AmeriHealth

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 AmeriHealth, including its 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 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 in accordance with URAC and NCQA guidelines 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. The inclusion of a code/modifier in this policy does not imply reimbursement. Eligibility, Benefits, Limitation, 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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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

Abdominoplasty and/or Panniculectomy (11.08.06e)

Covered: According to Certain Criteria

Panniculectomy is a surgical procedure in which a large, redundant apron of subcutaneous fat and abdominal skin (the panniculus) is removed from the lower abdomen. A redundant apron of skin and fat is created by a lack of underlying supportive tissue, does not respond to weight loss or exercise, and can occur in both morbidly obese and normal weight individuals.

Abdominoplasty is a surgical procedure that is performed to tighten a lax abdominal wall that involves the removal of excess skin and fat from the middle and lower abdomen; the skin is pulled downward and the underlying fascia (dense connective tissue that surrounds the muscles) is tightened. This procedure may also include reimplantation of the umbilicus (American Society of Plastic Surgeons [ASPS], 2007). During an abdominoplasty procedure, a large incision is made across the lower abdomen and the skin is separated from the abdominal wall up to the ribs. According to the ASPS, abdominoplasty is typically performed for cosmetic purposes. Cosmetic services are those provided to improve an individual's physical appearance, from which no significant improvement in physiologic function can be expected, regardless of emotional or psychological factors.

Panniculectomy

Under most circumstances, panniculectomy is a cosmetic service and, therefore, a benefit contract exclusion. However, this procedure is considered medically necessary and, therefore, covered for individuals who meet all of the following criteria:

- The panniculus hangs to or below the level of the pubis.
- Persistent, chronic irritation and/or infection are present in the area of the hanging panniculus, along with any of the following:
  - Ulceration
  - Necrosis
  - Suprapubic intertrigo
  - Panniculitis
- A six-month course of medical therapy has been ineffective in managing (or controlling) symptoms. Examples of agents that may be used for conservative treatment are: topically-applied skin barriers, supportive garments, and antifungal, antibacterial, and moisture-absorbing agents.
- Significant interference with activities of daily living or problems with ambulation.

Panniculectomy that is performed in conjunction with a hernia repair is considered medically necessary and, therefore, covered only if all of the above criteria for panniculectomy are met.

Panniculectomy that is performed in conjunction with an abdominal hernia repair to prevent the occurrence of future complications (such as infection, seroma, ischemia, and/or hernia recurrence) is considered a cosmetic service and, therefore, a benefit contract exclusion, unless all of the above criteria for panniculectomy are met. Panniculectomy that is performed to minimize the risk of hernia formation or recurrence is considered a cosmetic service and, therefore, a benefit contract exclusion.

Abdominoplasty

Abdominoplasty performed to remove excess skin and fat and to tighten the fascia of the abdominal wall is considered a cosmetic service and, therefore, a benefit contract exclusion.

Diastasis Recti Repair

Diastasis recti repair performed to tighten the fascia of the abdominal wall is considered a cosmetic service and, therefore, a benefit contract exclusion.

Documentation

All requests for the procedures mentioned in this policy require a review by the Company's Cosmetic Review Team and must include:

- Dated photographs of the panniculus hanging over the pubis and of the panniculus elevated to expose the chronic, persistent, and refractory skin infection or irritation.
- Office notes from the treating physician that reflect the chronic, persistent, and refractory skin infection or irritation that persists despite optimal medical care over a six-month period.

- A listing of the medications that were prescribed during a six-month period and the length of time the agents were used.

Supporting medical necessity documentation must be maintained in medical records and made available to the Company upon request.

Application and Removal of Tattoos (11.08.05c)

Covered: According to Certain Criteria

An elective tattoo is an indelible mark deliberately placed into the skin by pricking and staining with inks and other pigmented materials; its purpose can be either therapeutic or nontherapeutic (for decorative purposes). A traumatic tattoo is the result of an injury caused by forceful contact with a surface that results in pigment from debris, such as black asphalt or other particulate matter, to become embedded in the skin.

Therapeutic Tattoos

The application of a therapeutic tattoo is considered medically necessary and, therefore, covered for any of the following:

- To conceal a corneal leukoma (or leucoma), also known as Peter's anomaly
- To prepare an individual's skin for radiation therapy as required by a treatment plan
- To create a nipple and areola as part of a reconstructive breast procedure following mastectomy, trauma, or congenital absence

The removal of a therapeutic tattoo is considered medically necessary and, therefore, covered when performed to eliminate skin markings which were originally applied to an individual for the purpose of administering precise radiation therapy.

The application and/or removal of tattoos that do not meet medical necessity criteria as outlined above are considered cosmetic services and, therefore, a benefit contract exclusion.

Traumatic Tattoos

The removal of a traumatic tattoo is considered medically necessary and, therefore, covered to eliminate the pigment, debris, or other particulate matter that has been forcefully embedded into the skin of an individual.

Nontherapeutic Tattoos

The application and/or removal of tattoos performed solely to change the appearance of any portion of the body, without improving the physiologic functioning of that portion of the body including, but not limited to nontherapeutic tattoos, is considered cosmetic and, therefore, a benefit contract exclusion.

Documentation

The application or removal of tattoos requires review by the Company's Cosmetic Review Team and must include documentation. This documentation must include, but is not limited to, medical records and other health care professional reports. All documentation must be made available to the Company upon request. The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider.

Benefit Application

Subject to the terms and conditions of the applicable benefit contact, the application of a tattoo as part of breast reconstruction after mastectomy is a federal and/or state-mandated benefit and is covered under the medical benefits of the Company's products.

Assays of Genetic Expression in Tumor Tissue for Breast Cancer Prognosis (06.02.27b)

Covered: According to Certain Criteria

According to the American Cancer Society (ACS), breast cancer is the second leading cause of cancer death in women, after lung cancer. Early detection of the disease by mammography is especially valuable because it increases treatment options and saves lives.

Taking into account the medical circumstances and an individual's preference, treatment options may involve a lumpectomy (local removal of the tumor) or mastectomy (surgical removal of the breast). Treatment may also include the removal of axillary lymph nodes if the cancer has spread to these nodes. Radiation therapy, chemotherapy, and hormone therapy are adjuvant post-surgical treatment options that are used to prevent the recurrence of the cancer and/or progression of the disease. Typically, two or more of these methods are used.

Prognosis in breast cancer is currently based on an individual's age, tumor size, histology, status of the axillary lymph nodes, histologic type, and hormone receptor status. The subset of women with breast cancer that would benefit from adjuvant chemotherapy, radiation therapy, or hormone therapy after surgery is unclear. Individuals with the same set of risk factors can have a markedly different prognosis.

The Oncotype DX® test is a patented gene panel test that was developed for node-negative, estrogen receptor (ER)-positive breast cancer. The assay can be conducted on routine paraffin-embedded breast cancer tissue. Algorithmic weighting of gene expression yields a Recurrence Score (RS), which is strongly correlated with the recurrence of breast cancer. A key output of the Oncotype DX® test is its use in decision-making for adjuvant chemotherapy of nonmetastatic breast cancer. In addition, the test can be utilized as a prognostic tool to quantify the likelihood of recurrence and survival.

The MammaPrint® test is a gene expression profiling test that utilizes DNA microarray analysis on breast cancer tumors to determine the prognosis for the development of metastasis. The MammaPrint® test is currently not marketed in the US, and research of clinical trials and peer-reviewed literature does not establish the efficacy or clinical utility of this service.

The Oncotype DX® test is considered medically necessary and, therefore, covered as an assay of genetic expression in tumor tissues for breast cancer prognosis when all of the following criteria are met:

- A clinical diagnosis of stage I or stage II, estrogen receptor-positive, node-negative cancer of the breast is made.
- The individual's breast cancer is being treated with tamoxifen (females only).
- Clinical evidence that the test will significantly contribute to the prognosis and management of the individual is documented.
- Less than six months has elapsed since the initial diagnosis.

The Oncotype DX® test is covered once per diagnosis of breast cancer, per individual. As is true for other clinical laboratory tests, controls and confirmatory results are considered part of the initial payment for the test.

There is no data on the relevance of the test for the recurrence of metastatic breast cancer in an individual who already has a previous Oncotype DX® result. In this situation, the Oncotype DX® test is considered experimental/investigational and, therefore, not covered.

All other uses for the Oncotype DX® test are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

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

Cardiac Event Detection Monitoring (External Loop Monitoring) (07.02.12b)

Covered: According to Certain Criteria

Cardiac event detection monitoring typically involves long-term (30 days or more) monitoring of the heart rhythm of an individual with significant, but very infrequent, symptoms that are suggestive of transient cardiac arrhythmia. The infrequency of the arrhythmia makes it difficult to identify on a 24- or 48-hour continuous Holter monitor.

Cardiac event detection monitoring is initiated in either the office or home setting. The cardiac event detection monitoring device is an electrocardiogram (ECG) recording monitor approximately the size of a pager. The device has a continuous loop and can be worn externally for up to one month or longer. When symptoms of an arrhythmia are felt, an individual presses a button on the monitor to activate the ECG recording process. The cardiac event detection monitoring device's looping memory is individually programmed to record an ECG 30 to 90 seconds prior to activation. Information is then transmitted from the monitoring device over the phone to a central processing unit that produces a hard copy of the ECG.

Cardiac event detection monitoring is considered medically necessary and, therefore, covered for the following indications:

- To monitor the effectiveness of antiarrhythmic drug dosages

- To monitor individuals who have had surgical or ablative procedures for arrhythmias
- To establish the diagnosis of symptomatic transient cardiac arrhythmia when the symptoms are obscure and suggestive of a cardiac arrhythmia but difficult to identify on a 24- or 48-hour continuous Holter monitor

The following are clinical symptoms of arrhythmia:

- Chest pain
- Dizziness
- Dyspnea (shortness of breath)
- Lightheadedness
- Palpitations
- Syncope or near-syncope

The following are examples of arrhythmia:

- Atrial fibrillation or flutter
- Cardiac dysrhythmia
- Paroxysmal supraventricular tachycardia
- Paroxysmal tachycardia, unspecified
- Paroxysmal ventricular tachycardia
- Premature beats
- Transient ischemic episodes

All other uses for cardiac event detection monitoring (external loop monitoring) devices are considered not medically necessary and, therefore, not covered.

Cardiac event detection monitoring devices must be patient-activated and are not indicated for an individual who is unresponsive, comatose, severely confused, or otherwise unable to recognize symptoms or activate the recorder device.

Generally, symptomatic transient cardiac arrhythmias are detected within a two-month time of the start of the cardiac event detection monitoring. Therefore, reimbursement for cardiac event detection monitoring devices is made for two months within a 12-month period.

Supporting medical necessity documentation must be maintained in medical records and made available to the Company upon request. The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation must be made available to the Company upon request.

The use of cardiac event detection monitoring devices to diagnose and treat suspected arrhythmias should not be substituted for more conventional methods of diagnosis, such as a careful history, physical examination, and standard ECG and rhythm strip.

Providers of this service should be capable of receiving and recording transmissions 24 hours a day, 365 days a year. This includes receipt of the ECG signal as well as a voice transmission that relates any associated symptoms. The transmission should be received by a technician, nurse, or physician trained in the interpretation of ECGs and abnormal rhythms. A physician should be available for immediate consultation 24 hours a day to review the transmission in case of significant symptoms or ECG abnormalities. Providers should also be capable of notifying an individual's attending physician immediately, when indicated.

Any device used for cardiac event detection monitoring must be capable of transmitting ECG leads I, II, or III.

Cardiac event detection monitoring does not require precertification or referral for any line of business.

Electronic Speech Aids (05.00.23b)

Covered: According to Certain Criteria

Electronic speech aids are prosthetic devices that produce speech as the individual mouths words. Electronic speech aids create a vibrating tone from a battery-powered electronic circuit. Once the tone is introduced into the mouth, the individual shapes the sound into words.

Electronic speech aids are either extra-oral (or neck-held) and intra-oral. The extra-oral type is a cylindrical hand-held box that has a vibrating electronic sound source that is activated by control buttons. The head of the device is placed against the neck to produce sound as the individual mouths words.

The intra-oral type generates sound directly in the oral cavity via a small tube that is connected to an electronic speech aid. A newer version of the intra-oral type is mounted into an upper denture or an orthodontic retainer. This device consists of a loudspeaker, control circuit, and a control unit. The control unit transmits radio waves to the radio circuit, which converts the waves into an electronic signal; the loudspeaker is driven by the electronic signal to produce speech.

Voice amplifiers are personal voice amplification devices for individuals whose natural speaking voice is too quiet to be heard by others.

Electronic speech aids are considered medically necessary and, therefore, covered for individuals who have had a laryngectomy or who have a nonfunctional larynx.

Replacement batteries that are required for electronic speech aids can be purchased over the counter and are a benefit contract exclusion, as they do not meet the definition of durable medical equipment (DME). Therefore, these items are not covered and not eligible for reimbursement consideration.

Voice amplifiers (for use with or without an electronic speech aid) are not covered because they do not meet the criteria for DME.

The Company may conduct reviews and audits of services to our members regardless of the participation status of the provider. Medical record documentation must reflect the medical necessity of the care and services provided. These medical records may include, but are not limited to: records from the physician's office, hospital, nursing home, home health agencies, therapists and other health care professionals, and test reports. An order for each item billed must be signed and dated by the physician who is treating the patient and kept on file by the supplier. Medical record documentation must include a shipment affirmation or member's receipt of supplies and equipment. All documentation must be made available to the Company upon request.

Hair Transplants and Cranial Prostheses (Wigs) (11.08.01c)

Covered: According to Certain Criteria

Alopecia (hair loss) can be caused by aging, hormonal changes, genetic predisposition, or circumstances such as disease or physical trauma. In most disorders of alopecia, the hair follicle is either normal but has an abnormal growth cycle, or has been damaged. Hair transplants and cranial prostheses (wigs) are frequently used to treat hair loss.

Hair Transplants

Under most circumstances, hair transplants are considered cosmetic services and, therefore, a benefit contract exclusion. However, hair transplants are considered medically necessary and, therefore, covered for the treatment of permanent hair loss that is caused by any of the following conditions:

- Physical trauma (e.g., burns, lacerations)
- Surgery (e.g., tumor removal)
- Diseases that cause cicatricial (scarring) alopecia (e.g., discoid lupus erythematosus, scleroderma)

Hair transplants performed for indications other than those specified in the medical necessity criteria above are considered cosmetic and, therefore, a benefit contract exclusion.

Documentation

All requests for hair transplants require review by the Company's Cosmetic Review Team and must include:

- Color photographs
- Letter of medical necessity

Cranial Prostheses (Wigs)

Wigs are a standard benefit exclusion for all of the Company's products except Major Medical. When purchased as a group benefit, wigs are covered and eligible for reimbursement consideration by the Company according to the criteria specified in the group benefit contract. If the group benefit contract does not provide specific criteria for the coverage of wigs, they are covered when all of the following criteria are met:

- The member's purchased group benefit includes coverage of wigs, and the service is provided within the scope of the member's benefit contract.
- The wig has been ordered by a physician.
- Significant hair loss exists, with a projected duration of at least six months, due to a condition or injury such as, but not limited to:
  - Alopecia universalis/alopecia totalis
  - Alopecia areata
  - Burns
  - Chemotherapy/radiation therapy
  - Traumatic or surgical scalp avulsions

The Company does not provide benefits for wigs or other items that are intended to replace hair loss associated with either of the following:

- Male-pattern baldness/female-pattern hair loss
- Cosmetic purposes

When a benefit exists, coverage limitations for wigs, repair and replacement, and dollar amount related to lifetime and/or annual maximums vary by product or by group; therefore, individual member benefits must be verified.

In Vitro Allergy Testing (06.02.26a)

Covered: According to Certain Criteria

An allergy is defined as an acquired hypersensitivity to a substance (allergen) that does not normally cause a reaction. It is essentially a disorder of the immune system resulting in an antibody-antigen reaction. The most common manifestations of allergy involve the respiratory tract or the skin.

In vitro allergy testing detects antigen-specific immune globulin E (IgE) antibodies in serum. This type of testing may be required when direct skin testing is not possible for inhalant allergens (e.g., pollens, molds, dust, mites, animal danders), foods, insect stings, or other allergens such as drugs. In vitro allergy testing is appropriate for individuals who have skin reactions/conditions such as severe dermatographism, ichthyosis, or generalized eczema. It is also appropriate for uncooperative individuals (young children or individuals with mental and/or physical handicaps), individuals with a high risk of anaphylaxis from skin testing, or individuals for whom direct skin testing has been inconclusive.

In vitro allergy testing (enzyme-linked immunosorbent assay [ELISA], radioallergosorbent test [RAST], fluoroallergosorbent test [FAST], and multiple antigen simultaneous test [MAST]) for the measurement of serum IgE is considered medically necessary and, therefore, covered for determining if an individual's serum contains IgE antibodies.

In vitro allergy testing for allergen-specific IgE is considered medically necessary and, therefore, covered for determining if there are specific IgE antibodies against allergens.

ImmunoCAP technology is comparable to RAST and MAST and is considered medically necessary and, therefore, covered for determining specific IgE antibodies when in vitro allergy testing is indicated and performed within the laboratory setting.

- ELISA, RAST, FAST, and MAST are considered medically necessary and, therefore, covered up to a maximum of 30 tests per calendar year per individual (Current Procedural Terminology [CPT®] code 86003).

Multiallergen screening reported with CPT code 86005 is a qualitative test that does not quantify specific antigens; therefore, it is considered not medically necessary and not covered.

The following tests are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature:

- Leukocyte histamine release test
- Cytotoxic food testing
- ELISA/ACT qualitative antibody test
- Lymphocyte mitogen response assays (LMRA) by ELISA/ACT
- Immune globulin G (IgG) ELISA, indirect method

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Microprocessor-Controlled Prosthetic Knees (11.14.21a)

Covered: According to Certain Criteria

Following a lower limb amputation and after the appropriate healing of the surgical site, an individual may consider the use of a prosthetic leg to begin rehabilitation efforts in learning to ambulate. There are many different component types of a prosthetic limb, with more than 100 different prosthetic knee designs currently available on the market.

The microprocessor-controlled knee prosthesis is considered medically necessary and, therefore, covered as a component fitting in a lower limb prosthesis for individuals who meet all of the following criteria:

- The individual is motivated to ambulate.
- The individual will reach and maintain a defined functional state within a reasonable period of time.
- The individual has high mobility and stance stability needs and is at a functional level of 3 or 4 according to Medicare's classification scale of patient potential functional ability as described below:
  - Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance their quality of life or mobility. (Modifier K0)
  - Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator. (Modifier K1)
  - Level 2: Has the ability or potential for prosthetic ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator. (Modifier K2)
  - Level 3: Has the ability or potential for prosthetic ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion. (Modifier K3)
  - Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demand of the child, active adult, or athlete. (Modifier K4)

The microprocessor-controlled knee prosthesis is considered not medically necessary and, therefore, not covered for those individuals who do not meet all of the criteria listed above.

Documentation

The individual's medical record must reflect the need for the care provided. These medical records may include, but are not limited to, records from the physician's office, hospital, nursing home, home health agency, other health care professionals, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation must be made available to the Company upon request.

Prophylactic Mastectomy (11.08.19d)

Covered: According to Certain Criteria

Prophylactic mastectomy refers to the removal of the breast (unilateral or bilateral) in the absence of malignant disease, usually for the prevention of breast cancer. Prophylactic mastectomy is defined as either total (also referred to as simple), in which the intent is to remove the entire breast and nipple areolar complex, or subcutaneous, in which the nipple areolar complex is left intact for a more natural appearance. From a prophylactic standpoint, a total mastectomy is generally preferred over a subcutaneous mastectomy because there is less residual breast tissue remaining, which decreases the likelihood that cancer will develop in the future.

Prophylactic mastectomy is considered medically necessary and, therefore, covered in individuals at high or moderately-increased risk for developing breast cancer.

For the criteria below, first-degree relatives include parents, children, and siblings. Second-degree relatives include grandparents, aunts, and uncles. Third-degree

relatives include great-grandparents and first-degree cousins.

Individuals are considered at high risk for breast cancer when there is a history of **one or more** of the following (Hartmann et al, 1999):

- Two or more first-degree relatives with breast cancer
- One first-degree relative and two or more second-degree or third-degree relatives with breast cancer
- One first-degree relative with breast cancer before 45 years of age and one other relative (of any degree) with breast cancer
- One first-degree relative with breast cancer and one or more relatives (of any degree) with ovarian cancer
- One second-degree or third-degree relative with breast cancer and two or more relatives (of any degree) with ovarian cancer
- Three or more second-degree or third-degree relatives with breast cancer
- One first-degree relative with bilateral breast cancer
- Presence of a breast cancer BRCA1 or BRCA2 gene mutation in the individual consistent with a BRCA1 or BRCA2 mutation in a family member with breast or ovarian cancer
- The individual has a history of previous mastectomy for an invasive cancer.
- The individual has been diagnosed with invasive ductal carcinoma or lobular carcinoma in situ.

Individuals who are considered at moderately increased risk for breast cancer include any of the following:

- Individuals who, based on family history, with or without breast lesions associated with an increased risk, which may include, but is not limited to, atypical hyperplasia or individuals with any type of breast cancer diagnosed in the opposite breast.
- Individuals with such extensive mammographic abnormalities (e.g., cystic/dense breast tissue, calcifications) that adequate biopsy is impossible.

Requests for prophylactic mastectomy that do not meet medical necessity criteria are considered not medically necessary and, therefore, not covered.

Hartmann LC, Schaid DJ, Woods JE, et al. Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer. *N Engl J Med.* 1999;340(2):77-84.

Radiofrequency Ablation of Osteoid Osteomas (11.00.12a)

Covered: According to Certain Criteria

Osteoid osteomas are rare benign bone tumors in the long bones and spine that are predominantly found in children and young adults. Osteomas cause local inflammation and are almost always painful. The pain is unrelated to physical activity, tends to worsen at night, and may be relieved by nonsteroidal anti-inflammatory drugs (NSAIDs). When a tumor grows in close proximity to a joint, it may cause additional swelling, stiffness, and/or contractures. Secondary effects include growth disturbances, scoliosis, and/or osteoarthritis.

Osteoid osteomas do not have malignant potential. These tumors usually do not grow beyond 15 mm in diameter and may regress spontaneously or become dormant over several years. Osteoid osteomas have the potential to be managed with medical treatment alone. However, resolution is unpredictable, and some individuals cannot tolerate long-term NSAID therapy.

Treatment for osteoid osteomas involves the complete destruction of the growth center, or nidus, of the tumor.

Open excision and surgical removal of the tumor has been the treatment of choice and is generally successful. However, there are significant risks associated with open surgery including fracture, recurrence of larger tumors, incomplete resection due to inaccessible location, and excision of a large portion of bone due to difficulty locating the nidus. In weight-bearing bones, these risk factors are significant for postoperative recovery.

Radiofrequency ablation (RFA) has become a less invasive alternative for the treatment of osteoid osteomas. RFA is performed using an open surgical, laparoscopic, or percutaneous method. A drill and/or biopsy needle is used to penetrate the bony tumor and to introduce an RFA electrode into the nidus of the tumor. The electrode provides rapidly alternating currents of energy that generate heat to destroy a predictable zone of hard and soft tissue around the tumor. Because RFA specifically targets the nidus, it is less likely to destroy or weaken adjacent normal bone and allows the individual to have no limitation of postoperative physical activity. Results of the available studies support the use of RFA as an alternative to surgical excision for the treatment of osteoid osteomas

in individuals whose conditions have not been successfully managed by medical treatment.

RFA is considered medically necessary and, therefore, covered as a minimally invasive alternative to surgical resection of osteoid osteomas.

Removal of Breast Implants (11.08.14d)

Covered: According to Certain Criteria

Implanted breast prostheses are silicone shells filled with saline and/or silicone gel. The implantation can be either for medically necessary indications (e.g., reconstruction following mastectomy, surgery/trauma) or for cosmetic reasons. Reconstructive treatment is defined as any medical or surgical service designed to restore bodily function or to correct a deformity that has resulted from trauma or the treatment of disease. Cosmetic services are those provided to improve an individual's physical appearance, from which no significant improvement in physiologic function can be expected, regardless of emotional or psychological factors.

Complications can occur with breast implants that may require removal of the implant. Examples of complications include infection, extrusion (implant exposure at the surface of the skin), rupture, and contracture. Research evidence reveals that the incidence of microbial contamination of the luminal saline of the implant is unlikely. Normal saline is a physiologic solution such that it is consistent with an organism's normal functioning.

A contracture occurs when the capsule surrounding a breast implant tightens. Extreme cases can cause the breast to feel hard and painful. Disfigurement may also result if the capsule surrounding one implant contracts and the other does not, or if the capsule contracts unevenly. Contractures have been graded according to the Baker Classification as follows:

- Baker Grade I: Augmented breast feels as soft as a normal breast.
- Baker Grade II: Breast is less soft, and the implant can be palpated but is not visible.
- Baker Grade III: Breast is firm, palpable, and the implant (or its distortion) is visible.
- Baker Grade IV: Breast is hard, painful, cold, tender, and distorted. (US Food and Drug Administration [FDA], 2004)

Indications for Removal of Silicone Gel-Filled Implant(s)

The removal of silicone gel-filled implant(s) placed for reconstructive treatment or cosmetic purposes is considered medically necessary and, therefore, covered for the following indications:

- Documented implant rupture
- Extrusion
- Infection or rejection
- Siliconoma or granuloma
- Baker Class IV contracture (breast is hard, painful, cold, tender, and distorted)
- Interference with diagnosis of breast cancer
- Surgical treatment of breast cancer

Baker Class III Contracture

The removal of silicone gel-filled implant(s) placed for reconstructive purposes is considered medically necessary and, therefore, covered for the following indication:

- Baker Class III contracture (breast is firm, palpable, and the implant [or its distortion] is visible)

The removal of silicone gel-filled implant(s) placed for cosmetic purposes is considered a benefit contract exclusion for the following indication:

- Baker Class III contracture (breast is firm, palpable, and the implant [or its distortion] is visible)

This indication is not considered a medical or surgical complication, but rather a poor cosmetic outcome from the cosmetic surgical procedure.

Indications for Removal of Saline-Filled Implant(s)

The removal of saline-filled implant(s) placed for reconstructive treatment or cosmetic purposes is considered medically necessary and, therefore, covered for the following indications:

- Extrusion
- Infection or rejection
- Siliconoma or granuloma

- Baker Class IV contracture (breast is hard, painful, cold, tender, and distorted)
- Interference with diagnosis of breast cancer
- Surgical treatment of breast cancer

The removal of saline-filled implant(s) placed for reconstructive purpose is considered medically necessary and, therefore, covered for the following indication:

- Documented implant rupture

The removal of saline-filled implant(s) placed for cosmetic purposes is considered a benefit contract exclusion for the following indications:

- Rupture
- Baker Class III contracture (breast is firm, palpable, and the implant [or its distortion] is visible)

These indications are not considered medical or surgical complications, but rather poor cosmetic outcomes from cosmetic surgical procedures.

The removal of a breast implant(s) for any other indications is considered not medically necessary and, therefore, not covered.

Subsequent surgery to improve, correct, or further alter the appearance of a body part that has previously undergone a cosmetic surgical procedure is considered a revision of a previously performed cosmetic procedure. Under most circumstances, cosmetic services are considered benefit contract exclusions. Individual benefits must be verified.

Documentation

To support the medical necessity of the removal of a breast implant, the medical record documentation should include the medically necessary reason for the implant removal and the results of any mammogram, ultrasound, and/or magnetic resonance imaging (MRI) as appropriate.

Seat Lift Mechanisms (05.00.43c)

Covered: According to Certain Criteria

The seat lift mechanism is the portion of the patient lift chair that gently raises an individual to a standing position. It includes the metal frame on which the chair rests, the lift motor, the scissors mechanisms, and the hand control unit. The seat lift mechanism may be incorporated into a chair as a complete unit or supplied as a separate unit.

Seat lift mechanisms are considered medically necessary and, therefore, covered when an individual or the individual's caregiver is able to control the device and all of the following criteria are met:

- The individual has severe arthritis of the hip or knee or has a severe neuromuscular disease.
- The individual is completely incapable of standing up from a regular armchair or from any other chair in the home.
- The individual can ambulate.
- The individual has a durable medical equipment (DME) benefit.
- The individual has tried and failed the appropriate therapeutic modalities (e.g., medication, physical therapy) that would enable them to transfer from a chair to a standing position.
- The seat lift mechanism is supplied by a DME provider.
- The seat lift mechanism must be a part of the physician's course of treatment and prescribed to improve the individual's condition or to arrest or retard deterioration in the individual's condition.

Coverage is limited to the seat lift mechanism, even if it is incorporated into a chair (Healthcare Common Procedure Coding System [HCPCS] code E0627). Reimbursement for a seat lift mechanism that is incorporated into a chair (HCPCS code E0627) is limited, based on the allowance for the least costly alternative (HCPCS codes E0628, E0629). The chair itself is not covered and, therefore, not eligible for reimbursement consideration, with the following exception:

- A commode chair with an integrated seat lift mechanism (HCPCS codes E0170, E0171) is considered medically necessary and, therefore,

covered when an individual meets both of the following criteria:

- The individual meets all of the above criteria for a seat lift mechanism.
- The individual is incapable of utilizing regular toilet facilities for one of the following reasons:
  - The individual is confined to a single room.
  - The individual is confined to one level of the home and there is no toilet on that level.
  - The individual is confined to the home, and there are no toilet facilities in the home.

A wheelchair accessory seat lift mechanism (HCPCS code E0985) is considered medically necessary and, therefore, covered when an individual meets the requirements for a wheelchair and the above requirements for a seat lift mechanism, with the exception of the ability to ambulate.

The type of seat lift that operates by a spring-release mechanism with a sudden, catapult-like motion that jolts the individual from a seated to a standing position is not covered and, therefore, not eligible for reimbursement consideration.

Documentation

The individual's medical record must reflect the need for the care provided and may include, but not be limited to, records from the physician's office, hospital, nursing home, home health agency, other health care professionals, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation must be made available to the Company upon request.

Solid Organ Transplants (11.00.09b)

Covered: According to Certain Criteria

Organ and tissue transplantation is a process by which the organ and tissue are excised from a live or cadaveric donor, then implanted in a recipient patient.

Solid organ transplants are considered medically necessary and, therefore, covered when performed on carefully selected individuals who have severe diseases or irreversible organ damage and who meet the criteria established by the transplant center. The following organs are recognized as medically suitable for transplant consideration:

- Heart
- Heart-Lung
- Intestinal and multivisceral (stomach, duodenum, pancreas, liver, and intestine)
- Kidney
- Pancreas
- Pancreas-Kidney
- Liver
- Lung: Single/Double

Covered Transplants

Most benefit contracts that are subject to state mandates include coverage for all of the above transplants. In the absence of explicit exclusions, the transplants listed above are available under a group benefit contract. However, some groups (such as self-insured groups) may elect to exclude or add specific types of organ transplants to their group benefit contracts. Therefore, individual member benefits must be verified in order to determine the specific solid organ transplants covered by a benefit contract.

Member and Nonmember Information

When the recipient and the donor are both members, all products with transplant benefits cover both the recipient and the donor. Other combinations of member and nonmember donor/recipient coverage vary by product and group. Individual member benefits must be verified.

Travel Expenses

Travel and living expenses that are associated with an out-of-area transplant center, for either the donor or the recipient, are excluded from organ transplant coverage with the following exception:

- Reasonable transportation and reasonable accommodations for a Medicare Advantage member and a companion are covered out-of-network when the transplant services are not available in-network, subject to Plan authorization. However, if a Medicare Advantage member elects to receive transplant services out-of-network or out-of-area, the member is responsible for all associated travel expenses.

Psychiatric Evaluations

Psychiatric evaluations that are performed prior to an organ transplant are covered under the member's medical benefit. Reimbursement for the evaluation is in accordance with the provider's contract.

Sale of Organs for Transplantation

If an organ is sold rather than donated to the recipient, no benefits are provided for the purchase price of the organ.

Medicare Advantage Members

Medicare Advantage members must have transplants performed in a Medicare-approved facility. A list of Medicare-approved facilities is available on the Centers for Medicare & Medicaid Services (CMS) website at: *www.cms.hhs.gov/ApprovedTransplantCenters/01_overview.asp.*

Benefit Application

Group benefit contracts, specifically state-mandated products, may not include coverage for all of the transplants listed in this policy. In addition, some transplant benefits may be excluded from group benefit contracts. Individual member benefits must be verified.

Treatment of Medical and Surgical Complications (11.00.02e)

Covered: According to Certain Criteria

A complication is an untoward event that occurs in the course of another condition or during its treatment. Complications may be of either medical or surgical origin, may modify the course of the original condition, and may require revisions to the treatment plan.

The treatment of medical and surgical complications is considered medically necessary and, therefore, covered when, if left untreated, the complications would result in endangering the health of the individual. These medical and surgical complications include, but are not limited to, complications resulting from cosmetic or other noncovered procedures. Treatment is covered and eligible for reimbursement consideration by the Company based on the medical necessity for acute conditions such as, but not limited to:

- Deep vein thrombosis (DVT)
- Hemorrhage
- Infection
- Myocardial infarction (MI)
- Wound dehiscence

Outcomes following cosmetic procedures that have unsatisfactory cosmetic results are not considered medical or surgical complications and are, therefore, not covered by the Company.

Uterine Artery Embolization for the Treatment of Fibroids (11.06.04e)

Covered: According to Certain Criteria

Uterine fibroids (leiomyomas) are extremely common benign tumors that are located within the uterine cavity (submucosal fibroids), on the serosal surface of the uterus, and within the body of the uterine musculature (intramural fibroids).

Transcatheter uterine artery embolization (UAE), also known as uterine fibroid embolization (UFE), is a minimally invasive, uterine-sparing treatment option for individuals with uterine fibroids. UAE has several advantages over conventional hormonal suppression and surgical procedures, including: avoiding the side

effects of drug therapy and the trauma of surgery; lower rate of morbidity; and shorter recovery time. Along with hysteroscopic resection, myolysis, and laparoscopic myomectomy, UAE widens the treatment options for individuals requiring treatment without hysterectomy.

In most cases, UAE is performed bilaterally and requires overnight hospitalization. During or following the procedure, angiography is performed to assess the effectiveness of the procedure. A radiopaque contrast medium is injected through the catheter used during the procedure, and fluoroscopic images of the vessel are recorded. The radiologist interprets the images to evaluate the status of the blood vessel and the effectiveness of the treatment.

UAE is considered medically necessary and, therefore, covered as a treatment option for women with uterine fibroids who experience any of the following symptoms including, but not limited to:

- Menorrhagia (excessive menstrual bleeding) as a direct result from the fibroid (i.e., not resulting from hyperplasia, atypia, or cancer) that interferes with daily activities or causes anemia
- Pelvic pain or pressure
- Lower back pain
- Urinary symptoms related to compression of the bladder (e.g., urinary frequency, urgency)
- Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating)
- Dyspareunia (painful or difficult sexual relations)
- An abdominally palpable fibroid

UAE is considered appropriate for women with symptomatic uterine fibroids who meet any of the following criteria:

- The use of anesthesia places the individual at high surgical risk.
- The individual has medical contraindications to hysterectomy (e.g., morbid obesity).
- The use of hormonal therapy is contraindicated, or the individual is intolerant to or has previously failed a course of hormone therapy.
- The individual wishes to avoid hysterectomy.
- The individual has hydronephrosis.

UAE is considered experimental/investigational and, therefore, not covered for either of the following:

- Repeat UAE for an individual who has persistent symptoms of uterine fibroids following initial treatment with UAE.
- Treatment of an individual who may want to become pregnant.

The safety and/or efficacy of UAE for these individuals has not been established by a review of the available published literature.

Absolute Contraindications

Cancers of the endometrium, cervix, or ovaries are absolute contraindications for UAE.

Experimental/Investigational Policies

Cryosurgical Ablation of Breast Tumors (11.08.27c)

Not Covered: Considered Experimental/Investigational

Breast cancer is a common, malignant disease of the breast tissue. Malignant breast tumors may present as painless hard masses with irregular edges and/or mammographic abnormality. Early detection of the disease by mammography is valuable because it increases treatment options and saves lives.

Fibroadenomas are common, benign tumors of the breast. Surgery to remove fibroadenomas consists of an open excision to remove the tumor and typically a margin of surrounding breast tissue. Recently, cryosurgical ablation (cryosurgery) of breast tumors has been investigated as an alternative to standard surgery in removing breast tumors. Cryosurgery involves the freezing of designated tissue (e.g., tumor) with a coolant (e.g., liquid nitrogen) through a probe inserted in the tissue. Cryosurgery is performed as an open technique or as a laparoscopic procedure utilizing ultrasound guidance. The hypothesized advantages of cryosurgery include the use of local anesthetic versus general anesthetic, a smaller incision with improved cosmetic appearance, and reduction of postoperative scarring.

Currently, there is insufficient published literature to support the use of cryosurgery as an alternative to standard surgery for the treatment of breast tumors. Studies performed thus far on individuals with breast cancer are very small in size and lack control groups, randomization, and follow-up data. Although cryosurgery appears to be a promising alternative to standard surgery for ablating fibroadenomas in some individuals, it is unknown who would be an appropriate candidate for the procedure. Additionally, these studies have not demonstrated that cryosurgery is comparable or superior to standard surgical excision of breast tumors or whether it improves health outcomes.

Cryosurgical ablation of breast tumors 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.

Full-Body Computerized Tomography (CT) Scan Screening (09.00.24b)

Not Covered: Considered Experimental/Investigational

Computerized tomography (CT), which is sometimes called computerized axial tomography (CAT), has been used as an effective radiographic diagnostic tool for cross-sectional imaging since the 1970s. The US Food and Drug Administration (FDA) has approved the use of CT scans to confirm or exclude detectable anatomic abnormalities from benign and malignant etiologies in symptomatic individuals. The risks of radiation exposure from a typical diagnostic CT scan that is directed at a symptomatic target organ or disease state are accepted by the medical community as reasonable. The use of CT scanning as a screening tool for individuals who are asymptomatic but known to be at high risk for a particular disease (e.g., colon cancer, lung cancer) is under investigation. Study participants are exposed to a limited amount of radiation because only a specific organ or area of the body is scanned.

Full-body (also called whole-body, ultrafast, or electron beam computerized tomography [EBCT]) CT scan screening involves scanning the body from the neck to the pelvis. It is marketed as a preventive health care measure for asymptomatic individuals. Supporters believe that full-body CT scan screening can potentially save lives and avoid serious illness by finding the illness before it manifests or progresses.

The FDA prohibits manufacturers from promoting CT scan systems for full-body screening of asymptomatic individuals. The American College of Radiology has stated that there is insufficient evidence to justify the use of full-body CT scan screening for individuals with no symptoms or family history suggesting disease. In addition, public health agencies and national medical and professional societies (e.g., the American College of Cardiology, the American Heart Association, the American Association of Physicists in Medicine), as well as the Health Physics Society, do not recommend full-body CT scan screening. No published studies have demonstrated that full-body CT scan screening reduces morbidity or mortality when used to screen healthy,

asymptomatic individuals. The American Society of Radiation Technologists passed a resolution in June 2002 advising that CT scan screening should have a clinical basis and that it requires further scientific study. Full-body CT scan screening has not proved to be cost-efficient or effective in prolonging life.

Full-body CT scanning of asymptomatic individuals for screening purposes 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.

Magnetoencephalography (MEG) with Magnetic Source Imaging (MSI) (07.03.10a)

Not Covered: Considered Experimental/Investigational

Magnetoencephalography (MEG) is a noninvasive functional imaging technique in which the weak magnetic forces associated with the electrical activity of the brain are recorded externally on the scalp. Using mathematical modeling, the recorded data are then analyzed to provide an estimated location of the electrical activity. This information can be superimposed on an anatomic image of the brain, typically obtained via magnetic resonance imaging (MRI), to produce a functional/anatomic image referred to as magnetic source imaging (MSI). MSI differs from standard electroencephalography (EEG) in that it records the magnetic fields instead of the electrical activity. Although the conductivity, and thus measurement, of electrical activity recorded by an EEG is altered by surrounding brain structures, the magnetic fields are not. A high-resolution image is, therefore, a primary advantage of MSI.

The most thoroughly studied clinical application involves localization of the pre- and post-central gyri as a guide to surgical planning in individuals scheduled to undergo neurosurgery for epilepsy, brain neoplasms, arteriovenous malformations, or other brain disorders. These gyri contain the "eloquent" sensorimotor areas of the brain, the preservation of which is considered critical during any type of brain surgery. In normal situations, these areas can be identified anatomically by MRI, but in affected individuals the anatomy is frequently distorted by underlying disease processes. In addition, the location of the eloquent functions is variable even among normal individuals. Therefore, localization of the eloquent cortex often requires invasive intraoperative functional techniques such as cortical stimulation under local anesthesia or somatosensory-evoked responses on electrocorticography (ECoG). Although these techniques can be done at the same time as the planned resection, they are cumbersome and can add up to 45 minutes of anesthesia time. Furthermore, these techniques can be limited by the small surgical field.

Aside from the final health outcomes associated with surgery, it is critical to look at how the use of MSI could alter the preoperative workup or the surgery itself. For example, it is frequently suggested that MSI may simplify neurosurgery by enhancing preoperative surgical planning (i.e., presurgical MSI could simplify intraoperative EEG monitoring and thus shorten the overall operative time, or could possibly eliminate the need for intraoperative EEG). For individuals with epilepsy in which the epileptogenic focus cannot be localized with noninvasive EEG or positron emission tomography (PET) scans, MSI may provide an alternative to long-term EEG monitoring with implanted electrodes. Although elimination or shortening of invasive procedures is always welcome, ultimately, the final health outcomes associated with the various techniques should be at least equivalent.

MEG with MSI 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.

More Information

Policy change notifications available online

To better communicate policy changes to providers, articles regarding changes to medical policies are now published on *www.amerihealth.com/medpolicy.* These articles on policy changes will be available at least 30 days in advance of the proposed changes to policy.

Please follow these instructions to read notifications:

1. Visit *www.amerihealth.com/medpolicy.*
2. Select *Accept and Go to Medical Policy Online.*
3. Select *News & Announcements* from the Medical Policy column on the left sidebar.
4. Select links to notification articles.

Another new enhancement to the *News & Announcements* section is a listing of recently published policies to the website, arranged by month. These listings are updated daily, so please check back frequently to see what's new.

Physician volunteers needed to assist in developing medical policies

AmeriHealth is currently recruiting physicians to join its Policy Committee Advisory Panel. This panel is responsible for evaluating the scientific evidence and local standards of care addressed in the Company's 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 area(s) of expertise. As such, your contributions will significantly impact 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 are interested 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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