryo transfer (TET)
  - zygote intrafallopian transfer (ZIFT)
  - embryo transfer
  - blastocyst transfer
  - intracytoplasmic sperm injection (ICSI)* for male factor infertility only
  - cryopreservation of embryos and sperm
  - storage of embryos and sperm
  - thawing of embryos and sperm

Exclusions

- Intracytoplasmic sperm injection in the absence of male factor infertility
- Assisted embryo hatching
- Co-culture of embryos
- Cryopreservation of ovarian tissue, oocytes (immature) or testicular tissue (see note)
- Storage of ovarian tissue, oocytes (immature and mature) or testicular tissue
- Thawing of ovarian tissue, oocytes (immature and mature) or testicular tissue (see note)
- All services related to gestational surrogacy / gestational parent / gestational carrier
- Time lapse monitoring or imaging of embryos (EmbryoScope)
- Endometrial receptivity testing (for example, ERA® [Endometrial Receptivity Analysis])
- Prior sterilization procedure (tubal ligation, vasectomy)

Note: Cryopreservation and thawing of testicular tissue in adult men with azoospermia is considered medically necessary as part of the intracytoplasmic sperm injection procedure.

Cont.

Medical policy updates *Cont.*

Genetic testing — Preimplantation

- **Revised policy**
- **Effective date: March 1, 2022**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *Multiple**

Preimplantation genetic testing describes various adjuncts to an assisted reproductive procedure in which either maternal or embryonic DNA is sampled and genetically analyzed, thus permitting deselection of embryos harboring a genetic defect before implantation of the embryo into the uterus. Preimplantation genetic diagnosis is used to detect genetic evidence of a specific inherited disorder, in the oocyte or embryo, derived from mother or couple, respectively, that has a high risk of transmission. Preimplantation genetic screening is not used to detect a specific abnormality but instead uses similar techniques to identify a number of genetic abnormalities in the absence of a known heritable disorder.

Preimplantation genetic diagnosis may be considered established as an adjunct to in-vitro fertilization (IVF) in individuals or couples who have the IVF benefit, and who meet specific criteria.

Preimplantation genetic screening as an adjunct to IVF is considered experimental.

Inclusions

1. For preimplantation genetic diagnosis in an embryo identified as at elevated risk of a significant genetic disorder, the individual or couple must:
   - Have the benefit for in-vitro fertilization (IVF) and meet criteria to access the benefit (have a diagnosis of infertility); **and**
   - Meet one of the following criteria:
     a) Both partners are known carriers of a single gene autosomal recessive disorder
     b) One partner is a known carrier of a single gene autosomal recessive disorder and the partners have an offspring who has been diagnosed with that recessive disorder
     c) One partner is a known carrier of a single gene autosomal dominant disorder
     d) One partner is a known carrier of a single X-linked disorder
2. For preimplantation genetic diagnosis in an embryo identified as at elevated risk for a structural chromosomal abnormality, the individual or couple must:
   - Have the benefit for in-vitro fertilization (IVF) and meet criteria to access the benefit (have a diagnosis of infertility); **and**
   - One partner with balanced or unbalanced chromosomal translocation
3. Individual consideration may be given to the individual or couple who has the in-vitro fertilization benefit, and meets at least one criterion under 1 or 2 (above) but does not have a diagnosis of infertility.

Exclusions

All other situations than those specified above.

Preimplantation genetic screening (PGS) as an adjunct to IVF is considered experimental.

Cont.

Medical policy updates *Cont.*

Infertility diagnosis

- **Revised policy**
- **Effective date: March 1, 2022**
- **No referral required**
- **Procedure codes: *Multiple**

The scope of this policy is to define infertility in the context of a heterosexual couple.

Infertility is the result of a disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the male or female reproductive tract which prevents conception. Infertility is defined as failure to achieve pregnancy after 12 months of unprotected intercourse in women younger than 35 years of age, or after six months in women older than 35 years of age.

The safety and effectiveness of diagnostic testing for the evaluation of infertility have been established. These services may be considered useful in the diagnosis of a medical condition which may impact fertility.

Inclusionary and exclusionary guidelines

Refer to the member's specific certificate of coverage.

Magnetic resonance-guided focused ultrasound

- **Revised policy**
- **Effective date: March 1, 2022**
- **Referral required**
- **Procedure codes: *76999, *0398T**

Magnetic resonance-guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines 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 and exclusions

Magnetic resonance-guided high-intensity ultrasound ablation may be considered established for the following indications:

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

Magnetic resonance-guided high-intensity ultrasound ablation is considered investigational in all other situations, including, but not limited to:

- Treatment of uterine fibroids
- Treatment of other tumors (brain cancer, breast cancer, desmoid)
- Treatment of tremor-dominant Parkinson disease

Magnetic resonance imaging for detection and diagnosis of breast cancer

- **Revised policy**
- **Effective date: March 1, 2022**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *77046, *77047, *77048, *77049**

Magnetic resonance imaging (MRI) of the breast can be used to screen, detect or diagnose breast cancer.

The safety and effectiveness of magnetic resonance imaging of the breast have been established. It may be considered a useful diagnostic option for patients meeting criteria.

Inclusions

Note: All of the following policy statements refer to performing MRI of the breast with a breast coil and the use of contrast. MRI of the breast without the use of a breast coil, regardless of the clinical indication, is considered experimental.

A. MRI of the breast may be considered established for screening for breast cancer in patients at high risk of breast cancer.

Cont.

Medical policy updates *Cont.*

High-risk considerations

There is no standardized method for determining a woman's risk of breast cancer that incorporates all possible risk factors. There are validated risk prediction models, but they are based primarily on family history.

The following list includes individual factors known to indicate a high risk of breast cancer:

- Lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH)/atypical ductal hyperplasia (ADH)
- A known BRCA1 or BRCA2 variant
- Another gene variant associated with high risk: TP53 (Li-Fraumeni syndrome), PTEN (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), CDH1, ATM, CHEK2, PALB2, NBN, NF1
- Lifetime risk about 20% or greater of developing breast cancer as identified by models that are largely defined by family history
- Received radiotherapy to the chest between 10 and 30 years of age.

B. MRI of the breast is considered established for the following indications:

Suspected cancer:

- Single follow-up MRI at six months following a breast MRI with BI-RADS category 3 findings
- Differentiation of palpable mass from surgical scar tissue
- Lesion/abnormality characterization when other imaging (ultrasound, mammography) and physical examination are inconclusive, and inability to localize the lesion prevents biopsy from being performed
- Metastatic cancer of unknown primary and suspected to be of breast origin and/or axillary adenopathy and no mammographic or physical findings of primary breast carcinoma
- Evaluation of pathologic nipple discharge after nondiagnostic mammography and ultrasound
- Suspected breast implant-associated anaplastic large cell lymphoma in patients with textured implants when ultrasound is nondiagnostic
- Evaluation of a documented abnormality of the breast prior to obtaining an MRI-guided biopsy when there is documentation that other methods, such as palpation or ultrasound, are not able to localize the lesion for biopsy

Diagnostic workup and management

- To determine the extent of disease in biopsy-proven breast cancer in either of the following:
  - Ductal carcinoma in situ (DCIS) when the lesion is greater than 2 cm; or
  - Invasive carcinoma
- To define the relationship of the tumor to the fascia and its extension into the pectoralis major, serratus anterior, or intercostal muscles prior to surgery
- Evaluation of the contralateral breast in those patients with a new diagnosis of breast cancer when clinical and mammographic findings are normal
- Preoperative tumor mapping of the involved breast to evaluate the presence of multicentric disease in patients with clinically localized breast cancer who are candidates for breast-conservation therapy
- Presurgical planning in patients with locally advanced breast cancer (before and after completion of neoadjuvant chemotherapy) to permit tumor localization and characterization
- Suspected recurrence in patients with tissue transfer flaps (rectus, latissimus dorsi and gluteal) post-reconstruction
- Suspected recurrence in patients with a prior history of breast cancer when clinical, mammographic, and/or sonographic findings are inconclusive

Surveillance

- In patients with a personal history of breast cancer after breast conserving therapy or unilateral mastectomy who meet criteria for MRI breast screening (see inclusion A)

Exclusions

- Screening technique in average-risk patients
- Screening technique for the detection of breast cancer when the sensitivity of mammography is limited (for example dense breasts)
- Diagnosis of low-suspicion findings on conventional testing, immediate biopsy is not indicated, and the patient is referred for short-interval follow-up
- Diagnosis of a suspicious breast lesion to avoid biopsy

Cont.

Medical policy updates *Cont.*

Magnetic resonance imaging to monitor integrity of silicone-gel-filled breast implants

- **Revised policy**
- **Effective date: March 1, 2022**
- **No referral required — Use appropriate contracted vendor**
- **Procedure codes: *77046, *77047**

Magnetic resonance imaging for the assessment of silicone breast implants may be considered established in specified situations.

Inclusions

- To confirm the clinical suspicion of rupture of silicone breast implants

Exclusions

- Monitoring the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture

Telemedicine services

- **Revised policy**
- **Effective date: March 1, 2022**
- **No referral required**
- **Procedure codes: *Multiple**

Billing guidance in the policy was updated, based on new Place of Service code 10, effective Jan. 1, 2022, and revision of the Place of Service code 02.

Billing guidance

Modifiers/Place of Service

When the nomenclature of the code does not specify how the service is being delivered, then a modifier is required to clarify this. Use the modifier that is appropriate for the code.

Synchronous encounters

GT — Via interactive audio and video telecommunications systems **or**

95 — Synchronous telemedicine service provided by a real-time interactive audio and video telecommunications system

POS 02 — Telehealth provided other than in patient's home.

POS 10 — Telehealth provided in the patient's home.

Billing an originating site is not required, but may be used if clinically necessary.

Asynchronous encounters

GQ — Via asynchronous telecommunications system

POS 02 — Telehealth provided other than in patient's home

POS 10 — Telehealth provided in the patient's home

Temporomandibular joint disorder

- **New policy**
- **Effective date: Jan. 1, 2022**
- **Plan approval with clinical review**
- **Procedure codes: *Multiple**

Temporomandibular joint (TMJ) disorder refers to a group of disorders characterized by pain in the temporomandibular joint and surrounding tissues. Initial conservative therapy is generally recommended; there are also a variety of non-surgical and surgical treatment possibilities for patients whose symptoms persist.

In the clinical setting, TMJ disorder is often a diagnosis of exclusion and involves physical examination, patient interview and dental record review. Diagnostic testing and radiologic imaging is generally recommended only for patients with severe and chronic symptoms. Diagnostic criteria for TMJ disorder have been developed and validated for use in both clinical and research settings.

For many patients, symptoms of TMJ disorder are short-term and self-limiting. Conservative treatments, such as eating soft foods, rest, heat, ice, avoiding extreme jaw movements and anti-inflammatory medications are recommended prior to consideration of more invasive and/or permanent therapies, such as surgery.

Certain tests, non-surgical and surgical procedures are considered safe and effective for the diagnosis and treatment of temporomandibular joint disorders. They may be considered useful therapeutic options when indicated.

Cont.

Medical policy updates *Cont.*

Inclusions

The following **diagnostic procedures** when used to diagnose temporomandibular joint dysfunction:

- Diagnostic X-ray, tomograms and arthrograms
- Medical grade computed tomography (CT) scan or magnetic resonance imaging (MRI) (generally CT scans and MRIs are reserved for presurgical evaluations)
- Cephalograms (X-rays of jaws and skull)
- Pantograms (panoramic X-rays of maxilla and mandible)

The following **non-surgical treatments** for the treatment of TMJ dysfunction:

- Intraoral removable prosthetic devices/appliances (encompassing fabrication, insertion, adjustment) of any and all devices/appliances constructed (excludes dental devices — see below)
- Pharmacologic treatment (such as anti-inflammatory, muscle relaxing and analgesic medications).
- Trigger point therapy with anesthetic and/or corticosteroid for the treatment of myofascial pain syndrome, are limited to no more than four injections in a 12-month period, when **all** the following are met:
  - There is a regional pain complaint in the expected distribution of referral pain from a trigger point.
  - There is spot tenderness in a palpable taut band in a muscle.
  - There is restricted range of motion.
  - Conservative therapy (physical therapy, active exercises, ultrasound, heating or cooling, massage, activity modification or pharmacotherapy) does not result in adequate symptom relief within two to three weeks, or is not feasible.
  - Trigger point injections are provided as a component of a comprehensive therapy program.

The following **surgical procedures** for the treatment of TMJ dysfunction:

- Arthrocentesis, with or without ultrasound guidance
- Manipulation for reduction or dislocation of the TMJ
- Arthroscopic surgery in patients that objectively demonstrate (by physical examination or imaging) internal derangements (displaced discs) or degenerative joint disease who have failed conservative treatment
- Open surgical procedures (when TMJ dysfunction results from congenital anomalies, trauma or disease in patients who have failed conservative treatment) including, but not limited to, arthroplasties, condylectomies, condylotomies, meniscus or disc plication and disc removal

NOTE: *Dental restorations for reconstruction of tooth form and function that are a result of TMJ dysfunction and/or bruxism are considered a dental service and are not a covered medical-surgical benefit unless otherwise specified in the individual medical certificate.*

Exclusions

The following **diagnostic procedures** when used to diagnose bruxism (see note) and/or TMJ dysfunction:

- Electromyography (EMG), including surface EMG
- Kinesiography
- Thermography
- Neuromuscular junction testing
- Somatosensory testing
- Transcranial or lateral skull X-rays
- Intra-oral tracing or gothic arch tracing (intended to demonstrate deviations in the positioning of the jaws that are associated with TMJ dysfunction)
- Muscle testing
- Standard dental radiographic procedures
- Range of motion measurements
- Computerized mandibular scan (this measures and records muscle activity related to movement and positioning of the mandible and is intended to detect deviations in occlusion and muscle spasms related to TMJ dysfunction)
- Ultrasound/sonogram (ultrasonic Doppler auscultation)
- Arthroscopy of the TMJ for purely diagnostic purposes
- Joint vibration analysis
- Cone beam computed tomography (see note)
- Trigger point therapy for all other indications and/or any medications not listed above
- Image guidance of trigger point injections

The following **non-surgical procedures** for the treatment of TMJ dysfunction:

- Electrogalvanic stimulation

Cont.

Medical policy updates *Cont.*

- Iontophoresis
- Biofeedback
- Ultrasound
- Devices promoted to maintain joint range of motion and to develop muscles involved in jaw function
- Orthodontic services/treatment (dental appliance that is intended to treat malocclusion by tooth and support structure movement)
- Dental restorations/prosthesis/treatment/appliances (see note)
- TENS (transcutaneous electrical nerve stimulation)
- PENS (percutaneous electrical nerve stimulation)
- Acupuncture
- Platelet concentrates

Note: Intra-oral reversible orthotic device (also known as occlusal orthotic, occlusal guard or bite splint), including fabrication, insertion and adjustment of all devices fabricated, cone beam tomography and bruxism treatment are certificate exclusions in most cases. Refer to current certificate of coverage.

Transcatheter aortic valve implantation for aortic stenosis

- **Revised policy**
- **Effective date: March 1, 2022**
- **Plan approval with clinical review**
- **Procedure codes: * 33361, *33362, *33363, *33364, *33365, *33366, *33367, *33368, *33369. *33999**

Transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement) is a potential treatment for patients with severe aortic stenosis. Many patients with aortic stenosis are elderly or have multiple medical comorbidities, thus indicating a high, often prohibitive, risk for surgery. This procedure is being evaluated as an alternative to open surgery, or surgical aortic valve replacement (SAVR), for patients with aortic stenosis and as an alternative to nonsurgical therapy.

Transcatheter aortic valve implantation (TAVI), also known as transcatheter aortic valve replacement (TAVR) has been developed in response to this unmet need and was originally intended as an alternative for patients for whom surgery is not an option due to prohibitive surgical risk or for patients at high risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass.

Transcatheter aortic valve replacement performed with an FDA-approved transcatheter heart valve system, when performed via an approach consistent with the device's FDA-approved labeling, may be indicated for patients with aortic stenosis.

Inclusions

Transcatheter aortic valve replacement with a device approved by the U.S. Food and Drug Administration and performed via an approach consistent with the device's FDA-approved labeling is established for patients with aortic stenosis when **all** the following conditions are present:

- **One** of the following:
  - Severe aortic stenosis with a calcified aortic annulus; **or**
  - Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; **and**
- NYHA [New York Heart Association] heart failure class II, III or IV symptoms; **and**
- Left ventricular ejection fraction greater than 20%; **and**
- **One** of the following:
  - Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists including a cardiac surgeon; **or**
  - Patient is an operable candidate but is at high risk (see note on definition of predictive risk) for open surgery; **or**
  - Patient is at intermediate or greater surgical risk for open aortic valve replacement (only when used in concordance with FDA regulations for Sapien XT Transcatheter Heart Valve, see below) **or**
  - Patient is at low surgical risk (see note) for open aortic valve replacement (only when used in concordance with FDA regulations for Sapien 3, Sapien 3 Ultra, CoreValve Evolut R or CoreValve Evolut PRO)

Cont.

Medical policy updates *Cont.*

Edwards SAPIEN XT Transcatheter Heart Valve

- Severe aortic stenosis with a calcified aortic annulus and one or more of the following:
  - An aortic valve area of ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2
  - A mean aortic valve gradient ≥ 40 mmHg
  - A peak aortic-jet velocity ≥ 4.0 m/sec
  - Native anatomy appropriate for the 23, 26, or 29 mm valve system (between 18 and 28 mm)
- New York Heart Association (NYHA) heart failure Class II, III or IV symptoms
- Patient is not a candidate for open surgery, as judged by a heart team, including a cardiac surgeon, **or** to be at high or greater risk (see note) for open surgical therapy.
- Patient is at intermediate surgical risk (see note) for open aortic valve replacement.

Edwards SAPIEN™ and Edwards SAPIEN 3 Ultra

Patient with severe aortic valve stenosis who is at low risk (see note) for death or major complications associated with open-heart surgery

Medtronic CoreValve™ (Evolut) system

- Severe aortic stenosis with a calcified aortic annulus and one or more of the following:
  - An aortic valve area of ≤ 1.0 cm^2 **or** aortic valve area index ≤ 0.6 cm^2/m^2
  - A mean aortic valve gradient ≥ 40 mmHg
  - A peak aortic-jet velocity ≥ 4.0 m/sec
  - Native aortic annulus diameters between 23 and 31 mm
- New York Heart Association (NYHA) heart failure Class II, III or IV symptoms
- Patient with severe aortic valve stenosis who is at low risk or higher (see note) for death or major complications associated with open-heart surgery.

Portico™ Transcatheter Aortic Valve Implantation System

- Aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (for example, predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons risk score and other clinical comorbidities unmeasured by the STS risk calculator).

Note: *Definition of predictive risk factor based on the Society of Thoracic Surgeons (STS) predicted risk score for major complications and other clinical comorbidities unmeasured by the STS risk calculator for open surgery.*

- *Low risk – predicted operative risk score of less than 3% or 4%*
- *Intermediate risk – predicted operative risk score of 3% to 7%*
- *High risk – predicted operative risk score of 8% or higher;* ***or*** *judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of ≥ 15% within 30 days*

Exclusions

Transcatheter aortic valve replacement is considered experimental for all other indications, including but not limited to:

- The individual is an appropriate candidate for the standard, open surgical approach but has refused
- Hypersensitivity or contraindication to an anticoagulation/antiplatelet regimen
- Presence of active bacterial endocarditis or other active infections
- Presence of unicuspid or bicuspid aortic valve
- Non FDA-approved systems or approaches including
  - JenaValve system
  - Transcaval approach

Cont.

Medical policy updates *Cont.*

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

- **Revised policy**
- **Effective date: March 1, 2022**
- **Covered: Criteria apply**
- **Procedure codes: Established — *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.

Inclusionary and exclusionary guidelines

Inclusions (see note about authorization)

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 IMRT 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.
- Tumor that involves the base of skull and proton therapy is needed to spare the orbit, optic nerve, optic chiasm, or brainstem (sinonasal cancer).
- To treat melanoma of the uveal tract (including the iris, choroid, or ciliary body) and no evidence of metastasis or extrascleral extension.
- In the treatment of all pediatric tumor types (through 21 years of age).
- Repeat irradiation of previously treated fields where the dose tolerance of surrounding normal structures would be exceeded with 3D conformal radiation or IMRT.
- Hepatocellular carcinoma and intrahepatic cholangiocarcinoma to treat unresectable, non-metastatic hepatocellular cancer or intrahepatic cholangiocarcinoma with curative intent.

Note: *Use of proton beam therapy (PBT) 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 such as IMRT, 3-dimensional conformal radiation therapy).*

Exclusions

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

Cont.

Medical policy updates *Cont.*

Genetic testing for BRCA1 or BRCA2 for hereditary breastlovarian cancer syndrome and other high-risk cancers

- **Revised policy**
- **Effective date: March 1, 2022**
- **Covered, criteria apply**
- **Procedure codes: Established — *81212, *81215, *81216, *81217, *81162, *81163, *81164, *81165, *81166, *81167**

  Other codes (investigational, not medically necessary) *81479 (see note), *81432, *81433

*Note: *81479 is experimental when used to bill for OvaNext, BreastNext, BRCAplus, BROCA testing, or any other panel testing. Complete sequencing analyses, represented by the codes above for either BRCA 1 or BRCA 2, alone are seldom done in the clinical setting.*

Several genetic syndromes with an autosomal dominant pattern of inheritance that feature breast cancer have been identified. Of these, hereditary breast and ovarian cancer (HBOC) and some cases of hereditary site-specific breast cancer have in common causative variants in *BRCA* (breast cancer susceptibility) genes. Families suspected of having HBOC syndrome are characterized by an increased susceptibility to breast cancer occurring at a young age, bilateral breast cancer, male breast cancer, ovarian cancer at any age, as well as cancer of the fallopian tube and primary peritoneal cancer. Other cancers, such as prostate cancer, pancreatic cancer, gastrointestinal cancers, melanoma and laryngeal cancer occur more frequently in HBOC families. Hereditary site-specific breast cancer families are characterized by early onset breast cancer with or without male cases, but without ovarian cancer. For this policy, both will be referred to collectively as hereditary breast and/or ovarian cancer.

Germline variants in the *BRCA1* and *BRCA2* genes are responsible for the cancer susceptibility in the majority of HBOC families, especially if ovarian cancer or male breast cancer are features. However, in site-specific breast cancer, *BRCA* variants are responsible for only a proportion of affected families. *BRCA* gene variants are inherited in an autosomal dominant fashion through either the maternal or the paternal lineage. It is possible to test for abnormalities in *BRCA1* and *BRCA2* genes to identify the specific variant in cancer cases and to identify family members with increased cancer risk. Family members without existing cancer who are found to have BRCA variants can consider preventive interventions for reducing risk and mortality.

Inclusionary and exclusionary guidelines

Inclusions

Patients with cancer or with a personal history of cancer (affected patients):

Genetic testing for *BRCA1* and *BRCA2* variants in cancer-affected individuals may be considered appropriate under any of the following circumstances:

- Individuals with any blood relative with a known pathogenic/likely pathogenic variant in a cancer susceptibility gene
- Individuals meeting the criteria below but with previous limited testing (single gene and/or absent deletion duplication analysis)
- *Personal* history of breast cancer and one or more of the following:
  - Diagnosed age ≤45 years; or
  - Diagnosed 46 to 50 years with:
    - An additional primary breast cancer (synchronous or metachronous); or
    - ≥1 close relative with breast, ovarian, pancreatic, or prostate cancer at any age; or
    - An unknown or limited family history
  - Diagnosed at any age with:
    - ≥1 close blood relative with **any**:
      - » Breast cancer diagnosed ≤50 years
      - » Ovarian cancer any age
      - » Metastatic, intraductal/cribiform prostate cancer, or high-risk or very high-risk group prostate cancer any age
      - » Pancreatic cancer any age
      - » Triple-negative breast cancer
    - ≥3 total diagnoses of breast cancer in patient and/or close blood relative; or
    - ≥2 close blood relatives with breast or prostate cancer (any grade) at any age
    - Lobular breast cancer with personal or family history of diffuse gastric cancer
  - Ashkenazi Jewish ancestry
- *Personal* history of male breast cancer at any age
- *Personal* history of epithelial ovarian carcinoma (including fallopian tube cancer or peritoneal cancer) at any age

Cont.

Medical policy updates *Cont.*

- *Personal* history of exocrine pancreatic cancer at any age
- *Personal* history of metastatic, intraductal/cribiform histology prostate cancer at any age; or high-risk group or very high-risk group prostate cancer at any age
- *Personal* history of prostate cancer at any age with:
  - ≥1 close blood relative with ovarian cancer, pancreatic cancer, or metastatic or intraductal/cribiform prostate cancer at any age or breast cancer <50 years; or
  - >2 close blood relatives with breast or prostate cancer (any grade) at any age; or
  - Ashkenazi Jewish ancestry
- *Personal* history of cancer and a mutation identified on tumor genomic testing that has clinical implications if also identified in the germline
- *Personal* history of cancer and to aid in systemic therapy decision-making for PARP-inhibitors for human epidermal receptor 2 (HER2)-negative metastatic and HER2-negative early stage, high-risk breast cancer
- *Personal* history of cancer and to aid in systemic therapy decision-making for PARP inhibitors for ovarian cancer, prostate cancer, pancreatic cancer or platinum therapy for prostate cancer and pancreatic cancer

Patients without cancer or without history of cancer

Genetic testing for BRCA1/BRCA2 variants of individuals unaffected by cancer may be appropriate under the following circumstances:

- An affected or unaffected individual with a first- or second-degree blood relative meeting any criterion listed above for "Patients with cancer" (except individuals who meet criteria only for systemic therapy decisionmaking). If the individual with cancer has pancreatic cancer or prostate cancer (metastatic or intraductal/cribriform or high-risk group or very high-risk group) then only first-degree relatives should be offered testing unless there are other family history indications for testing.
- An affected or unaffected individual who otherwise does not meet the criteria above but has a probability >5% of a BRCA1/2 pathogenic variant based on prior probability models (for example, Tyrer-Cuzick, BRCAPro, Pennll).

Exclusions

- Patients not meeting any of the above criteria
- Genetic testing for *BRCA1* and *BRCA2* variants in minors
- BRCA and BART testing as a screening test for cancer in women in the general population.
- BRCA and BART testing for unaffected individuals of high-risk populations (for example, Ashkenazi Jewish descendant) *who have no relatives* with a history of breast, ovarian, fallopian tube or primary peritoneal cancer at any age

Genetic testing-noninvasive prenatal screening for fetal aneuploidies, microdeletions, and twin zygosity using cell-free fetal DNA

- **Revised policy**
- **Effective date: March 1, 2022**
- **Covered: criteria apply**
- **Procedure codes: Established — *81420, *81507, *81599, *81479 (see notes)**
- **Other codes: (investigational, not medically necessary, etc.) *81422 (effective 1/1/17), *0060U, *0168U**

Notes:

If the codes above do not apply and the test involves multianalyte assays and an algorithmic analysis [when specified as cell-free fetal DNA-based prenatal testing involving multianalyte assays and an algorithmic analysis for fetal aneuploidy]

If the codes above do not apply and the test does not involve an algorithmic analysis [when specified as cell-free fetal DNA-based prenatal testing involving multianalyte assays and an algorithmic analysis for fetal aneuploidy]

Standard aneuploidy screening involves combinations of maternal serum markers and fetal ultrasound done at various stages of pregnancy. The detection rate for various combinations of noninvasive testing ranges from 60% to 96% when the false positive rate is set at 5%. When tests indicate a high risk of a trisomy syndrome, direct karyotyping of fetal tissue obtained by amniocentesis or chorionic villous sampling (CVS) is required to confirm that T21 or another trisomy is present. Both amniocentesis and CVS are invasive procedures and have procedure-associated risks of fetal injury, fetal

Cont.

Medical policy updates *Cont.*

loss and infection. A new screening strategy that reduces unnecessary amniocentesis and CVS procedures or increases detection of T21, T18, and T13 could improve outcomes. Confirmation of positive noninvasive screening tests with amniocentesis or CVS is recommended; with more accurate tests, fewer women would receive positive screening results.

Commercial, noninvasive, sequencing-based testing of maternal serum for fetal trisomy syndromes is now available. The testing technology involves the detection of cell-free fetal DNA fragments present in the plasma of pregnant women. As early as eight to 10 weeks of gestation, these fetal DNA fragments comprise 6% to 10% or more of the total cell-free fetal DNA in a maternal plasma sample. The tests are unable to provide a result if the fetal fraction is too low (i.e., <4%). The fetal fraction can be affected by maternal and fetal characteristics. For example, the fetal fraction was found to be lower at higher maternal weights and higher with increasing fetal crown-rump length.

Inclusionary and exclusionary guidelines

Inclusions

- Nucleic acid sequencing-based testing of maternal plasma to screen for trisomy 21 in women with singleton and twin pregnancies. (Karyotyping would be necessary to exclude the possibility of a false positive nucleic acid sequencing-based test.)
- Concurrent nucleic acid sequencing-based testing of maternal plasma for trisomy 13 and/or 18 in women who are eligible for and are undergoing nucleic acid sequencing-based testing of maternal plasma for trisomy 21.
- Nucleic acid sequencing-based testing of maternal plasma for fetal sex or fetal sex chromosome aneuploidy only when certain fetal abnormalities are noted on ultrasound such as cases of ambiguous genitalia or cystic hygroma when the determination of fetal sex is necessary to help guide medical management.

Exclusions

- Nucleic acid sequencing-based testing of maternal plasma for trisomy 21 in women with multiple gestation pregnancies
- Nucleic acid sequencing-based testing of maternal plasma for trisomy 13 and/or 18, other than in the situations specified above
- Nucleic acid sequencing-based testing of maternal plasma for fetal sex determination and/or fetal sex chromosome aneuploidies other than the situation specified above
- Nucleic acid sequencing-based testing of maternal plasma for microdeletions
- Nucleic acid sequencing-based testing of maternal plasma for twin zygosity
- Vanadis® NIPT of maternal plasma to screen for trisomy 21, 18 and 13
- For other aneuploidies or genetic disorders not specified above

Positron emission tomography (PET) for oncologic conditions

- **Revised policy**
- **Effective date: March 1, 2022**
- **Covered: Criteria apply**
- **Procedure codes:**
  - **Established: *78608, *78609, *78811, *78812, *78813, *78814, *78815, *78816, *78999, G0253, A9593, A9594, A9595**
  - **Other codes (investigational, not medically necessary, etc.) G0219, G0252**

Positron emission tomography (PET) scans are based on the use of positron-emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia or water. The radionuclide tracers simultaneously emit two high-energy photons in opposite directions that can be simultaneously detected (referred to as coincidence detection) by a PET scanner, consisting of multiple stationary detectors that encircle the area of interest.

A variety of tracers are used for PET scanning, including oxygen-15, nitrogen-13, carbon-11, and fluorine-18. Because of their short half-life, some tracers must be made locally using an onsite cyclotron. The radiotracer most commonly used in oncology imaging has been fluorine-18 coupled with fluorodeoxyglucose (FDG), which has a metabolism related to glucose metabolism. FDG has been considered useful in cancer imaging since tumor cells show increased metabolism of glucose. The most common malignancies studied have been melanoma, lymphoma, lung, colorectal and pancreatic cancer.

For this policy, PET scanning is discussed for the following four applications in oncology.

Cont.

Medical policy updates *Cont.*

Diagnosis. Diagnosis refers to use of PET as part of the testing used in establishing whether a patient has cancer.

- Staging. This refers to use of PET to determine the stage (extent) of the cancer at the time of diagnosis before any treatment is given. Imaging at this time is generally to determine whether the cancer is localized. This may also be referred to as initial staging.
- Restaging. This refers to imaging following treatment in two situations. Restaging is part of the evaluation of a patient in whom a disease recurrence is suspected based on signs and/or symptoms. Restaging also includes determining the extent of malignancy following completion of a full course of treatment.
- Surveillance. This refers to use of imaging in asymptomatic patients (patients without objective signs or symptoms of recurrent disease). This imaging is completed six months or more (12 months or more for lymphoma) following completion of treatment.
- This policy only addresses the use of radiotracers detected with the use of dedicated PET scanners. Radiotracers such as FDG may be detected using single-photon emission computerized tomography (SPECT) cameras, a technique that may be referred to as FDG-SPECT imaging. The use of SPECT cameras for PET radiotracers presents unique issues of diagnostic performance and is not considered in this policy.

Inclusionary and exclusionary guidelines

PET scans may be considered *appropriate* for the following oncologic conditions:

Anal cancer

- **Inclusions:**
  - For the diagnosis, staging, restaging and monitoring of anal cancer
- **Exclusions:**
  - Conditions not listed above

Bladder cancer

- **Inclusions:**
  - For the staging or restaging of muscle invasive bladder cancer
- **Exclusions:**
  - Conditions not listed above

Bone cancer

- **Inclusions:**
  - For the staging of Ewing sarcoma and osteosarcoma
- **Exclusions:**
  - For the staging of chondrosarcoma

Brain cancer

- **Inclusions:**
  - For diagnosis and staging, where lesions metastatic from the brain are identified but no primary is found
  - For restaging, to distinguish recurrent tumor from radiation necrosis
- **Exclusions:**
  - Conditions not listed above

Breast cancer

- **Inclusions:**
  - Staging and restaging of breast cancer
  - Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive
  - Staging axillary lymph nodes
- **Exclusions:**
  - For the differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography
  - For predicting pathologic response to neoadjuvant therapy for locally advanced disease

Cancer of unknown primary

- **Inclusions:**
  - Patients with an unknown primary who meet **all** the following criteria:
    - In patients with a single site of disease outside the cervical lymph nodes.
    - Patient is considering local or regional treatment for a single site of metastatic disease.
    - Patient has received a negative workup for a occult primary tumor.

Cont.

Medical policy updates *Cont.*

- The PET scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

- **Exclusions:**
  - For patients with an unknown primary, including, but not limited to the following:
    - As part of the initial workup of an unknown primary
    - As part of the workup of patients with multiple sites of disease

Cervical cancer

- **Inclusions:**
  - For the initial staging of patients with locally advanced cervical cancer.
  - For the evaluation of known or suspected recurrence.
- **Exclusions:**
  - For the initial diagnosis of cervical cancer in all other situations.

Colorectal cancer

- **Inclusions:**
  - Staging and restaging (initial and subsequent treatment strategy) to detect and assess resectability of hepatic or extrahepatic metastases of colorectal cancer,
  - To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when standard imaging, including CT scan, is negative
- **Exclusions:**
  - When used as a technique to assess the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer
  - When used as a technique contributing to radiotherapy treatment planning

Endometrial cancer

- **Inclusions:**
  - Detection of lymph node metastases, and
  - Assessment of endometrial cancer recurrence
- **Exclusions:**
  - Conditions not listed above

Esophageal cancer

- **Inclusions:**
  - Staging and restaging of esophageal cancer
  - Determining response to preoperative induction therapy
- **Exclusions:**
  - Detection of primary esophageal cancer

Gastric (stomach) cancer

- **Inclusions:**
  - Diagnosis, staging and restaging of gastric carcinoma if other imaging is inconclusive
  - Determining response to preoperative induction therapy
- **Exclusions:**
  - Conditions not listed above

Head and neck cancer

- **Inclusions:**
  - For the evaluation of the head and neck in the diagnosis of suspected head and neck cancer
  - For the initial staging of the disease
  - For restaging of residual or recurrent disease during follow up after treatment for head and neck cancer
- **Exclusions:**
  - Conditions not listed above

Hepatobiliary cancer

- **Inclusions:**
  - When standard imaging studies are equivocal or nondiagnostic regarding extent of disease
  - When standard imaging prior to planned curative surgery has been performed and has not demonstrated metastatic disease
- **Exclusions:**
  - Conditions not listed above

Lung cancer

- **Inclusions:**
  - Patients with a solitary pulmonary nodule as a single-scan technique (not dual-time) to distinguish between benign

Cont.

Medical policy updates *Cont.*

and malignant disease when prior CT scan and chest X-ray findings are inconclusive or discordant

- To determine resectability for patients with a presumed solitary metastatic lesion from lung cancer
- As a staging or restaging technique in those with known **non-small-cell** lung cancer
- PET scanning may be considered **established** in staging of small-cell lung cancer if limited stage is suspected based on standard imaging

- **Exclusions:**
  - PET scanning in staging of small-cell lung cancer if extensive stage is established and in all other aspects of managing small-cell lung cancer
  - Conditions not listed above

Lymphoma, including Hodgkin's disease

- **Inclusions:**
- PET scanning as a technique for staging lymphoma either during initial staging or for restaging at follow-up
- **Exclusions:**
  - Conditions not listed above

Melanoma

- **Inclusions:**
  - Assessing extranodal spread of malignant melanoma at initial staging or at restaging during follow-up treatment for advanced disease
- **Exclusions:**
  - In managing stage 0, I or II melanoma
  - When used as a technique to detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy

Multiple myeloma

- **Inclusions:**
  - For the initial and subsequent treatment strategy of multiple myeloma
- **Exclusions**
  - N/A

Merkel cell carcinoma

- **Inclusions:**
  - As clinically indicated

Neuroendocrine tumors

- **Inclusions:**
  - For the diagnosis, staging, restaging and monitoring of neuroendocrine tumors
- **Exclusions:**
  - Conditions not listed above

Ovarian cancer

- **Inclusions:**
  - Initial staging of ovarian cancer
  - For the evaluation of patients with signs and/or symptoms of suspected ovarian cancer **recurrence** (restaging) when standard imaging, including CT scan, is inconclusive
- **Exclusions:**
  - For the initial evaluation (not staging) of known or suspected ovarian cancer in all other situations

Pancreatic cancer

- **Inclusions:**
  - For the initial diagnosis and staging of pancreatic cancer when other imaging and biopsy are inconclusive
- **Exclusions:**
  - Evaluating other aspects of pancreatic cancer

Penile cancer

- **Inclusions:**
  - Staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis.
- **Exclusions:**
  - All other indications

Pleural, thymus, heart and mediastinum cancer

- **Inclusions:**
  - For surgical resection being considered and metastatic disease has not been detected by CT or MRI
  - For restaging after induction chemotherapy if the patient is a surgical candidate
- **Exclusions:**
  - All other indications

Prostate cancer

- **Inclusions:**

Cont.

Medical policy updates *Cont.*

  - PET scanning with ^{11}C-choline for evaluating response to primary treatment in prostate cancer
  - PET scanning with Gallium Ga-68 prostate-specific membrane antigen (PSMA)-11 and Piflufolastat fluorine-18 for the following indications: as an alternative to standard imaging of bone and soft tissue for initial staging, for the detection of biochemically (elevated PSA) recurrent disease, and as workup for progression with bone scan plus CT or MRI for the evaluation of bone, pelvis, and abdomen

- **Exclusions:**
  - PET scanning for all other indications

Renal cell carcinoma

- **Inclusions:**
  - For initial treatment strategy, subsequent treatment strategy and surveillance of biopsy proven kidney cancer
- **Exclusions:**
  - N/A

Soft tissue sarcoma

- **Inclusions:**
  - For initial staging prior to resection of an apparently solitary metastasis
  - When the grade of a unresectable tumor remains in doubt after biopsy
  - Differentiation of suspected tumor from radiation or surgical fibrosis
  - Determination of response to therapy, gastrointestinal stromal tumor (GIST) for initial staging and re-staging when there is documented recurrence
- **Exclusions:**
  - When used in evaluation of soft tissue sarcoma, including but not limited to the following applications:
    - Distinguishing between low grade and high grade soft tissue sarcoma
    - Detecting locoregional recurrence
    - Detecting distant metastasis

Testicular cancer

- **Inclusions:**
  - PET scanning in the evaluation of residual mass following chemotherapy of stage IIB and III seminomas
- **Exclusions:**
  - All other indications

Thyroid cancer inclusions:

  - For the initial treatment strategy of thyroid cancer types known not to concentrate radioactive iodine (RAI)
  - For subsequent treatment strategy for differentiated thyroid cancer of follicular cell origin which is known to concentrate radioactive iodine (RAI), in the following situations:
    - When done following prior treatment with thyroidectomy and radioiodine ablation

      and
    - With a current serum thyroglobulin > 10 ng/ml (except in the setting of documented anti-thyroglobulin antibodies,) **and**
    - With a negative whole body RAI scan in the past
- **Exclusions:**
  - For the evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations

Vaginal/vulvar cancers

- **Inclusions:**
  - Radiation planning
  - Standard imaging studies are equivocal or nondiagnostic for recurrent or progressive disease
  - Restaging of local recurrence when pelvic exenteration surgery is planned
- **Exclusions:**
  - All other indications

Cancer surveillance

- **Inclusions:**
  - N/A
- **Exclusions:**
  - When used as a surveillance tool for patients with cancer or with a history of cancer. A scan is considered surveillance if performed more than six months after completion of cancer therapy (12 months for lymphoma) in patients without objective signs or symptoms suggestive of cancer recurrence.

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Medical policy updates *Cont.*

Proprietary laboratory analyses (PLA) codes

- **Revised policy**
- **Effective date: March 1, 2022**
- **Plan approval with clinical review**
- **Procedure codes: *Multiple**

Proprietary Laboratory Analyses (PLA) codes are a part of the overall code sets developed and released by the American Medical Association — Current Procedural Terminology (AMA-CPT) editorial panel. These are alpha-numeric codes consisting of four numbers ending in a capital U. They are meant to represent specific laboratory tests developed by a proprietary lab.

The PLA code set includes:

- Advanced Diagnostic Laboratory Tests (ADLTs)
- Clinical Diagnostic Laboratory Tests (CDLTs)
- Multianalyte Assays with Algorithmic Analyses (MAAA)
- Genomic Sequencing Procedures

PLA codes describe proprietary analyses and may be provided by "one, sole source" laboratory or may be licensed to multiple labs that may provide the analysis.

Proprietary labs apply for assignment of PLA codes for their products. For the AMA-CPT editorial board to issue a specific code, the Proprietary Lab test must be performed on human specimens and the PLA CODE must be formally requested by the Lab through completion of an AMA-CPT Code Request application.

When the PLA code is released, it generally is not released with information clearly demonstrating that clinical validity or clinical utility have been proven **or** that a definitive positive incremental impact on clinical outcomes has been established.

PLA codes are updated quarterly.

PLA codes are considered experimental until the laboratory test the code represents is formally documented as established.

Established CPT codes may be used to represent and reimburse testing for incremental codes or multi-target codes.

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

– Not applicable

Noncovered services

Miscellaneous genetic and molecular diagnostic tests

- **Revised policy**
- **Effective date: March 1, 2022**
- **Plan approval with clinical review**
- **Procedure codes: *Multiple**

There are numerous commercially available genetic and molecular diagnostic, prognostic and therapeutic tests for individuals with certain diseases or asymptomatic individuals with a future risk. This evidence review evaluates miscellaneous genetic and molecular diagnostic tests not addressed in a separate review. If a separate evidence review exists, then conclusions reached there supersede conclusions here. The main criterion for inclusion in this review is the limited evidence on the clinical validity for the test. As a result, these tests do not have clinical utility, and the evidence is insufficient to determine that technology results in an improvement in the net health outcome.

Diagnostic, prognostic and therapeutic genetic testing of (1) an affected (symptomatic) individual's germline to benefit the individual (excluding reproductive testing) or (2) of an asymptomatic individual to determine future risk of disease is considered experimental for the following:

- Celiac PLUS
- Colon Sentry®
- Crohn's Prognostic
- DNA Methylation Pathway Profile
- FirstSight™
- GI Effects® (Stool)
- IBD sgi Diagnostic™
- ImmunoGenomic® Profile
- Know Error™
- ResponseDX®: Colon
- SEPT9 methylated DNA (for example: ColoVantage®, Epi proColon®)
- Envisia™ Genomic Classifier (Veracyte™)

Cont.

Medical policy updates *Cont.*

Subchondroplasty

- **New policy**
- **Effective date: March 1, 2022**
- **Procedure codes: *27899, *29999, *L8699, *0707T**

The Subchondroplasty® (SCP) procedure is a minimally invasive fluoroscopically assisted procedure that targets and fills subchondral bone defects associated with chronic bone marrow lesions frequently associated with osteoarthritis, primarily of the knee and ankle.

A substance called AccuFill (a calcium phosphate mineral compound) is injected arthroscopically into the subchondral defect. It hardens quickly once injected and mimics the strength of normal cancellous bone, and is replaced with new bone during the healing process. It is designed to treat subchondral defects associated with chronic bone marrow edema.

The Subchondroplasty® (SCP®) procedure is considered experimental.

Evidence-based conclusions regarding safety, efficacy and the impact on net health outcomes have yet to be determined.

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

- Not applicable