AmeriHealth

Special Note: The Fall 2008 edition of the CGPU will be the last issue. Look for further details in the Fall issue.

CODING GUIDELINES AND POLICY UPDATE

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www.amerihealth.com/medpolicy

Important note:

The medical policies referenced in this document apply to all HMO, POS, and PPO products of the AmeriHealth companies and their affiliates.

This document was developed to assist AmeriHealth 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 benefits 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 in accordance with URAC and NCQA guidelines; therefore when new medical evidence becomes available, 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 benefits 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 benefits program, the terms of the benefits program will govern. The inclusion of a code/modifier in this policy does not imply reimbursement. Eligibility, Benefits, Limitations, Exclusions, Precertification/ Referral Requirements, Provider Contracts, and Policy still apply.

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.

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VIEW FULL POLICIES ONLINE

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

Medical Policies

Catheter Ablation of Cardiac Arrhythmias (11.02.06d)

Covered: According to Certain Criteria

Catheter ablation of cardiac arrhythmias is a nonsurgical procedure used to correct an abnormality in the heart's electrical conduction system. Alterations or defects in the conduction system can lead to an arrhythmia that causes the heart to beat too fast or too slow, or to pump in an ineffective rhythmic pattern. Abnormal pumping of the heart causes the body's vital organs to receive less than optimal blood flow, which often has serious consequences.

Catheter ablation of cardiac arrhythmias is considered medically necessary and, therefore, covered for individuals who have any of the following symptomatic arrhythmias:

- Paroxysmal supraventricular tachycardia (PSVT)
- Supraventricular tachycardia (SVT)
- Accessory bypass tract arrhythmia (Wolff-Parkinson-White syndrome)
- Atrial tachyarrhythmia (when ablation is intended to modify the atrioventricular (AV) junction to obtain ventricular rate control)
- Sustained atrioventricular nodal reentrant tachycardia
- Atrial tachycardia, atrial flutter, or atrial fibrillation
- Pulmonary vein isolation (PVI) may be recommended for individuals with atrial fibrillation.
- Ventricular tachyarrhythmia associated with structural heart disease (i.e., ischemic or idiopathic cardiomyopathy)
- Sustained monomorphic ventricular tachycardia or bundle branch reentrant ventricular tachycardia in the absence of structural heart disease (i.e., ischemic or idiopathic cardiomyopathy)
- Tachy-brady syndrome

In addition, at least one of the following criteria must be met:

- The individual cannot tolerate pharmacologic management of the arrhythmia.
- The arrhythmia is drug-resistant.
  - Drug-resistant arrhythmia is defined as continued arrhythmia that has failed at least one trial of an antiarrhythmic drug at a therapeutic dose.
- Pharmacologic management of the arrhythmia is contraindicated in the individual.
- The procedure is being used as first-line therapy for either of the following:
  - An individual who has tachy-brady syndrome
  - A pre-menopausal woman with arrhythmia who is planning pregnancy

Debridement of Mycotic and Symptomatic Non-Mycotic Hypertrophic Nails (11.08.17a)

Covered: According to Certain Criteria

The debridement of nails is the removal of nail substance, either partial or complete, that is causing local pathology. Debridement temporarily reduces the size or girth of a portion of an abnormal nail plate; it does not remove the entire nail plate. Debridement is most commonly performed without anesthesia for one or more of the following purposes:

- Relief of pain
- Treatment of infection (e.g., bacterial, fungal, and/or viral)
- Temporary removal of an anatomic deformity (e.g., onychauxis [thickened nail] or certain types of onychocryptosis [ingrown nail])
- Exposure of conditions below the nail for treatment and/or diagnosis (e.g., biopsy, culture)
- Prophylaxis to prevent further complications (e.g., ulceration under the nail in an individual with lack of sensation and onychauxis)

Debridement of mycotic and symptomatic non-mycotic hypertrophic nails is considered medically necessary every 60 days in the absence of a systemic condition when clinical evidence and documentation of mycotic and symptomatic non-mycotic hypertrophic conditions of the nail are provided and one of the following criteria is met:

- For ambulatory individuals, there must be a marked limitation of ambulation, pain, and/or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

- For non-ambulatory individuals, there must be evidence of pain and/or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

Debridement of mycotic and symptomatic non-mycotic hypertrophic nails performed more often than every 60 days is considered not medically necessary and, therefore, not covered unless documentation (e.g., nail size, color, thickness) is provided in the medical record to substantiate the increased frequency.

Whirlpool treatment performed prior to the debridement of mycotic and symptomatic non-mycotic hypertrophic nails to soften the nails or skin is considered part of routine foot care services and, therefore, not eligible for separate reimbursement.

Benefit application

Some benefit contracts exclude routine or palliative foot care. However, when the medical necessity criteria listed in the medical policy are met, debridement of mycotic and symptomatic non-mycotic hypertrophic nails is not considered routine or palliative.

Capitation

In geographic areas with a capitated podiatry program, routine foot care is included in the capitated podiatry program.

Endovascular Stent-Graft Repair of Thoracic Aortic Aneurysm (11.02.17b)

Covered: According to Certain Criteria

An aortic aneurysm is an abnormal bulge or dilation in the wall of the aorta, the body's largest artery. Thoracic aortic aneurysms can occur anywhere along the aorta above the diaphragm, including the ascending aorta, the aortic arch, and the descending thoracic aorta. Dissection (leakage or rupture) of an aneurysm can lead to serious morbidity or mortality, especially in large vessels such as the aorta. The causes of an aortic aneurysm may be acquired from conditions such as atherosclerosis, chronic hypertension, trauma, and syphilis, or from congenital conditions such as connective tissue disorders (e.g., Marfan's syndrome).

Based on a review of the available literature, including the controlled trials with the GORE TAG Thoracic Endoprosthesis, the use of endovascular stent-grafts for the treatment of a thoracic aortic aneurysm is associated with improved or comparable outcomes when compared to traditional open surgical repair.

Endovascular stent-graft repair of a thoracic aortic aneurysm is considered medically necessary and, therefore, covered when the individual presents with all of the following:

- An aneurysm that is limited to the descending thoracic aorta
- Adequate iliac/femoral access
- An aortic inner diameter in the range of 23-37 mm
- Greater than or equal to 2 cm of nonaneurysmal aorta proximal and distal to the aneurysm
- No evidence of dissection or rupture

Diameter specifications are based on the parameters identified for the U.S. Food and Drug Administration (FDA)-approved use of the GORE TAG endoprosthesis.

Endovascular stent-grafts are considered experimental/investigational and, therefore, not covered for the treatment of thoracic aneurysms in other anatomic locations (e.g., ascending thoracic aorta, aortic arch) or in the treatment of aortic dissections or rupture as these are considered off-label indications.

Evaluation and Management (E&M) of Diabetic Peripheral Neuropathy with Loss of Protective Sensation (LOPS) (07.03.15a)

Covered: According to Certain Criteria

Peripheral neuropathy is a nerve disorder that can affect the upper and lower extremities of an individual with diabetes. This condition can lead to weakness, pain, numbness, and loss of feeling in the arms, hands, legs, and feet of an individual with diabetes. The lower extremities are most likely to be affected before the upper extremities. Peripheral neuropathy is the most common cause of lower extremity amputation in individuals with diabetes.

Peripheral neuropathy leads to loss of protective sensation (LOPS), whereby an individual is unable to feel minor trauma from mechanical, thermal, or chemical sources. Sores or blisters may appear on areas of the foot, and may go unnoticed due to the numbness or loss of sensation. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing. Injuries to the foot that are not promptly treated may lead to amputation due to the spread of infection to the bone.

Peripheral neuropathy with LOPS, secondary to diabetes, is a localized disorder of the feet. LOPS is diagnosed through sensory testing with the 5.07 monofilament using established guidelines such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases. Five sites should be tested on the plantar surface of each foot. The areas must be tested randomly, since the loss of protective sensation may be patchy in distribution and the individual may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, two or more of the five sites on either foot tested with the Semmes-Weinstein nonfilament must be documented as presenting absence of sensation to diagnose peripheral neuropathy with LOPS. Foot examinations are necessary to allow for early interventions to offset serious complications, which typically afflict individuals with diabetic peripheral neuropathy with LOPS.

The evaluation and management (E&M) of diabetic peripheral neuropathy with LOPS is considered medically necessary and, therefore, covered every six months for individuals who have a documented diagnosis of diabetic sensory neuropathy with LOPS.

Guidelines

Procedure codes G0245 and G0246 are not eligible for separate reimbursement when they are billed in addition to an E&M code, a Consultation code, and/or a routine foot care code.

When reporting procedure codes G0245 and G0246, the documentation in the medical record should contain the following:

- The individual's history
- A physical examination that should include all of the following:
  - Visual inspection of forefoot and hindfoot (including toe web spaces)
  - Evaluation of protective sensation
  - Evaluation of foot structure and biomechanics
  - Evaluation of vascular status and skin integrity
  - Evaluation of the need for special footwear
- Patient education

High-Frequency Chest Wall Oscillation Devices (05.00.14c)

Covered: According to Certain Criteria

A high-frequency chest wall oscillation device is designed to enhance the mobilization of bronchial secretions. The device is an inflatable vest that is connected by two tubes to a small air-pulse generator. Oscillating positive air pressure causes the vest to inflate and deflate up to 25 times a minute, creating a vibratory motion that aids in the mobilization of secretions. The action of the device creates mini-coughs that dislodge mucus from the bronchial walls, thus increasing mobilization of the mucus toward the central airways. The oscillating action also thins the secretions and makes them easier to remove by coughing or suctioning.

A 4- to 6-week trial of a high-frequency chest wall oscillation device is considered medically necessary and, therefore, covered for the treatment of individuals with a documented history that confirms a failure of standard treatments (e.g., manual chest percussion, postural drainage) to adequately mobilize retained bronchial secretions and one of the following diagnoses:

- Cystic fibrosis
- Bronchiectasis confirmed by computed tomography (CT) scan and documentation of one of the following:
  - Daily productive cough for at least six continuous months
  - Frequent (i.e., more than two per year) exacerbations of respiratory infection requiring antibiotic therapy

Continued coverage of the device after the trial is considered medically necessary and, therefore, covered when the effectiveness of the device has been demonstrated by:

- Documentation that the device has been used daily or as prescribed
- Documentation of increased expectoration of mucus

If the trial of the device is successful and the individual wishes to continue using the device, continued authorization for the device must be obtained. The ordering physician must provide a letter of medical necessity to the Company stating compliance with the above requirements.

High-frequency chest wall oscillation devices for any diagnosis other than cystic fibrosis or bronchiectasis are considered not medically necessary and, therefore, not covered because the available published literature does not support the use of this device for the treatment of any other diagnosis.

Refer to the policy on repair and/or replacement of durable medical equipment (DME) to determine the Company's reimbursement position for these services.

American Association for Respiratory Care (AARC) guidelines

According to the AARC, therapy with a high-frequency chest wall oscillation device should be re-evaluated or modified if any of the following complications occur with use of the device:

- Hypoxemia
- Increased intracranial pressure
- Acute hypotension during therapy
- Pulmonary hemorrhage
- Pain or injury to muscles, ribs, or spine
- Vomiting and aspiration
- Bronchospasm
- Dysrhythmias

According to the AARC, the following conditions are a partial list of contraindications for devices or procedures that externally manipulate the thorax:

- Absolute contraindications include:
  - Head and neck injury until stabilized
  - Active hemorrhage with hemodynamic instability
- Relative contraindications include:
  - Intracranial pressure (ICP) greater than 20 mm Hg
  - Recent spinal surgery (e.g., laminectomy) or acute spinal injury
  - Active hemoptysis
  - Empyema
  - Bronchopleural fistula
  - Pulmonary edema associated with congestive heart failure
  - Large pleural effusions
  - Pulmonary embolism
  - Rib fracture, with or without flail chest
  - Surgical wound or healing tissue
  - Individuals in whom increased intracranial pressure is to be avoided (e.g., individuals who will be undergoing/who have undergone neurosurgery or eye surgery, individuals with a history of aneurysm)
  - Uncontrolled hypertension
  - Distended abdomen
  - Esophageal surgery
  - Recent gross hemoptysis related to recent lung carcinoma treated surgically or with radiation therapy
  - Uncontrolled airway at risk for aspiration (feeding tube or recent meal)
  - Subcutaneous emphysema
  - Recent epidural spinal infusion or spinal anesthesia
  - Recent skin grafts or flaps on the thorax
  - Burns, open wounds, or skin infections of the thorax
  - Recently placed transvenous pacemaker or subcutaneous pacemaker (particularly if mechanical devices are used)
  - Suspected pulmonary tuberculosis
  - Lung contusion
  - Bronchospasm
  - Osteomyelitis of the ribs
  - Osteoporosis

- — Coagulopathy
- — Chest wall pain

Additional clinical criteria

Manufacturers make high-frequency chest wall oscillation device vests to fit individuals based upon chest measurements. Currently, the smallest vest accommodates a chest circumference of 18 inches; the largest vest accommodates a chest circumference of 68 inches.

Pulse Oximetry Device in the Home Setting (05.00.31b)

Covered: According to Certain Criteria

A pulse oximetry device indirectly measures the arterial oxygen saturation levels in the blood by using a noninvasive sensor probe on the ear or finger. This reading provides an estimation of arterial oxyhemoglobin saturation (SaO^2) by utilizing selected wavelengths of light to determine the saturation of oxyhemoglobin (SpO^2). The American Academy of Respiratory Care (AARC) suggests that pulse oximetry may temporarily suffice when direct measurements of arterial oxyhemoglobin saturation are not available or cannot be performed in a timely fashion. They also suggest that this measurement may be an adequate assessment of SaO^2 when the acid-base status and/or partial oxygen tension in arterial blood (PaO^2) are not required. The AARC recommends pulse oximetry for individuals who require continuous and prolonged monitoring.

A pulse oximetry device in the home setting is used for individuals on assisted ventilation or home oxygen therapy who require frequent adjustments in oxygen concentration. It can also be used for individuals who have progressive conditions with frequently fluctuating SpO^2 levels.

A pulse oximetry device in the home setting is considered medically necessary and, therefore, covered for individuals who meet all of the following criteria:

- Home oxygen therapy is required
- Adjustments in oxygen concentration are required due to desaturation from an acute or chronic condition
- A trained caregiver, or the individual for whom the device is being prescribed, has the physical and cognitive capacity to adjust the oxygen levels according to established guidelines set forth by the prescribing physician
- One or more of the following conditions are present:
  - — Apnea
  - — Asthma
  - — Bronchiectasis
  - — Bronchopulmonary dysplasia
  - — Central nervous system disorders affecting respiratory control
  - — Chronic airway obstruction
  - — Chronic interstitial lung disease
  - — Chronic obstructive pulmonary disease
  - — Congestive heart failure
  - — Cor pulmonale
  - — Cystic fibrosis
  - — Emphysema
  - — Laryngotracheomalacia
  - — Lung mass
  - — Neuromuscular diseases (e.g., multiple sclerosis, amyotrophic lateral sclerosis [ALS])
  - — Pertussis syndrome
  - — Pneumonoconiosis
  - — Pulmonary fibrosis
  - — Severe gastroesophageal reflux or severe oral feeding issues
  - — Sleep apnea
  - — Status post acute respiratory distress syndrome (ARDS)
  - — Other apnea or respiratory distress

When the above criteria are not met, the use of a pulse oximetry device in the home setting is considered not medically necessary and, therefore, not covered.

Routine Foot Care (07.07.01d)

Covered: According to Certain Criteria

Routine (i.e., palliative or cosmetic) foot care is typically performed by a podiatrist or primary care physician for the purposes of inspecting and treating an individual's feet for sequelae of systemic conditions, including a decrease in circulation, skin, and nail irregularities; alteration in nerve sensations; foot deformities; swelling; ulceration; or drainage.

Routine foot care includes the treatment of:

- Corns, also known as a clavus: a thickened hard growth of skin
- Calluses, also known as a tyloma or tylomata: a thickening of skin of the horny layer due to locations of pressure or friction
- Plantar keratosis, hyperkeratosis, and keratotic lesions: outer layers of skin that become overgrown and thick
- Bunions (except capsular or bone surgery thereof): inflammation from long-term pressure and irritation at the joint area located at the base of the great toe
- Nails (except surgery for ingrown nails)

When a benefit exists, routine foot care is considered medically necessary and, therefore, covered every 60 days when both of the following criteria are met:

- The individual has peripheral vascular disease or peripheral neuropathic disease as a result of one or more of the diagnoses listed below:
  - Alcoholism
  - Amyotrophic lateral sclerosis (ALS)
  - Amyloid neuropathy
  - Angiokeratoma corporis diffusum (Fabry's disease)
  - Arteriosclerosis obliterans (ASO) (e.g., arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)
  - Arteritis of the feet
  - Buerge's disease (thromboangiitis obliterans)
  - Chronic indurated cellulitis
  - Chronic thrombophlebitis
  - Chronic venous insufficiency
  - Diabetes mellitus
  - Hereditary sensory radicular neuropathy
  - Intractable edema, secondary to a specific disease (e.g., congestive heart failure, kidney disease, hypothyroidism)
  - Lymphedema, secondary to a specific disease (e.g., Milroy's disease, malignancy)
  - Malabsorption (celiac disease, tropical sprue)
  - Malnutrition (general, pellagra)
  - Pernicious anemia (e.g., carcinoma, hereditary disorders, chronic renal disease, traumatic injury)
  - Raynaud's disease
- The individual has one of the following:
  - A **Class A** finding: Nontraumatic amputation of foot or integral skeletal portion thereof
  - Two of the following **Class B** findings:
    - Absent posterior tibial pulse
    - Absent dorsalis pedis pulse
    - Advanced trophic changes (at least three of the following are required):
      - Hair growth (decrease or absence)
      - Nail changes (thickening)
      - Pigmentary changes (discoloration)
      - Skin texture (thin, shiny)
      - Skin color (rubor or redness)
  - One **Class B** finding (see above) and two of the following **Class C** findings:
    - Claudication
    - Temperature changes (e.g., cold feet)
    - Edema
    - Paresthesias (abnormal spontaneous sensations in the feet)
    - Burning

Whirlpool treatment performed prior to routine foot care, to soften the nails or skin, is considered part of routine foot care services and, therefore, not eligible for separate reimbursement.

Guidelines

When nail trimming is performed as an individual service, report the appropriate individual service code. When routine foot care is performed as a comprehensive service, report the appropriate comprehensive Healthcare Common Procedure Coding System (HCPCS) code instead of reporting the codes for the individual services.

All codes for routine foot care services should be reported only once per visit regardless of the number of lesions or nails treated.

Capitation

In geographic areas with a capitated podiatry program, routine foot care is included in the capitated podiatry program. Refer to the applicable policies on services included in capitation.

Sacral Nerve Stimulation for Continence Control (11.17.04e)

Covered: According to Certain Criteria

A sacral nerve stimulator is a surgically implanted device (i.e., InterStim® Therapy, Medtronic, Inc.; Minneapolis, MN) that is used to manage urinary urge incontinence, urgency/frequency incontinence, and/or nonobstructive urinary retention. Urinary urge incontinence is defined as the leakage of urine with a strong urge to void. Urinary urgency/frequency incontinence involves the uncontrolled urge to urinate that results in the frequent excretion of small volumes of urine. Urinary retention is defined as the inability to empty the bladder completely.

Sacral nerve stimulation (SNS) consists of both a temporary test stimulation to determine if an implantable stimulator will be effective and a permanent implantation after a successful test stimulation.

SNS that utilizes the **temporary** test stimulation is considered medically necessary and, therefore, covered for the treatment of urinary urge incontinence, urgency/frequency syndrome, and/or nonobstructive urinary retention when both of the following criteria are met:

- The condition must be refractory to conventional therapy (documented behavioral, pharmacologic, and/or surgical corrective therapy).
- Individuals must keep a diary to record voiding patterns so that the clinical effectiveness of the temporary implant procedure can be properly evaluated.

SNS that utilizes the **permanent** placement of the implantable device is considered medically necessary when the following criterion is met:

- Individuals must complete a successful test stimulation (i.e., at least a 50 percent reduction in the frequency of incontinent episodes).

SNS is considered not medically necessary and, therefore, not covered for individuals who:

- Have not had an appropriate response to a test stimulation
- Are unable to operate the neurostimulator
- Have stress incontinence
- Have mechanical obstructions (e.g., urethral strictures, benign prostatic hyperplasia, cancer)
- Have specific neurologic conditions that are associated with secondary manifestations (e.g., diabetes with peripheral nerve involvement, multiple sclerosis, spinal cord injury/lesions, cerebrovascular accident, detrusor hyperreflexia)
- May be exposed to diathermy (e.g., shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy)
- Are pregnant
- Are under the age of 16
- Are undergoing bilateral stimulation with InterStim® therapy

Claim Payment Policy

Direct Access Obstetrics/ Gynecology (OB/GYN) (00.09.01c)

Members with Direct Access OB/GYN Benefits Do Not Require a Referral from a Primary Care Physician to Obtain Covered Services from a Network OB/GYN

The Company's health maintenance organization (HMO) and point-of-service (POS) products (commercial and Medicare) allow female members to obtain covered services from the following participating provider types without a referral from their primary care physician (PCP):

- Obstetrics (OB)
- Gynecology (GYN)
- Obstetrics/Gynecology (OB/GYN)
- Gynecologic Oncology
- Maternal Fetal Medicine
- Midwifery
- Reproductive Endocrinology/Infertility

Female members can obtain care from the above provider types for services that include, but are not limited to, preventive care, problem-related OB/GYN conditions, and routine OB/GYN care.

Waiving the referral prerequisite does not change or supersede other product requirements (e.g., obtaining certain services [e.g., laboratory, radiology] from the designated capitation site).

In products where members are able to self-refer to providers for care and services, members are advised to use participating providers in order to receive the highest level of benefits.

Medicare

Direct Access Obstetrics/Gynecology applies to Medicare Advantage members. In accordance with Medicare, the Company will provide or arrange for necessary specialist care and give members the option of direct access to a women's health specialist within the provider network for routine and preventive health care services. The Company will arrange for necessary specialist care outside of the provider network when network providers are unavailable or inadequate to meet a member's medical needs.

Mandates

This policy is consistent with applicable state mandates.

Experimental/Investigational Policies

Breast Ductal Lavage and Breast Duct Endoscopy (11.08.28)

Not Covered: Considered Experimental/ Investigational

Breast ductal lavage is a minimally invasive procedure in which samples of breast duct cells are collected to determine if they are normal, atypical, suspicious, or malignant. It is believed that most breast cancers begin in the epithelial cells lining the interior of the breast milk ducts. Breast ductal lavage has been developed as a means of facilitating cell collection for cytologic analysis for those at high risk for breast cancer. A microcatheter is inserted into the ductal opening on the breast to extract breast duct epithelial cells for cytologic evaluation. There is a paucity of published literature on the topic. It has not yet been determined whether breast ductal lavage is as effective as standard diagnostic procedures in detecting early breast cancer.

Breast duct endoscopy enables direct visual examination of the lining of the milk ducts of the breast to search for abnormal tissue. Because it is hypothesized that breast cancer starts in the lining of the milk ducts or lobules, breast duct endoscopy collects cells from these ducts for evaluation.

Breast duct endoscopy has been investigated in the following clinical situations:

- As a diagnostic alternative to surgical excision for individuals with spontaneous nipple discharge
- As a follow-up test for women with atypical cytology as detected by breast ductal lavage
- As a means of defining margins of surgical resection in the presence of intraductal disease
- As a means of delivering therapeutic agents directly to the tissue (e.g., photodynamic therapy, laser ablation, topical biological agents)

To date, there is a paucity of published literature that allows for any firm conclusions regarding the diagnostic ability of breast duct endoscopy and how it would assist the physician in determining the need for further intervention.

Breast ductal lavage 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.

Breast duct endoscopy 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.

Cold Laser Therapy (07.00.14c)

Not Covered: Considered Experimental/ Investigational

Cold laser therapy, also referred to as low-energy laser therapy or low-level laser therapy, refers to the use of polarized red-beam or near-infrared light to provide pain relief for various acute and chronic conditions. In contrast to more powerful surgical lasers, low-level laser light has low power, usually 5-500 milliwatts with wavelengths of 600-1000 nm. When applied to the skin, cold laser therapy does not burn and produces little or no sensation. The light energy penetrates into tissues, where it works on the cellular and extracellular systems (e.g., neurologic, vascular, immune, lymphatic) by increasing serotonin levels to result in pain relief or healing.

Although many studies of cold laser therapy have been published, the overall efficacy, magnitude, and duration of effect have not been sufficiently well established. Therefore, well-designed, randomized, controlled studies are needed to establish the safety and efficacy of this service.

Cold laser therapy is considered experimental/ investigational and, therefore, not covered because the safety and/or efficacy of this service cannot be established by a review of the available published literature.

Using the Current Procedural Terminology (CPT®) procedure code 97026 (infrared therapy) or any other code to report cold laser/low-level laser therapy is a misrepresentation of the actual service rendered. These services are subject to post-payment review and audit procedures.

Billing guidelines

Cold laser therapy is described by HCPCS code S8948 and should not be billed with any other code.

Microwave Thermotherapy for Primary Breast Cancer (11.08.26a)

Not Covered: Considered Experimental/ Investigational

Focused microwave phased-array thermotherapy is a system being evaluated as a type of heat therapy to kill tumor cells of primary breast carcinomas. This therapy is being studied in conjunction with lumpectomy in individuals with early stage breast cancer, and in conjunction with preoperative chemotherapy.

The thermotherapy system works by placing microwave applicators on either side of the compressed breast. The applicators then illuminate a large area of breast tissue. A probe is placed within the breast to monitor the interstitial temperature. The technique is based on the microwave heating that occurs in high-water-content breast carcinoma compared with the surrounding low-water-content of healthy breast tissue. It is theorized that, if successful, microwave therapy could function similarly to whole-breast irradiation following breast-conserving surgery (i.e., destroying microscopic residual cancer cells). For individuals with locally advanced primary breast cancer, microwave thermotherapy may shrink the size of the tumor, thus necessitating a less invasive breast surgery.

Currently, there are no thermotherapy devices approved by the FDA for the treatment of breast cancer. The Microfocus™ APA 1000 System (Celsion Corp.; Columbia, MD) is currently involved in phase II clinical trials through the FDA.

Microwave thermotherapy for primary breast cancer 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.

Prolotherapy (11.14.15b)

Not Covered: Considered Experimental/ Investigational

The term "prolotherapy" is a derivation of "proliferative injection therapy." Prolotherapy consists of a series of intraligamentous and intratendinous injections of sclerosing agents which alleviate chronic pain by inducing the proliferation of new cells. There are three classes of proliferant solutions used in prolotherapy: chemical irritants (e.g., phenol), osmotic shock agents (e.g., hypertonic dextrose and glycerin), and chemotactic agents (e.g., morrhuate sodium, a fatty acid derivative of cod liver oil). Prolotherapy should not be confused with trigger point injections, which relieve pain by infusing anesthetics and/or anti-inflammatory agents into affected areas.

Prolotherapy has been studied for a number of sources of pain, including fibromyalgia, arthritis, tendonitis, degenerative disc disease, and plantar fasciitis. However, few randomized, placebo-controlled trials have been done to study its efficacy. The medical effectiveness of prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents has not been established.

Prolotherapy is considered experimental/investigational because the safety and/or efficacy of this service cannot be established by review of the available published literature.

Reporting prolotherapy using the trigger point injection CPT procedure code or any other code is a misrepresentation of the actual service rendered. These services are subject to post-payment review and audit procedures.

Scintimammography (09.00.39)

Not Covered: Considered Experimental/ Investigational

Scintimammography, also known as mammoscintigraphy, has been proposed primarily as an adjunct to standard film mammography using radiopharmaceutical agents (radioactive tracer [e.g., technetium-99m sestamibi]) to provide tumor-specific imaging of the breast. Scintimammography is performed by infusing a radiopharmaceutical into an individual in order to evaluate the breast using planar or single positron emission computed tomography (SPECT).

The proposed purpose of scintimammography is to improve patient selection for biopsy in order to reduce the number of negative biopsies when plain-film mammography is indeterminate or limited in individuals with dense breast tissue or a history of previous surgery and/or radiotherapy. Scintimammography has also been proposed for the detection of axillary lymph node metastases in individuals with breast carcinoma; however, it has not been fully investigated for this purpose. There is insufficient data comparing the use of scintimammography for decision-making regarding nodal dissection versus standard nodal dissection.

Although scintimammography is currently being performed, the published medical literature does not support its efficacy in differentiating malignancies when compared with surgical biopsy.

Scintimammography is considered experimental/ investigational because the safety and/or efficacy of this service cannot be established by review of the available published literature.

Not Medically Necessary Policy

Electron Beam Computed Tomography (EBCT) for Screening Evaluations (09.00.02d)

Not Covered: Considered Not Medically Necessary

Electron beam computed tomography (EBCT), which is also known as ultrafast CT, cine-computerized X-ray tomography or high-speed computed X-ray tomography, uses an electron beam gun to permit very rapid scanning that creates images at greater speeds by rotating a standard X-ray tube around an individual. The data is gathered into a continuous spiral or helix rather than individual slices. EBCT's speed of image acquisition allows for unique imaging of the heart.

EBCT software permits quantification of calcium area and density, which are translated into calcium scores. Calcium scores have been investigated as a technique for detecting coronary artery calcification. For symptomatic individuals, calcium scores are viewed as a diagnostic technique to determine the necessity of coronary angiography. For asymptomatic individuals, calcium scores are viewed as a screening tool for coronary artery disease. However, current evidence in the peer-reviewed literature does not establish that EBCT results in improved health outcomes. Guidelines published jointly by the American College of Cardiology and the American Heart Association indicate that for asymptomatic individuals, studies have not shown that the detection of coronary artery calcification improves upon the prognostic information from risk factor models such as the Framingham Heart Study or the National Cholesterol Education Program – III. No studies have compared EBCT against other noninvasive tests such as exercise treadmill testing.

EBCT performed to quantify the amount of calcium in the coronary arteries or to predict the risk for development of coronary artery disease is considered not medically necessary and, therefore, not covered because the available published literature does not support its use.

More Information

Policy change notifications available online

To better communicate updates to our medical and claim payment policies, we will be posting notifications online prior to the policy's effective date. The notifications will be listed by the intended effective date, and we will provide the policy in its entirety for you to become familiar with it in advance. To read these notifications, please follow these instructions:

1. Visit *www.amerihealth.com/medpolicy.*
2. Select *Accept and Go to Medical Policy Online.*
3. Select *Policy Notifications* from the Medical Policy column on the left sidebar.
4. Select the date under Policy Effective Date for the policy notification you wish to view.

Notifications will be posted frequently, so please check the site often.

Physician volunteers needed to assist in developing medical policies

AmeriHealth 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 AmeriHealth 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 areas of expertise. As such, your contributions will significantly affect the care of patients in your region.

At this time, AmeriHealth 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 AmeriHealth 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
AmeriHealth
1901 Market Street
Philadelphia, PA 19103-1480

Contact Provider Services

Provider Services	New Jersey	Delaware
HMO Policies/Procedures/Eligibility/Claims	1-800-821-9412	1-800-888-8211
PPO Policies/Procedures/Claims	1-800-595-3627	1-800-888-8211

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