



CODING GUIDELINES AND POLICY UPDATE

Important Note:

The medical policies referenced in this document apply to all HMO, POS, and PPO products of Independence Blue Cross ("IBC"), including its affiliates, as well as to traditional indemnity products to the extent the applicable covered services are underwritten by IBC or its affiliates. Please note that some of IBC's traditional indemnity products are jointly underwritten by Highmark Blue Shield and therefore Highmark's medical policy may apply. You may refer to the member's ID card for the entity that is responsible for underwriting the product.

This document was developed to assist IBC in administering the provisions of its benefits programs and does not constitute medical advice. Professional providers are responsible for providing medical advice and treatment. Even though this document may conclude that a particular service or item is medically necessary, such conclusion is NOT based upon the terms of a particular member's benefit plan. Members must refer to their specific benefit program for the terms, conditions, limitations and exclusions of coverage.

Please note that the Policy Bulletins which are referenced herein describe the status of a specific topic at the time the Policy Bulletin was created. Policy Bulletins are updated biennially and when new medical evidence becomes available, therefore, they are subject to change.

Please be aware that the actual Policy Bulletins which are discussed herein are used as a guide only. Coverage decisions are made on a case-by-case basis by applying Policy Bulletin criteria to the member's medical history, condition, and proposed course of treatment as well as the member's benefit program. Providers should review Policy Bulletins with Members as treatment options are discussed, as the Policy Bulletins are designed to be used by our professional staff in making coverage determinations and can be highly technical.

Information contained in this document and the actual Policy Bulletin does not constitute an offer of coverage, medical advice, or guarantee of payment. Please note that, if there is a conflict between the Policy Bulletin and a member's benefit program, the terms of the benefit program will govern.

Please note that providers who opted out of the class action settlement may not be entitled to certain claim payment policy changes. Therefore, any payments made pursuant to such policy changes to providers who opted out of the class action settlement are subject to retroactive adjustments.

INSIDE THIS ISSUE

Medical Policies

- Apligraf® and Dermagraft® (11.08.20b)
- Endometrial Ablation (11.06.05a)
- Fetal Fibronectin Enzyme Immunoassay (06.02.04b)
- First-Trimester Prenatal Screening for Fetal Aneuploidy (09.00.36c)
- Percutaneous Lumbar Discectomy (11.15.15a)
- Transcatheter Arterial Chemoembolization (TACE) of Hepatic Malignancies (07.05.06a)

Experimental/Investigational Policies

- Adrenal Tissue Transplantation to Brain (11.15.14b)
- Electrical Impedance Scanning of the Breast (07.07.08a)
- Hippotherapy (10.00.01a)
- Percutaneous Intradiscal Annuloplasty (IDET/PIRFT) (11.14.14c)
- Protonics® Device (07.08.02b)
- Surface Electromyogram (SEMG) (07.03.20)

Claim Payment Policies

- Collection and Interpretation of Physiologic Data are Not Eligible for Separate Reimbursement (00.10.21a)
- Dental Extractions Prior to Cardiac Surgery, Radiation Therapy, or Transplant Surgery are Considered Eligible for Reimbursement When Certain Criteria are Met (04.00.03a)
- Nonprescription Smoking Deterrent Agents are Not Considered Eligible for Reimbursement (08.00.29b)

View Full Policies Online

The descriptions provided in this document are summaries. Full descriptions of these policies are available online at www.ibx.com/medpolicy under the Medical section.

Medical Policies

Apligraf® and Dermagraft® (11.08.20b)

COVERED: ACCORDING TO CERTAIN CRITERIA

Apligraf is a bi-layered skin product approved by the U.S. Food and Drug Administration (FDA) for use in the treatment of noninfected partial- or full-thickness skin ulcers due to venous insufficiency (i.e., venous stasis ulcers) or full-thickness neuropathic diabetic foot ulcers. Apligraf is manufactured from newborn male foreskin and consists of two primary layers: the epidermal layer and the dermal layer. The epidermal layer is formed by human keratinocytes and has a well-differentiated stratum corneum. The dermal layer is composed of human fibroblasts (capable of forming collagen fibers) in a bovine type I collagen matrix.

Dermagraft is a single-layered skin product derived from cryopreserved human fibroblasts. It is FDA-approved for use in the treatment of full-thickness diabetic foot ulcers that have been present for longer than six weeks and extend through the dermis but do not expose tendon, muscle, joint capsule, or bone. It has also been granted an FDA humanitarian device exemption (HDE) for the treatment of wounds associated with dystrophic epidermolysis bullosa. This product is manufactured from newborn male foreskin and is composed of fibroblasts, an extracellular matrix, and a bioabsorbable polyglactin mesh scaffold, onto which human fibroblasts are seeded. The fibroblasts proliferate to fill the interstices of the scaffold and secrete human dermal collagen, matrix proteins, growth factors, and cytokines to create a three-dimensional human dermal substitute containing metabolically active lining cells.

Medically Necessary Indications for Apligraf® and Dermagraft®

APLIGRAF®

Ulcers Secondary to Venous Insufficiency

Apligraf is considered medically necessary and, therefore, covered for the treatment of ulcers secondary to venous insufficiency when all of the following medical necessity criteria are met:

- The treatment is specific to noninfected partial- or full-thickness skin ulcers due to a clinical diagnosis

of venous insufficiency for which the individual is medically managed.

- The ulcer has been present for a minimum of 12 weeks.
- The ulcer has been treated with conventional nonsurgical therapy for a minimum of eight weeks, fails to decrease in size, and shows no improvement (e.g., granulation or progression towards closure).
- At least one traditional skin graft has failed.
- The individual is self-sufficient with follow-up care or has the required support system to participate in the follow-up care associated with Apligraf treatment.

Diabetic Foot Ulcers

Apligraf is considered medically necessary and, therefore, covered for the treatment of diabetic foot ulcers when all of the following medical necessity criteria are met:

- The individual is medically managed for type 1 or type 2 diabetes.
- The treatment is specific to noninfected, full-thickness neuropathic diabetic foot ulcers that have been present for a minimum of four weeks.
- The ulcer is located on the plantar, medial, or lateral surface of the foot (excluding the heel) and shows no signs of infection, tunnels and tracts, cellulitis, eschar, or obvious necrotic material that will interfere with the device adherence and wound healing.
- The ulcer extends through the dermis but does not expose the tendon, muscle, joint capsule, or bone.
- The neuropathic diabetic foot ulcer has failed to respond to conservative measures of at least four weeks' duration (i.e., non-weight-bearing regimen, debridement of necrotic and callused tissue, and acceptable methods of wound care [e.g., saline-moistened dressings]).
- The extremity must be free of active Charcot's arthropathy.
- The extremity must have adequate arterial blood supply to support tissue growth.
- The individual is self-sufficient with follow-up care or has the required support system to participate in the follow-up care associated with Apligraf treatment.

DERMAGRAFT®*Diabetic Foot Ulcers*

Dermagraft is considered medically necessary and, therefore, covered for the treatment of diabetic foot ulcers when all of the following medical necessity criteria are met:

- The individual is medically managed for type 1 or type 2 diabetes.
- The treatment is specific to noninfected, full-thickness diabetic foot ulcers that have been present for a minimum of six weeks.
- The ulcer is located on the plantar, medial, or lateral surface of the foot or heel, and shows no sign of infection, tunnels and tracts, cellulitis, eschar, or obvious necrotic material that will interfere with device adherence and wound healing.
- The ulcer extends through the dermis but does not expose the tendon, muscle, joint capsule, or bone.
- The ulcer has failed to respond to documented conservative measures of at least four weeks' duration (i.e., non-weight-bearing regimen, debridement of necrotic and callused tissue, and acceptable methods of wound care [e.g., saline-moistened dressings]).
- The extremity must be free of active Charcot's arthropathy.
- The extremity must have adequate arterial blood supply to support tissue growth.
- The individual is self-sufficient with follow-up care or has the required support system to participate in the follow-up care associated with Dermagraft treatment.

Dystrophic Epidermolysis Bullosa

Dermagraft is considered medically necessary and, therefore, covered for the treatment of wounds associated with dystrophic epidermolysis bullosa when all of the following medical necessity criteria are met:

- The device will be utilized per the HDE specifications of the FDA.
- An institutional review board (IRB) has approved the use of Dermagraft for the treatment of wounds associated with dystrophic epidermolysis bullosa to ensure that it will be used in accordance with the

FDA-labeled indication. Please note: Documentation of the IRB approval may be requested by the Company to ensure compliance with such indication.

Documentation that the medical necessity criteria for Apligraf and Dermagraft have been met must be present in the individual's medical record and made available to the Company upon request. This includes evidence that conservative measures have failed (e.g., there has been no change in baseline size or depth and no granulation or progress towards healing).

Not Medically Necessary

The frequency of Apligraf and Dermagraft applications must be consistent with each individual's specific history, response to the application, and the product safety criteria. Repeating application without signs of improvement or exceeding the frequency of application as indicated by the labeling instructions is considered not medically necessary and, therefore, not covered. The safety and effectiveness of Apligraf have not been established for individuals receiving more than five applications. The safety and effectiveness of Dermagraft have not been established for individuals receiving more than eight applications.

Experimental/Investigational

All nonlabeled indications for Apligraf and Dermagraft are considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of these services cannot be established by review of the available published literature.

Endometrial Ablation (11.06.05a)**COVERED: ACCORDING TO CERTAIN CRITERIA**

Endometrial ablation is a procedure for the treatment of menorrhagia (excessive menstrual flow) for premenopausal women for whom childbearing is complete. It is an alternative to a hysterectomy that uses an energy source to ablate (i.e., destroy) endometrial tissue. Endometrial ablation is used when other treatments, such as hormone therapy and dilation and curettage (D&C), have either failed to reduce menstrual flow or are contraindicated. Women with abnormally shaped uteri, fibroids, or polyps are generally not considered candidates for endometrial ablation.

During the procedure, an energy source is used to ablate endometrial tissue. Each of the following methods uses a different energy source to deliver the treatment:

- Laser ablation
- Electrosurgical ablation (e.g., resecting loop using electric current, electric rollerball)
- Thermal ablation (e.g., liquid-filled balloons, heated saline)
- Cryoablation (freezing)
- Radiofrequency ablation
- Microwave ablation

Endometrial ablation, with or without hysteroscopic guidance using an FDA-approved device, is considered medically necessary and, therefore, covered for women with menorrhagia when they are unresponsive to or have a contraindication to either hormonal therapy or D&C.

Fetal Fibronectin Enzyme Immunoassay (06.02.04b)

COVERED: ACCORDING TO CERTAIN CRITERIA

Fetal fibronectin (fFN) is a biochemical marker that is measured in cervicovaginal secretions to evaluate the risk of preterm labor (PTL) and delivery in women with symptoms of preterm labor. Its absence is a strong indicator that preterm delivery will not occur within the ensuing 14 days.

The fFN immunoassay has been studied as a method to more accurately rule out PTL. When the fFN enzyme is not detected between 21 and 37 weeks' gestation, the probability of PTL within the next 14 days decreases significantly. The fFN immunoassay's negative predictive value of greater than 95 percent renders it a useful adjunct to clinical findings in the management of PTL symptoms. Prospective and observational studies have been reported on the use of the fFN immunoassay in relation to the rate of hospitalization for PTL. When the study results were compared with those of the baseline period before the fFN immunoassay was performed, fewer admissions for PTL occurred during the year when the fFN immunoassay was performed, and there was no increase in preterm delivery rates. There have been no data supporting the use of the fFN immunoassay in asymptomatic individuals with or without additional risk factors. In addition, there have

been no data to support the use of the fFN immunoassay in women with triplet or higher gestations.

The fFN immunoassay is considered medically necessary and, therefore, covered for women who meet all of the following indications:

- Singleton or twin gestation between 24 weeks and 34 weeks, 6 days
- Intact amniotic membranes
- Cervical dilation less than 3 cm
- Symptoms suggestive of PTL

The fFN immunoassay is considered experimental/investigational and, therefore, not covered for all indications not approved by the FDA including, but not limited to:

- As part of routine clinical monitoring in asymptomatic pregnant women with singleton gestation and no risk factors for PTL
- As part of routine clinical monitoring in asymptomatic pregnant women at risk for PTL, including those with history of preterm birth, uterine malformation, cervical incompetence, or history of two or more spontaneous second-trimester abortions
- As part of routine clinical monitoring in women with triplet or higher gestation regardless of whether or not they are symptomatic
- As a test to identify women at term being considered for induction who are likely to deliver within 24 to 48 hours and, therefore, might be successful at induction

First-Trimester Prenatal Screening for Fetal Aneuploidy (09.00.36c)

COVERED: ACCORDING TO CERTAIN CRITERIA

First-trimester triple screening includes ultrasound measurement of fetal nuchal translucency (NT) and serum measurement of pregnancy-associated plasma protein-A (PAPP-A) and at least one form of beta-hCG (free b-hCG, total b-hCG, or invasive trophoblast antigen [ITA]). First-trimester triple screening has a detection rate for Down syndrome and other aneuploidies that is comparable to second trimester quadruple screening (alpha-fetoprotein [AFP], b-hCG, E3, and inhibin-A), with the advantage of providing information about the fetus earlier in the course of pregnancy.

If a definitive diagnosis is desired after a positive screening, chorionic villus sampling (CVS) can then be performed.

Small differences in NT measurements can significantly impact the accuracy of risk prediction of Down syndrome and other aneuploidies. Therefore, ultrasonographer training and ongoing quality assurance are essential to maintain the integrity of this screening method.

First-trimester screening for fetal aneuploidy, including Down syndrome, is considered medically necessary and, therefore, covered when all of the following measurements are performed:

- Fetal NT
- One form of beta subunit of human chorionic gonadotropin (e.g., free b-hCG, total b-hCG, or ITA)
- PAPP-A

The use of NT measurements alone as a screening tool for fetal aneuploidy is considered experimental/investigational and, therefore, not covered because of the high false-positive screening rate of the test in the absence of maternal serum markers.

In geographic areas with a capitated radiology program, fetal ultrasound to measure NT is excluded from capitation and should only be conducted by ultrasonographers who are certified to perform ultrasounds for this purpose.

Percutaneous Lumbar Discectomy (11.15.15a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Individuals with herniated discs improve without surgery 80 to 90 percent of the time. A physician may try to treat this condition conservatively with bedrest, medication (e.g., analgesics for pain control, anti-inflammatory agents to reduce swelling, muscle relaxants), and/or physical therapy. Herniation of the disc can be caused by strain, trauma, or disc degeneration and usually occurs in the lumbar region. For individuals who do not respond to conservative treatments, other treatments may be explored, such as percutaneous lumbar discectomy (PLD).

PLD is a surgical procedure used to treat herniated lumbar discs and can be performed either manually or

using an automated device. When PLD is performed manually, cutting forceps are used to remove the nuclear material from within the disc annulus. During automated PLD, a probe is used to excise small pieces of the nucleus by aspiration.

PLD is considered medically necessary and, therefore, covered for individuals who meet all of the following criteria:

- Their predominant symptom is acute unilateral leg pain, localized to a single dermatome (i.e., radicular pain) that is consistent with a contained disc herniation (the nucleus pulposus remains contained in the annulus fibrosus). The individual may also have acute and intractable discogenic (intervertebral disc disarrangement) back pain that is consistent with a contained disc herniation.
- Their neurologic signs or symptoms are consistent with a contained disc herniation (e.g., sensory abnormalities, positive straight leg raising test, reflex alterations, weakness).
- Their herniated lumbar disc (L1-L2 through L5-S1) is confirmed by magnetic resonance imaging (MRI), computed tomography (CT), or myelography that is consistent with the signs and symptoms of a contained disc herniation, with no evidence of a free fragment or sequestered disc.
- Their history of conservative therapy (e.g., bedrest, medications [analgesics for pain control, anti-inflammatory agents to reduce swelling, muscle relaxants], and/or physical therapy) has failed to relieve pain and other symptoms.

PLD is considered not medically necessary and, therefore, not covered for the following indications:

- A suspected symptomatic herniated disc that has been previously treated with chemonucleolysis or surgery
- A noncontained disc or free fragment of disc
- Vertebral disease, such as spinal stenosis or spondylolisthesis
- Signs and symptoms associated with pathology such as cauda equina syndrome (e.g., impairment of bladder or bowel function, progressive neurologic dysfunction)

Transcatheter Arterial Chemoembolization (TACE) of Hepatic Malignancies (07.05.06a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Transcatheter arterial chemoembolization (TACE) is a regional therapy being used as an alternative to ablative or systemic treatment when malignant hepatic tumors are not amenable to surgery. TACE involves the administration of a chemotherapeutic agent (usually doxorubicin, mitomycin C, or cisplatin) into the hepatic artery, followed by arterial embolization. A poppy seed oil (lipiodol), which concentrates in hepatocellular carcinoma (HCC) and carcinoid tumors, is commonly used as a suspension medium and embolic agent for the chemotherapeutic agent(s); however, other frequently used embolizing agents include polyvinyl alcohol, collagen, and gelatin sponge powder and pledgets. Embolization provides a longer dwell time and greater concentration of the chemotherapeutic drug in the tumor while sparing functional liver tissue. The procedure is also known as hepatic artery chemoembolization (HACE), but it should not be confused with intrahepatic arterial chemotherapy in which high-dose chemotherapy is infused into the hepatic artery without embolization.

TACE is commonly performed by interventional radiologists and usually requires overnight hospitalization.

Medical Necessity

When **all** eligibility criteria listed below are met, TACE is considered medically necessary and, therefore, covered for **any** of the following conditions:

- Treatment of unresectable HCC
- Reduction of tumor bulk to treat symptoms associated with unresectable hepatic metastases of neuroendocrine tumors (e.g., carcinoid and pancreatic islet cell tumors)
- Treatment of carcinoid syndrome that has failed systemic octreotide therapy
- As a bridge to transplantation for individuals with HCC who are already on an orthotopic liver transplantation (OLT) waiting list, to retard tumor progression and accommodate waiting list times
- Treatment of liver metastases from ocular (uveal) melanoma

Eligibility Criteria (ALL criteria must be met for any of the above conditions)

- A patent portal vein on superior mesenteric arterial portovenography
- A tumor burden less than 50 percent of liver volume OR, when TACE is used as a bridge to transplantation, the following OLT criterion must be met:
 - One tumor of less than 5 cm or 3 tumors of less than 3 cm each
- Adequate liver function as determined by a Child-Pugh score of A or B
- The absence of any contraindications to angiography
- The absence of any extrahepatic metastases

Experimental/Investigational

TACE is considered experimental/investigational and, therefore, not covered when it is used for any of the following conditions because the safety and/or efficacy of these uses cannot be established by a review of the available published medical literature:

- As a neoadjuvant or adjuvant therapy pre- or post-curative resection or for recurrent HCC after curative resection
- For other types of liver metastases, including those from colorectal carcinoma, soft-tissue sarcoma, cholangiocarcinoma, and breast carcinoma

Experimental/Investigational Policies

Adrenal Tissue Transplantation to Brain (11.15.14b)

NOT COVERED: CONSIDERED EXPERIMENTAL/ INVESTIGATIONAL

Parkinson's disease is a chronic and progressive disease of the central nervous system that causes the loss of dopaminergic cells in the brain, which leads to the depletion of dopamine, an essential neurotransmitter for motor function regulation in the body. The major signs and symptoms of Parkinson's disease usually begin after age 40 and include resting tremor, rigidity, and bradykinesia.

Proponents of adrenal-to-brain tissue transplantation believe that transplanted adrenal tissue may restore the lost dopamine activity in the corpus striatum. Adrenal-to-brain transplantation is intended to ameliorate the symptoms of Parkinson's disease by replacing the lost neural cell function in the brain of an affected individual with a graft of either the individual's own adrenal medullary tissue (autograft) or with adrenal tissue from an aborted fetus (allograft). The tissue may be implanted into the caudate nucleus of the brain at the lateral ventricle, or into the putamen; it is usually done by stereotactic technique with a cannula rather than by open craniotomy.

Studies using autografted adrenal medullary tissue have been discontinued because of poor results. Studies of fetal adrenal tissue allografts continue, but have not shown lasting benefits.

Adrenal-to-brain tissue transplantation is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this service cannot be established by review of the available published literature.

Electrical Impedance Scanning of the Breast (07.07.08a)

NOT COVERED: CONSIDERED EXPERIMENTAL/ INVESTIGATIONAL

Electrical impedance scanning of the breast, a noninvasive imaging procedure that does not emit any radiation, involves the transmission of continuous electricity into the body, either through an electrode patch attached to the arm or a hand-held cylinder. This small electrical current then travels through the breast where it is measured at skin level by a probe placed on the breast. A computer screen displays two-dimensional images of the breast that are generated from the measurements of electrical impedance. Impedance is a measurement of how material affects the flow of electricity. Breast cancer cells conduct electricity differently than normal breast cells and tend to have a lower electrical impedance. Cancerous images may appear as bright spots on the computer screen.

Based on a review of the literature, study results on the diagnostic performance of electrical impedance scanning have reported an inferior performance and contrast with the FDA Summary of Safety and Effectiveness. Current published literature has indicated that electrical impedance imaging has not undergone enough clinical testing to be used as a recommended part of breast cancer screening. Further research is recommended on the use of this diagnostic tool.

Electrical impedance scanning of the breast is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of the service cannot be established by review of the available published literature.

Hippotherapy (10.00.01a)

NOT COVERED: CONSIDERED EXPERIMENTAL/ INVESTIGATIONAL

Hippotherapy is a treatment modality that uses the movement of a horse to assist patients with movement dysfunction. Patients with spastic cerebral palsy have exaggerated stretch reflexes, muscle spasms, and increased deep tendon reflexes that impair ambulation. The natural swaying motion of the horse produces a pelvic movement in the rider similar to human ambulation. It is also hypothesized that the variations in the horse's movements can prompt equilibrium responses in children with cerebral palsy.

The majority of medical literature on hippotherapy consists of small case series involving children with cerebral palsy. The remaining few case series addressed individuals with traumatic brain injury, neuromuscular disorders, segmental instabilities of the spine, post-rehabilitation of lumbar intervertebral disk, and paraplegia. One randomized trial of 19 patients revealed no significant effects in the majority of measured outcomes. No randomized clinical trials support hippotherapy as beneficial or more beneficial than other forms of therapy, such as physical therapy and occupational therapy. Further studies (particularly randomized control trials with adequate sample size) are needed to determine the safety and/or efficacy of hippotherapy. No scientific conclusion can be made at this time to support the use of this service.

Hippotherapy is a benefit contract exclusion for most Company products.

When not a specific benefit contract exclusion, hippotherapy is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this service cannot be established by review of the available published literature.

Percutaneous Intradiscal Annuloplasty (IDET/PIRFT) (11.14.14c)

NOT COVERED: CONSIDERED EXPERIMENTAL/ INVESTIGATIONAL

Percutaneous intradiscal annuloplasty is a minimally-invasive procedure intended to treat chronic low back pain related to disc disease. Two of the most common types are intradiscal electrothermal therapy (IDET) and percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). The devices used to perform IDET or PIRFT are indicated for the coagulation and decompression of disc material to treat symptomatic individuals who have annular disruption of contained herniated discs (per the FDA). Theoretically, the mechanism of action in each procedure is designed to compress collagen fibers within the disc annulus without causing excessive damage and to thermocoagulate nerve tissue to achieve pain relief. However, the mechanism of action of pain relief is not fully understood. Percutaneous intradiscal annuloplasty is usually performed in an outpatient setting using local anesthesia.

Percutaneous intradiscal annuloplasty, by any method (e.g., IDET, PIRFT), is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this service cannot be established by review of the available published literature.

Protonics® Device (07.08.02b)**NOT COVERED: CONSIDERED EXPERIMENTAL/
INVESTIGATIONAL**

Although the precise etiology of patellofemoral pain (PFP) is unknown, it is commonly described as an imbalance of muscle strength that leads to maltracking of the patella in the femoral trochlear groove. The condition, also known as patellofemoral dysfunction (PFD) or patellofemoral syndrome (PFS), is common in the female athlete. PFP most commonly occurs on stair climbing or after prolonged sitting. Traditional management consists of: orthotics, taping, and/or bracing to correct patellar hypermobility; and/or activity modification and therapeutic exercise to strengthen the quadriceps and stretch the hamstrings.

The Protonics® device (Empi®, St. Paul, Minn.) is a long leg brace with a hinged knee that provides variable resistance to flexion. The Protonics® device uses programmable resistance to activate muscle groups in the back of the thigh (hamstrings), buttocks, and abdominals and deactivate other muscles during knee flexion. Theoretically, the resistance system reduces the forward tilt of the femur, thus reducing PFP. In addition, the muscles are compelled to relearn proper movement, which, with repetition, will continue even when the device is removed.

Evidence to support the theoretical basis of the Protonics® device is controversial and has not been validated. Available studies that address the use of the device are poorly conceived and designed, with inconsistent measurements, subjects, and outcomes. No published long-term outcomes compare Protonics® to traditional treatments for PFP and no long-term outcomes validate that the device induces muscles to relearn proper movement. Therefore, there continues to be insufficient published literature to support the use of the Protonics® device.

The Protonics® device is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this device cannot be established by review of the available published literature.

**Surface Electromyogram (SEMG)
(07.03.20)****NOT COVERED: CONSIDERED EXPERIMENTAL/
INVESTIGATIONAL**

Conventional electrodiagnostic evaluation through the use of a needle electromyogram (NEMG) is an invasive procedure that has a proven and long-established place in the diagnosis, treatment, and monitoring of disorders of the nerves and muscles.

Surface electromyogram (SEMG) is a noninvasive, computer-based technique that records the electrical impulses of the nerves and muscles through electrodes that are placed on or passed over the surface of the skin. SEMG differs from NEMG with respect to technical requirements and electrical properties. SEMG electrodes measure from a wide area of muscle, have a relatively narrow frequency band, have low-signal resolution, and are highly susceptible to movement artifact.

There are few studies that directly compare the effectiveness of SEMG with NEMG for diagnosing disorders of the nerves and muscles. The extensive literature on NEMG techniques shows, however, that a number of different parameters must be measured to ensure reasonable sensitivity to adequately assess muscular activity. Since SEMG cannot measure critical parameters such as muscle resting state and insertional activity, the clinical utility of SEMG is considered limited.

According to the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), there are no clinical indications for the use of SEMG in the diagnosis and treatment of disorders of the nerves or muscles.

SEMGs are considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this service cannot be established by review of the available published literature.

Claim Payment Policies

Collection and Interpretation of Physiologic Data Are Not Eligible for Separate Reimbursement (00.10.21a)

Physiologic data are measurements (e.g., blood pressure, electrocardiogram [ECG], interstitial glucose levels) that provide the physician with information necessary to monitor the individual's health and to provide appropriate treatment.

The data is measured, stored digitally, and then reported by the individual and/or their caregiver to the physician in either an electronic or a written format, depending on the device used to collect the data.

The Company covers the collection and interpretation of physiologic data, but does not consider them distinct and separate services. The Company considers the collection and interpretation of physiologic data to be integral to the evaluation and management (E&M) service rendered at the time of their collection or when the results are presented and the treatment options are discussed with the individual. Therefore, the collection and interpretation of physiologic data are not eligible for separate reimbursement.

Dental Extractions Prior to Cardiac Surgery, Radiation Therapy, or Transplant Surgery are Considered Eligible for Reimbursement When Certain Criteria are Met (04.00.03a)

At times, based on an individual's medical condition, it may be medically necessary to perform dental extractions prior to the initiation of cardiac surgery (when there is risk for bacterial endocarditis from procedures such as valve replacement or surgical correction of tetralogy of Fallot), radiation therapy, or transplant surgery to prevent medical complications or infections.

Dental extractions prior to cardiac surgery, radiation therapy, or transplant surgery are covered and eligible for reimbursement consideration by the Company.

- Individual benefits must be verified as some group contracts exclude coverage for dental extractions prior to cardiac surgery, radiation therapy, or transplant surgery.

Nonprescription Smoking Deterrent Agents are Not Considered Eligible for Reimbursement (08.00.29b)

Nonprescription smoking deterrent agents are medications that aid in smoking cessation by temporarily reducing the symptoms associated with nicotine withdrawal. These medications may be provided orally or by transdermal patch, nasal spray, or chewing gum. Most of the medications are available over the counter (nonprescription). Nonprescription drugs do not, by federal law, require a physician prescription.

Nonprescription smoking deterrent agents are not covered under the medical or pharmacy benefits of the Company's products.

For information on prescription agents used for smoking cessation, refer to the applicable Company formulary.

More Information

Physician Volunteers Needed to Assist in Developing Medical Policies

Independence Blue Cross (IBC) is currently recruiting physicians to join our Policy Committee Advisory Panel. This panel is responsible for evaluating the scientific evidence and local standards of care addressed in our medical policies.

Medical policies are research-based documents that allow IBC to evaluate the medical necessity of services, devices, biologics, and procedures for its members. In addition, medical policies provide guidelines for obtaining benefits and reimbursement in accordance with a member's plan. As a volunteer consultant on the Policy Committee Advisory Panel, you will evaluate proposed medical policies based on your area(s) of expertise. As such, your contributions will significantly impact the care of patients in your region.

At this time, IBC is seeking physician consultants in the following specialties:

- Neurosurgery
- Orthopedics
- Urology
- Vascular Surgery
- Physical Medicine and Rehabilitation
- Rheumatology
- Cardiology
- Gastroenterology
- Pain Medicine

To qualify as a member of the Policy Committee Advisory Panel, you must:

- Maintain board certification for each specialty or subspecialty for which you wish to consult.
- Maintain an active clinical practice in each specialty or subspecialty for which you wish to consult.
- Understand and agree to adhere to our confidentiality statement.
- Maintain a high ethical standard, evidenced by the absence of any IBC investigation into personal or group claims practices.
- Complete and sign a Conflict of Interest Statement and Confidentiality Agreement prior to becoming a member of the advisory panel.

If you meet the above criteria and have an interest in sharing your expertise as a member of the Policy Committee Advisory Panel, please submit your curriculum vitae to:

Gerald W. Peden, M.D., M.A.
 Senior Medical Director
 Claim Payment Policy Department
 Independence Blue Cross
 1901 Market Street
 Philadelphia, PA 19103-1480

Contact Provider Services

Provider Services	Philadelphia Area	Outside Philadelphia
HMO Policies/Procedures/Eligibility/Claims	215-567-3590	1-800-227-3119
PPO Policies/Procedures/Claims	215-567-3694	1-800-332-2566



The Blue Cross words and symbols are registered marks of the Blue Cross and Blue Shield Association, an association of Independence Blue Cross and Blue Shield.