

CODING GUIDELINES AND POLICY UPDATE

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 biennially and when new medical evidence becomes available, therefore, they are subject to change.

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

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

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

Medical Policies

Abatacept (Orencia®) (08.00.62b)

COVERED: ACCORDING TO CERTAIN CRITERIA

Abatacept (Orencia®) is a soluble fusion protein produced by recombinant deoxyribonucleic acid (DNA) technology. It is a selective costimulation modulator that consists of human cytotoxic T-lymphocyte-associated antigen-4 linked to a modified portion of human immunoglobulin G1 (IgG1). The activation of T lymphocytes has been implicated in the pathogenesis of rheumatoid arthritis (RA). Abatacept (Orencia®) works by interrupting T lymphocyte activation.

Abatacept (Orencia®) is considered medically necessary and, therefore, covered for moderate-to-severe active RA when all of the following criteria are met:

- The individual has had an inadequate response to at least one disease-modifying antirheumatic drug (DMARD) or tumor necrosis factor (TNF) inhibitor.
- The drug is prescribed by a rheumatologist.
- The individual is 18 years of age or over.

All other uses of abatacept (Orencia®) are considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this drug in the diagnosis or treatment of other conditions cannot be established by a review of the available published literature.

Allergy Immunotherapy (07.00.21a)

COVERED: ACCORDING TO CERTAIN CRITERIA

The three basic treatments for allergy are avoidance therapy, pharmacologic therapy, and immunotherapy. When known allergens are unavoidable and not effectively controlled with pharmacologic agents, allergy immunotherapy may be necessary.

Allergy immunotherapy, also known as hyposensitization/desensitization, involves the regular subcutaneous administration of an antigen. An individual begins therapy with a very small dose of antigen, with a gradual dose increase over a period of several months or even years. The injections are generally administered once or twice per week and are intended to increase the individual's immunity to the allergen by developing a degree of tolerance to it. This regimen leads to a lessening of the individual's symptoms.

Allergy immunotherapy is considered medically necessary and, therefore, covered when the following medical necessity criterion is met:

- An eligible health care provider has evaluated the individual, prepared the antigens to be administered, and documented a treatment plan and dosage regimen in the individual's medical record. This regimen must include the maintenance dose. Prior to initiating therapy, the composition of the maintenance concentrate should be determined and documented.

After one year of allergy immunotherapy, the efficacy of the therapy must be assessed. If there is no improvement after one year, a revision of the treatment plan is necessary, or other treatment options or discontinuation of the therapy should be considered.

Sublingual immunotherapy is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this therapy has not been established by a review of the available published literature.

Vial Preparation of Non-Venom Antigens

Current Procedural Terminology (CPT®*) antigen codes 95144-95149 and 95170 are for a single dosage. When billing these codes, eligible health care providers must specify the number of doses provided.

CPT code 95165 represents the preparation of the maintenance concentrate vial. This preparation is the highest concentration of a vaccine (antigen extract) that is projected to be the therapeutically effective dose. As in the case of venoms, some non-venom antigens cannot be mixed together (i.e., they must be prepared in separate vials). An example of this is mold and pollen. Therefore, some individuals will be injected at one time from one vial (which contains all of the appropriate antigens in one mixture), while other individuals will be injected at one time from more than one vial. A billable unit dose of antigen taken from the maintenance concentrate vial is defined as a 1-cc aliquot. Reimbursement of CPT code 95165 is for the preparation of this maintenance concentrate vial and is based upon the number of 1-cc maintenance concentrate aliquots it contains.

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This does not mean that an eligible health care provider must remove 1-cc aliquot doses from the maintenance concentrate vial. It means that the practice expenses payable for the preparation of a 10-cc vial remain the same regardless of the size or number of aliquots removed from the vial. Therefore, an eligible health care provider may not bill this vial preparation code for more than 10 doses per vial. (Note that this code does not include the injection of antigen(s); the injection of antigen(s) is separately billable.)

When a multidose maintenance concentrate vial contains less than 10-cc, an eligible health care provider should bill for the number of 1-cc aliquots that may be removed from the vial. That is, an eligible health care provider may bill up to a maximum of 10 doses per multidose vial but should bill for fewer than 10 doses per vial when there is less than 10-cc in the vial. The following are billing examples:

- If a 10-cc multidose vial is filled to 6-cc with maintenance concentrate, an eligible health care provider may bill for six doses, since six 1-cc aliquots may be removed from the prepared maintenance concentrate vial.
- If a 5-cc multidose vial is completely filled, an eligible health care provider may bill for five doses for this prepared maintenance concentrate vial.
- If an eligible health care provider removes 0.5-cc aliquots from a 10-cc prepared maintenance concentrate vial for 20 doses from one vial, he/she may only bill for 10 doses.
- If an eligible health care provider prepares two 10-cc maintenance concentrate vials, he/she may bill for 20 doses; however, he/she may remove aliquots of any amount from those vials. For example, an eligible health care provider may remove 0.5-cc aliquots from one vial, and 1-cc aliquots from the other vial, but may bill no more than 20 doses.
- If an eligible health care provider prepares a 20-cc maintenance concentrate vial, he/she may bill for 20 doses, since the practice expense is calculated based on the eligible health care provider's removing 1-cc aliquots from one vial. If an eligible health care provider removes 2-cc aliquots from this vial, thus getting only 10 doses, he/she may nonetheless bill for 20 doses because 20 doses reflects the actual practice expense of preparing the vial.

- If an eligible health care provider prepares a 5-cc maintenance concentrate vial, he/she may bill for five doses, based on the way that the practice expense component is calculated. However, if an eligible health care provider removes ten 0.5-cc aliquots from the vial, he/she may still bill only five doses because the practice expense of preparing the vial is the same, without regard to the number of additional doses that are removed from the vial.

Allergy Shots and Visit Services on the Same Day

Visits billed on the same day as an allergy injection (CPT® code 95115 or 95117) should not be billed with allergy injection services 95115 or 95117 unless the visit represents another separately identifiable service.

Reasonable Supply of Antigens

Reimbursement may be made for a reasonable supply of antigens. To reflect industry standards and guidelines, a reasonable supply of a specific antigen is considered to be not more than a 12-month supply (104 doses of each extract within a calendar year).

Maintenance concentrate vials of vaccine are not to be shared. Individual maintenance concentrate vials of vaccine must be prepared for each individual.

Venom Extract

There is no maximum limitation on venom (stinging) extract.

Billing Requirements

The appropriate CPT codes must be used when submitting claims for the preparation and provision of an antigen or venom by an eligible health care provider who may or may not be providing the actual immunotherapy injection.

- A multiplier can be used with the appropriate code range. A multiplier (number of units) is representative of the number of doses prepared and provided, not the number of vials.

Single-dose vials of antigen (CPT code 95144) must be billed only if the physician is supervising, preparing, and providing the antigen to be injected by someone other

than the physician. However, if code 95144 is reported in conjunction with an injection code (95115 or 95117), reimbursement for code 95144 will be made under the rate for code 95165.

An office visit evaluation and management (E&M) code must not be billed when administering immunotherapy injections unless it refers to a separately identifiable medical problem and service. In this case, the E&M code must have Modifier 25 appended to indicate that a significant, separately identifiable E&M service was performed on the same day as the immunotherapy service.

If an individual's doses are adjusted (e.g., because of individual reaction), and the antigen provided is actually more or fewer doses than originally anticipated, an eligible health care provider must make no change in the number of doses for which he/she bills. The number of doses anticipated at the time of the antigen preparation is the number of doses to be billed. An eligible health care provider is to identify the number of doses scheduled when the vial is provided. This means that in cases where the individual actually gets more doses than originally anticipated (because dose amounts were decreased during treatment), and in cases where the individual gets fewer doses (because dose amounts were increased), no change is to be made in the billing. This is applicable to non-venom and venom antigens.

Subsequent dilutions of the maintenance concentrate are not eligible for reimbursement as preparations (CPT® code 95165). For example, taking a 1-cc aliquot from the maintenance concentrate vial and mixing it with 9-ccs of dilutant in a new multidose does not constitute a new preparation.

In a diluted vial, there are no associated allergen costs, since they have already been billed in preparation of the initial vial. Do not bill for preparation of dilutions of antigen.

If it is medically necessary, an eligible health care provider may bill for preparation of more than one multidose vial.

Subject to the terms and conditions of the applicable benefit contract, allergy immunotherapy is covered under the medical benefit for most of the Company's products when the medical necessity criteria listed in the medical policy are met.

Autologous Chondrocyte Transplantation (ACT/Cartice[®]) (11.14.06d)

COVERED: ACCORDING TO CERTAIN CRITERIA

Articular cartilage is a flexible, elastic tissue that covers the surface of the tibia, femur, and the underside of the patella and allows smooth articulation of the joints. Injuries are often associated with pain, loss of function, and disability and can lead to more extensive joint damage due to the limited repair capability of hyaline cartilage.

Autologous chondrocyte transplantation (ACT) (Cartice[®], Genzyme Tissue Repair, Cambridge, MA) is a two-stage procedure that regenerates hyaline-like cartilage by harvesting chondrocytes from a patient's own articular cartilage, expanding the cells in vitro, and transplanting them into defects in the knee. The surgery is followed by continuous passive motion with partial weight-bearing for up to 12 weeks.

There have been no large, well-designed, controlled, randomized trials that compare ACT/Cartice[®] with other treatment methods for articular cartilage injuries. Also, it is still unknown whether the positive results of this procedure are due to the cultured chondrocytes or to the periosteal flap and the rehabilitation process. However, studies have shown good long-term outcomes with some evidence that hyaline-like tissue results from the procedure. Outcomes are better in young individuals who have isolated lesions of the femoral condyles (84 to 90 percent) than in those with patellar defects (74 percent).

ACT/Cartice[®] should only be used with debridement, placement of a periosteal flap, and recommended rehabilitation. It is not indicated when osteoarthritis or joint instability is present.

ACT/Cartice[®] is considered medically necessary and, therefore, covered for the repair of symptomatic, cartilaginous defects of the femoral condyle (medial, lateral, or trochlear) that are caused by acute or repetitive trauma in individuals who have had an inadequate response to a prior arthroscopic or other surgical repair procedure and who meet all of the following criteria:

- The individual has reached skeletal maturity.
- The isolated full-thickness defect is 2.5 cm² to 10 cm² in size.

- The knees are stable and aligned with no associated pathology.
- There is no meniscal deficiency or degenerative arthritis.
- The lesion is surrounded by normal articular cartilage.
- The patient has the ability to comply with the postoperative rehabilitation protocol.

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

Cochlear Implant (11.01.02e)

COVERED: ACCORDING TO CERTAIN CRITERIA

A cochlear implant allows direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or improperly functioning in the cochlea of an individual who has moderate, severe, or profound sensorineural hearing impairment.

The following criteria is used to measure the severity of hearing loss:

- Moderate hearing loss is defined as a bilateral hearing threshold of 40-60 dB.
- Severe hearing loss is defined as a bilateral hearing threshold of 70-90 dB.
- Profound hearing loss is defined as a bilateral hearing threshold of 90 dB and above.

The cochlear implant consists of external and internal components. The external components include a microphone, a sound processor, and a transmitter. The internal components are implanted surgically and include a receiver placed in the temporal bone and an electrode array that extends from the receiver into the cochlea through an opening in the round window of the middle ear.

Cochlear implants have typically been used unilaterally. However, in recent years, interest in bilateral cochlear implantation has arisen. The proposed auditory benefits of bilateral cochlear implants are to improve the understanding of speech in noise and the localization of sounds (or spatial hearing). Improvements in speech intelligibility may occur with bilateral cochlear implants through binaural summation (i.e., signal processing of sound input from two sides). Binaural summation is

thought to provide a better representation of sound and to allow an individual to separate noise from speech. Speech intelligibility and localization of sound may also be improved with head shadow and squelch effects (i.e., when the ear closer to the noise receives sound at a different frequency and intensity). Head shadow and squelch effects are useful in sorting noise and identifying the direction of sound.

There is a distinction between cochlear implants and cochlear electromagnetic devices, which are considered hearing aids. Cochlear implants have both external and internal components. They are not considered hearing aids because they produce an electrical signal that directly stimulates the auditory nerve.

Aural rehabilitation (also known as auditory rehabilitation) is a post-cochlear implant program that focuses on improving the individual's ability to interpret the auditory information that is received through the implant. The program emphasizes the recognition of specific speech sounds, word discrimination and identification, and conversational skills.

A unilateral or bilateral implantation of a U.S. Food and Drug Administration (FDA)-approved single or multichannel cochlear implant is considered medically necessary and, therefore, covered for individuals who are one year of age or older and who meet all of the following criteria:

- The individual has a documented diagnosis of bilateral pre- or post-linguistic moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids.
 - In adults, limited benefit is defined by test scores of less than or equal to 40 percent correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition.
 - In children (ages 1-17), limited benefit is defined as a failure to develop basic auditory skills, and in older children, it is defined as less than or equal to 30 percent correct on open-set tests in the best-aided listening condition.
- The individual has the cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.

- The cochlear lumen is accessible, structurally suited to implantation, free of middle ear infection, and free of lesions in the auditory nerve and acoustic areas of the central nervous system.

Bilateral cochlear implants may be performed at the same time or subsequently.

A cochlear implant must be used in accordance with the labeling approved by the FDA. No single processor for bilateral cochlear implantation has been approved by the FDA.

Aural rehabilitation associated with a cochlear implant is covered and eligible for reimbursement if the individual meets the medical necessity criteria listed above for the implantation of the device. The rehabilitation program generally consists of six-to-ten sessions that last about two hours each. Aural rehabilitation services reported using CPT® codes 92626, 92627, 92630, and 92633 are not considered speech therapy and, therefore, not applied to the member's speech therapy benefit.

Accessories for covered devices required for the proper functioning of a cochlear implant (e.g., specialized batteries), including replacement items, are considered medically necessary and, therefore, covered and eligible for reimbursement consideration.

Assistive listening devices for use with a cochlear implant (e.g., telephone microphone) are neither covered nor eligible for reimbursement consideration because they do not meet the definition of durable medical equipment (DME), as they are not primarily medical in nature.

Upgrades to an existing external system for aesthetic improvement, such as a smaller profile component or a switch from a body-worn model to a behind-the-ear (BTE) model, are deluxe features that are considered not medically necessary because they serve no medical purpose. Therefore, these upgrades are neither covered nor eligible for reimbursement consideration.

Subject to the terms and conditions of the applicable benefit contract, cochlear implantation (unilateral and bilateral) is covered under the medical benefits of the Company's products when the medical necessity criteria listed in the medical policy are met.

Compression Garments (05.00.37a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Compression garments are two-way stretch knit fabrics that are worn over an area of the body. They can be used to treat burns, lymphedema, or various venous stasis ulcers; to prevent clots; and/or to provide general comfort. The stretch and resistance of the garments, together with the natural movement of muscles and blood vessels during normal activity, help with circulation and increase the effectiveness of lymphatic vessels, thus reducing edema and pain.

Compression garments are available and prescribed to be used for specific parts of the body (e.g., glove-to-axilla, foot-to-knee, or upper/lower trunk), and stockings are available in varying pressures and lengths (e.g., waist length, thigh length, full length, and below-the-knee).

TYPES OF COMPRESSION GARMENTS

Burn Garments

Compression burn garments (e.g., bodysuits and leotards) help burns to heal with less scarring by applying pressure and flattening the burn area. They also protect the skin, promote circulation within the damaged tissues, and decrease pain and itching.

Lymphedema Garments

A compression garment that is used in lymphedema therapy is referred to as a gradient pressure aid. Gradient pressure aids (e.g., gloves, gauntlets, and sleeves) help to control the excessive accumulation of lymphatic fluid in an upper extremity.

Gradient Compressions Stockings

Gradient compression stockings (e.g., Jobst stockings) can be used to treat chronic venous insufficiency and lymphedema and to prevent and treat venous stasis ulcers. These stockings deliver pressure to the leg that is tightest at the ankle, with the amount of compression gradually decreasing as the stocking moves up the leg.

Antiembolism Stockings

Antiembolism (surgical or thrombo-embolic deterrent [TED]) stockings are typically used for individuals during a hospitalization that requires bed confinement or during a postsurgery recuperation period. These stockings can also be used to help prevent leg fatigue and the discomfort

associated with varicose veins. Antiembolism stockings offer equalized compression throughout the stocking, while gradient compression stockings offer graduated pressure throughout the stocking. Antiembolism stockings do not require a physician's prescription and can be purchased over the counter.

The requirements for the coverage of compression garments for commercial and Medicare Advantage members are as follows:

COMMERCIAL MEMBERS

Burn and Lymphedema Garments

Burn and lymphedema garments are considered medically necessary and, therefore, covered when one of the following medical necessity criteria is met:

- When a compression burn garment (Healthcare Common Procedural Coding System [HCPCS] codes A6501-A6513) is prescribed following a burn injury
- When a gradient pressure aid (e.g., glove or gauntlet) (HCPCS codes S8420-S8428) or a mastectomy sleeve (HCPCS code L8010) is prescribed as part of a postmastectomy lymphedema program.

Gradient Compression Stockings

Gradient compression stockings (e.g., Jobst stockings) (HCPCS codes A6530-A6549) are considered medically necessary and, therefore, covered when they are prescribed by a physician to treat conditions including, but not limited to, chronic venous insufficiency and lymphedema and to prevent and treat venous stasis ulcers.

- Limitations of coverage for gradient compression stockings are as follows: Coverage is limited to 12 individual gradient compression stockings (or six pairs of stockings if the individual requires the stockings for both lower extremities) (HCPCS codes A6530-A6549) within a calendar year. Additional stockings are considered not medically necessary and, therefore, not covered.

Antiembolism Stockings

Antiembolism (surgical or TED) stockings (HCPCS codes A4490-A4510) are considered medically necessary and, therefore, covered when they are being used to prevent and/or treat conditions such as, but not limited to, deep vein thrombosis.

- Limitations of coverage for antiembolism stockings are as follows: Coverage is limited to 12 individual antiembolism stockings (or six pairs of stockings if the individual requires the stockings for both lower extremities) (HCPCS codes A4490-A4510) within a calendar year. Additional stockings are considered not medically necessary and, therefore, not covered.

MEDICARE ADVANTAGE MEMBERS

Burn and Lymphedema Garments

Burn garments are considered medically necessary and, therefore, covered when a compression burn garment (HCPCS codes A6501-A6513) is prescribed following a burn injury.

Gradient pressure aids (e.g., glove or gauntlet) (HCPCS codes S8420-S8428) and mastectomy sleeves (HCPCS code L8010) are not covered by Medicare and, therefore, are not eligible for reimbursement consideration for Medicare Advantage members.

Gradient Compression Stockings

Below-the-knee gradient compression stockings (e.g., Jobst stockings) with pressure between 30 mm Hg and 50 mm Hg (HCPCS codes A6531 and A6532) are considered medically necessary and, therefore, covered when the stocking is used to secure a primary dressing over a debrided venous stasis ulcer.

All other gradient compression stockings (HCPCS codes A6530 and A6533-A6549) are not covered by Medicare and, therefore, are not eligible for reimbursement consideration for Medicare Advantage members.

Antiembolism Stockings

Antiembolism (surgical or TED) stockings are not covered by Medicare and, therefore, are not eligible for reimbursement consideration for Medicare Advantage members.

Gemtuzumab Ozogamicin (Mylotarg®) (08.00.35c)

COVERED: ACCORDING TO CERTAIN CRITERIA

Gemtuzumab ozogamicin (Mylotarg®) is an intravenous chemotherapy agent. It is composed of a recombinant humanized IgG4 kappa antibody that is conjugated with a cytotoxic antitumor antibiotic that is isolated from fermentation of a bacterium. The antibody portion of gemtuzumab ozogamicin (Mylotarg®) binds specifically to the CD33 antigen, which is a sialic acid-dependent adhesion protein that is found on the surface of leukemic myeloblasts and immature normal cells of myelomonocytic lineage.

Gemtuzumab ozogamicin (Mylotarg®) is considered medically necessary and, therefore, covered for the following FDA-approved indication: individuals with CD33-positive acute myeloid leukemia in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy.

All other uses for gemtuzumab ozogamicin (Mylotarg®) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by a review of the available published literature.

Gemtuzumab ozogamicin (Mylotarg®) is neither indicated as a first-line therapy, nor is it covered when used as an adjunct to other chemotherapy.

Invasive Continuous Glucose Monitoring Systems (05.00.24c)

COVERED: ACCORDING TO CERTAIN CRITERIA

Blood glucose monitoring has been shown to be an important tool in maintaining glycemic control and avoiding complications of diabetes. Invasive continuous glucose monitoring systems (CGMSs) are minimally invasive systems that record interstitial glucose levels every five minutes. Invasive CGMSs are approved by the FDA and consist of three main components: glucose sensor, transmitter, and monitor. Every invasive CGMS has a disposable sensor, which is inserted subcutaneously in the abdominal area. Each sensor lasts up to three days and takes about 288 glucose readings per day.

PHYSICIAN-OWNED INVASIVE CGMSs

The physician-owned invasive CGMS is loaned to an individual who uses it as an adjunctive device to standard fingerstick monitoring for detecting trends and patterns in glucose levels. The device continuously records interstitial glucose levels for periods of 24 to 72 hours. The system is calibrated at least twice a day by entering a glucose measurement obtained from a standard home fingerstick blood glucose meter.

The detailed glucose trend and pattern information is then downloaded and reviewed by a physician, who (based on this information) can adjust the individual's medication, diet, or exercise regimen. Invasive CGMS is intended only for one-time or occasional testing and to supplement, not replace, self-testing of blood glucose.

PATIENT-OWNED INVASIVE CGMSs

The only practical use of a patient-owned CGMS is as a replacement for a standard fingerstick glucose monitor. However, patient-owned CGMSs have not been demonstrated as safe and effective in terms of their independent reliability for making insulin dosage decisions and adjustments.

MEDICALLY NECESSARY

When reported as a professional service, 24-to-72-hour continuous subcutaneous glucose monitoring for detecting trends and patterns in glucose levels with a physician-owned invasive CGMS is considered medically necessary and, therefore, covered for individuals who meet either one of the following criteria:

- The individual has Type I or Type II diabetes and all of the following:
 - Diabetes management instruction from a health care professional
 - A documented average of four glucose self-tests per day during the previous month
 - A program of multiple, daily injections of insulin (at least two per day) with a self-adjusted insulin dose based on self-testing results, or the individual who has Type I diabetes treated with an implanted insulin pump

- One or more of the following while on the multiple daily insulin injection regimen:
 - o Glycated hemoglobin (HbA1c) values less than four or greater than nine
 - o Unexplained large fluctuations in daily glucose values before meals
 - o Unexplained frequent hypoglycemic attacks
 - o Episodes of ketoacidosis or hospitalizations for out-of-control glucose levels
- Women who have Type I or Type II diabetes and are newly pregnant or have developed gestational diabetes that requires insulin therapy

This service must be reported only once per monitoring period regardless of the number of days involved.

Continuous subcutaneous glucose monitoring must be performed for a minimum of 24 hours to show glucose trends effectively. The recommended monitoring period is 72 hours. A monitoring period of less than 24 hours or greater than 72 hours is considered not medically necessary and, therefore, not covered.

Invasive CGMS is intended only for one-time or occasional testing and to supplement, not replace, self-testing of blood glucose levels; frequent requests for continuous subcutaneous glucose monitoring are considered not medically necessary and, therefore, not covered.

EXPERIMENTAL/INVESTIGATIONAL

When requested as DME, patient-owned invasive CGMSs are considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of these devices has not been established by a review of the available published literature.

Metal-on-Metal Total Hip Resurfacing (11.14.20a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Degenerative joint disease (DJD) of the hip is a painful and debilitating disease. Typically, after the failure of conventional therapeutic interventions (e.g., analgesics, weight loss, assistive devices), individuals with DJD of the hip require a primary total hip arthroplasty (THA). THA involves the replacement of the entire femoral head and stem with a metal prosthesis; the acetabular surface is then fitted with an articulating metal prosthetic component.

The primary THA is a highly successful procedure that has predictable and relatively minor complications. However, when younger adults receive a THA, they have a higher probability of outliving the usefulness of the implant. If a repaired joint fails, a revision of the THA becomes necessary (i.e., ipsilateral hip joint revision). Because the femoral head is cut away during the primary THA, there is significantly less operable bone for the ipsilateral hip joint revision.

Metal-on-metal total hip resurfacing is an alternative surgical procedure in which the femoral head is reshaped and capped with a prosthetic head, and the acetabular surface is fitted with an articulating prosthetic component. The major benefit of metal-on-metal total hip resurfacing is the preservation of the femoral neck and femoral canal. Maintaining these structures allows a metal-on-metal total hip resurfacing to facilitate the conversion to a THA, if required. Additionally, the resurfaced, prosthetic head is similar in size to a normal femoral head, thus increasing the stability of the joint and decreasing the risk of dislocation that is associated with THA.

Metal-on-metal total hip resurfacing is considered medically necessary and, therefore, covered for individuals who have noninflammatory arthritis (which includes, but is not limited to, osteoarthritis, traumatic arthritis, avascular necrosis, and dysplasia) or inflammatory arthritis (which includes, but is not limited to, rheumatoid arthritis) of the hip.

Neuropsychological Testing (07.03.08a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Neuropsychological testing (NPT) is intended to diagnose and characterize the neurocognitive effects of disorders that impinge directly or indirectly on the brain or to monitor the progress of an individual who is being treated for an acquired brain injury.

NPT consists primarily of individually conducted ability tests that are known to be sensitive to the functional integrity of the brain (e.g., abstraction, memory and learning, attention, language, problem solving, sensory motor functions, constructional praxis, etc.), which may be altered as a result of a number of conditions. NPT can help detect the effects of developmental medical problems of a neurologic origin, such as epilepsy or a genetic disorder. The tests are objective and quantitative in nature, and they require an individual to directly demonstrate a level of competence in a particular cognitive domain.

The duration of NPT depends upon factors such as the nature of the problem being evaluated, the individual's level of impairment, and the individual's endurance level and ability to cooperate with examination requests. Portions of NPT may be performed over several days.

Examples of tests that may be included in an NPT battery include the Bender Visual-Motor Gestalt Test, the Benton Serial Digit Learning Test, the Hopkins Verbal Learning Test, the California Verbal Learning Test, the Knox Cube Test, the Wisconsin Card Sorting Test, and the Wechsler Memory Scale. The two most common batteries are the Halstead-Reitan Neuropsychological Test Battery (which may include tests of intelligence and other supplemental assessments) and the Luria-Nebraska Neuropsychological Battery.

NPT does not rely on subjective information that is collected by the following methods:

- Questionnaires (e.g., the Minnesota Multiphasic Personality Inventory-2)
- Rating scales (e.g., the Hamilton Depression Rating Scale)
- Projective techniques (e.g., the Rorschach or Thematic Apperception Test)
- Brief screening measures (e.g., the Folstein Mini-Mental Status Examination)

For individuals who have had an organic brain injury, loss of memory, or significant change in behavior *or* a significant change in mental status that is not due to a metabolic disorder and has not responded to acute medical therapy, NPT is considered medically necessary and, therefore, covered for either of the following indications:

- To establish a baseline before proceeding with either of the following:
 - A neurosurgical procedure (e.g., epilepsy surgery)
 - The initiation of medication for a neurologic condition (e.g., Parkinson's disease)
- To diagnose and/or manage the neurocognitive effects of any of the following medical conditions:
 - Cerebrovascular disease
 - Delirium/confusional state or dementia of any etiology
 - NPT can be used to distinguish between normal aging and mild dementia caused by conditions such as, but not limited to, early Alzheimer's disease, infectious disease, or a psychological disorder that presents with a similar constellation of symptoms.
 - Depression that presents with neurologic symptomatology
 - Intracranial neoplasm
 - Movement disorders
 - Neurologically complicated attention deficit disorders with or without hyperactivity (e.g., hydrocephalus)
 - Neurologically complicated developmental delays
 - Seizure disorders
 - Traumatic brain injury

An individual must be neurologically and cognitively able to understand and participate in all activities that are necessary to perform NPT.

When assessing previously diagnosed brain dysfunction, initial or repeat NPT is considered medically necessary and, therefore, covered for either of the following circumstances:

- There is reasonable suspicion of a new problem, relapse, or deterioration of the individual's condition.
- The individual has reached a treatment plateau, and an assessment of remaining functional deficits will

determine if additional intervention can enhance the individual's functioning.

Unless a comorbid condition of a neurologic nature exists, NPT is considered not medically necessary and, therefore, not covered for conditions such as, but not limited to, the following:

- Mental retardation
- Autistic spectrum disorders
- Developmental disability
- Attention deficit/hyperactivity disorder
- Tourette's syndrome
- Educational or screening purposes in an otherwise normal individual
 - Screening to evaluate an individual for learning disabilities or for educational planning should be performed by the child's school as per the federal mandate, the Individuals with Disabilities Education Act.

NPT is considered medically necessary and, therefore, covered when making difficult diagnostic determinations for the pediatric population when other diagnostic methods have failed to produce an accurate diagnosis.

Self-administered or self-scored inventories, mental status examinations, or tests of cognitive function (e.g., the Folstein Mini-Mental Status Examination) are not considered to be NPT since they are typically performed as part of a more general clinical examination or interview.

NPT consists primarily of individually administered tests that comprehensively sample ability domains that are known to be sensitive to the functional integrity of the brain. Although there are numerous components of NPT, it is the responsibility of the provider to determine which tests are most appropriate for each individual. Every individual does not need the full battery of tests; some individuals may only need a subset of tests.

Comprehensive NPT should only be performed by a doctoral level psychologist who has obtained the level of training and experience that meets the standards developed for clinical practice as a neuropsychologist. Such training may be established by board certification or by documentation of training and experience. Documentation of the provider's credentials should be made available to the Company upon request. Neurologists and psychiatrists are eligible to submit claims

on behalf of a neuropsychologist whom they employ to provide this service.

Portions of the NPT battery may be administered either by a computer or by a technician under the direction of the psychologist. Each portion of the tests should be reported using the CPT® code that appropriately represents the service performed.

Certain computer-based tests (such as Impact™ or Headminder) are considered medically necessary and, therefore, covered for detecting cognitive impairment following a mild traumatic brain injury such as a sports-related concussion. An eligible health care provider (including, but not limited to, a sports medicine physician) should report these tests using CPT code 96120. This code is not an hourly code; it should be reported only once per testing session.

When used for screening purposes or baseline assessment in the absence of an injury or neurologic condition, computer-based testing is considered not medically necessary and, therefore, not covered.

Based on currently accepted standards of practice, testing beyond seven hours is considered not medically necessary and, therefore, not covered. When testing is performed over several days, the cumulative testing time should be reported on the same claim form upon completion of the testing; each hour of service should be reported as one unit.

Omalizumab (Xolair®) (08.00.55a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Omalizumab (Xolair®) is a monoclonal antibody that binds to naturally occurring human immunoglobulin E (IgE). It inhibits the binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils. A reduction in the number of surface-bound IgE on the high-affinity IgE receptor-bearing cells limits the release of mediators of the allergic response and plays a significant role in asthma attacks. Treatment with omalizumab (Xolair®) also reduces the number of high-affinity IgE receptors on basophils in individuals with atopic asthma.

Omalizumab (Xolair®) is considered medically necessary and, therefore, covered for the treatment of moderate-to-severe persistent asthma in individuals who are at least 12 years of age, who had a positive skin test or in vitro

reactivity to a perennial aeroallergen, and whose symptoms are inadequately controlled with inhaled corticosteroids.

Moderate persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as symptoms that occur daily and at least once a week at night, a peak expiratory flow variability greater than 30 percent, and a forced expiratory volume in one second that is more than 60 percent but less than 80 percent.

Severe persistent asthma is defined by the NHLBI as continual symptoms, limited physical activity, frequent exacerbation and nighttime symptoms, a peak expiratory flow variability greater than 30 percent, and a forced expiratory volume in one second that is less than or equal to 60 percent.

All other uses of omalizumab (Xolair®) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by a review of the available published literature.

Osteochondral Allograft Transplantation (11.14.12a)

COVERED: ACCORDING TO CERTAIN CRITERIA

Hyaline cartilage found on the articular surface of the human knee is flexible and elastic but has little regenerative ability. Traumatic injury to the knee that interferes with smooth joint motion can result in severe pain and instability and often leads to degenerative conditions. Treatments such as debridement, subchondral drilling, and microfracture tend to produce fibrocartilage that degenerates over time. Osteochondral autograft transplantation (OAT) and autologous chondrocyte transplantation (ACT) may result in the formation of some hyaline tissue, but these procedures are only recommended for small defects.

Osteochondral cadaver allografting is an alternative for repair of large, full-thickness osteochondral knee defects. Fully formed grafts that match the size and contour of the defect are harvested from the exact donor site of the defect being repaired. During arthotomy, the defect is fully debrided and the allograft is implanted and secured with screws. Transplantation of intact articular cartilage avoids the morbidity that may occur from harvesting autografts; in addition, the allograft makes it easier to contour the surface and attain the required height of the damaged

cartilage. Donors must be between 15 and 45 years of age, and grafts must be processed within 24 hours of death. Transplantation should be performed within 72 hours of processing, although some investigators have extended the window to five to seven days post-processing. Studies are underway to assess the optimum storage time for fresh allografts.

The dense, avascular nature of intact hyaline cartilage tends to afford protection from host response, and removing marrow components can attenuate the response to blood and bone marrow cells in allograft bone. Consequently, at this time, immunology of fresh allogenic transplants is not an issue and the donor and recipient are not matched for immunologic response.

Most investigators agree that osteochondral allograft transplantation should be offered for full-thickness unipolar osteochondral defects larger than 2 cm² in size resulting from trauma or osteochondritis dissecans in individuals who have failed a prior cartilage resurfacing procedure. In addition, it has been shown that allografting is more likely to succeed when provided to active individuals younger than 50 years of age with stable knees and intact menisci.

Contraindications to osteochondral allograft transplantation include inflammatory arthritis, steroid dependency, uncorrected malalignment, ligament insufficiency, or any other conditions that may affect graft incorporation.

Transplantation requires arthrotomy with extensive post-operative rehabilitation. Continuous passive motion is provided post-operatively, and non-weight bearing is recommended for as long as 12 weeks post-surgery; return to normal activities with full weight bearing takes 16 weeks. Participation in sports is not recommended until six months post-surgery.

Osteochondral allograft transplantation is considered medically necessary and, therefore, covered for the treatment of symptomatic unipolar cartilaginous defects of the femoral condyle caused by trauma or osteochondritis dissecans in active individuals who meet all of the following criteria:

- The individual has reached skeletal maturity.
- The individual has an isolated full-thickness unipolar defect larger than 2 cm² in size.

- The individual has stable and aligned knees without meniscal deficiency (or corrective surgery is planned prior to or in combination with the transplantation).
- The individual has failed a prior cartilage resurfacing procedure.
- The individual has the ability and willingness to comply with the post-operative rehabilitation protocol.

All other uses of osteochondral allograft transplantation are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

Osteochondral Autograft Transplantation (11.14.09b)

COVERED: ACCORDING TO CERTAIN CRITERIA

Osteochondral autograft transplantation (OAT) (also known as osteochondral autograft transplant system [OATS] or autogenous osteochondral mosaicplasty) involves harvesting osteochondral cylinders that include overlays of normal articular cartilage from minimal-weight bearing knee areas and transplanting them into articular sites.

Depending on the size of the lesion being treated, OAT is done in one of two stages: open or arthroscopic. Any malalignment or ligamentous instability that may have produced or contributed to the lesion should be corrected prior to, or concurrent with, treatment of the defect and included in the rehabilitation plan. Rehabilitation can take up to 12 weeks, and continuous passive motion may be used postoperatively to improve the joint surface contour.

Contraindications for OAT include: degenerative or rheumatoid joint disease; and diffuse lesions or joint space narrowing. Knee instability or malalignment is a contraindication if it is not corrected prior to or at the time of surgery.

While OAT is an accepted procedure for osteochondral defects in the knee, less is known about the procedure for defects of the talus. Based on a review of the available published literature, the effect on the long-term integrity of the knee donor site, the reaction of the different characteristics between knee and ankle cartilage, and the durability of donor plugs taken from the knee are unknown. Currently, there are no agreed upon surgical guidelines for performing OAT to treat talus defects.

In addition, based on the only available randomized controlled trial, other less invasive procedures may be equally effective.

OAT is considered medically necessary and, therefore, covered when all of the following criteria are met:

- The individual has reached skeletal maturity.
- The individual has a full-thickness, unipolar 1-3 cm² defect on the femoral condyle or patellar articular surface.
- The individual has a stable knee without meniscal deficiency that is surrounded by healthy articular cartilage capable of supporting the graft.
- The individual has the ability and willingness to comply with the post-operative rehabilitation protocol.

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

Refractive Keratoplasty (11.05.01c)

COVERED: ACCORDING TO CERTAIN CRITERIA

Refractive keratoplasty is a generic term that includes numerous surgical procedures that reshape the cornea of the eye to correct vision problems such as myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (a distortion of the image on the retina caused by irregularities in the cornea or lens of the eye).

Refractive keratoplasty is considered medically necessary and, therefore, covered when performed by corneal relaxing incision (CPT[®] code 65772), corneal wedge resection (CPT code 65775), or conductive keratoplasty (CPT code 66999) for the correction of astigmatism resulting from trauma or previous eye surgery.

All other refractive keratoplasty procedures and related services performed for the correction of refractive defects (e.g., myopia, hyperopia, or astigmatism) in order to eliminate or reduce the need for prescription or corrective vision lenses are a benefit contract exclusion and, therefore, not covered and not eligible for reimbursement consideration for most of the Company's products.

For some of the Company's products, these services are a benefit option; therefore, individual member benefits must be verified.

Treatment of Varicose Veins of the Lower Extremities (11.02.01e)

COVERED: ACCORDING TO CERTAIN CRITERIA

Varicose veins are dilated, tortuous, superficial vessels that result either from defective valves within the saphenous veins, from intrinsic weakness of the vein wall, from high intraluminal pressure, or, on rare occasion, from arteriovenous fistulas. Varicose veins of the lower extremities protrude from the skin surface in a rope-like manner.

Laser ablation, endoluminal radiofrequency ablation, transilluminated powered phlebectomy, stab phlebectomy, sclerotherapy, and stripping and ligation of varicose veins of the lower extremities are considered medically necessary and, therefore, covered when both of the following criteria are met:

- An individual has failed a three-month trial of conservative medical management (which may have included the use of support hose, leg elevation, and weight reduction, when appropriate)
- An individual is symptomatic (e.g., itching, heaviness, tension, pain), and the varicosities result in one or more of the following in the affected extremity:
 - Symptoms that impair mobility or activities of daily living
 - Demonstrable (bulging) veins above the surface of the skin
 - Recurrent superficial phlebitis
 - Skin ulceration
 - Bleeding
 - Refractory-dependent edema or other complications from venous stasis (e.g., dermatitis)

Additionally, when injecting varicose veins of the lower extremities with sclerosing solution, both of the following criteria must be met:

- There is no saphenofemoral insufficiency or disease/occlusion of the deep venous system.
- The varicosities are equal to or greater than 3mm.

When billing for sclerotherapy of multiple veins in one leg, providers should report CPT code 36471 (injection of sclerosing solution; multiple veins, same leg). The correct quantity to bill for this service is one unit per code, regardless of the number of veins being injected.

Laser ablation, endoluminal radiofrequency ablation, transilluminated powered phlebectomy, stab phlebectomy, sclerotherapy, and stripping and ligation of varicose veins of the lower extremities are considered not medically necessary and, therefore, not covered unless a three-month trial of conservative medical management has been attempted and failed.

Since ultrasound-monitored or duplex-guided techniques for sclerotherapy of varicose veins (echosclerotherapy) have not been shown to definitively increase the effectiveness or safety of this procedure, echosclerotherapy is considered not medically necessary and, therefore, not covered for the treatment of varicose veins of the lower extremities for all individuals for any reason.

Treatment of asymptomatic varicose veins of the lower extremities and spider veins using the procedures described above is considered cosmetic. Services that are cosmetic are a benefit contract exclusion for all of the Company's products.

Ligation and division of the long saphenous vein at the saphenofemoral junction or distal interruptions are not eligible for reimbursement if it is determined that a percutaneous suture was placed instead of a true ligation.

Claim Payment Policies

Whole-Body Integumentary Photography and Dermatoscopy are Not Eligible for Reimbursement when Billed Alone or in Conjunction with Other Services (07.07.05a)

Familial melanoma has been associated with dysplastic nevi (also called atypical moles). Dysplastic nevi may vary in size, shape, and color and are markers for increased risk of melanoma, the deadliest form of skin cancer. Early identification and management of melanoma is important because prognosis improves with early diagnosis and treatment. Regular visual examination of the skin by the individual and/or medical provider is the usual method of lesion surveillance. A biopsy is performed if the lesion is suspect for melanoma. Lesions are considered suspicious if they are asymmetrical, have an irregular border, contain more than one shade of pigment, and/or have a diameter greater than 6mm.

Whole-body photography and dermatoscopy (also known as dermoscopy, epiluminescence microscopy, skin surface microscopy, and incidence light microscopy) are noninvasive techniques performed in the office setting for the detection and monitoring of dysplastic nevi for melanoma.

Dermatoscopy uses a digital camera with specialized software and reflective light optics to capture the asymmetry, color, size, and borders of lesions. The high resolution of the images enables the clinician to get detailed information about a suspicious mole. The images may also be compared with previous photographs to determine whether the growth is benign or malignant, or whether new moles have developed. With a digital imaging system, new lesions or lesions that have changed may appear to flash or pulsate when compared with the previous images.

The following are not considered distinct and eligible services; therefore, they are not eligible for reimbursement when billed alone or in conjunction with other services:

- The taking of/or inspection of photographs
- Whole-body integumentary photography and whole-body photography
- Dermatoscopy

Therapeutic Radiology Port Films are Considered Eligible for Separate Reimbursement (09.00.23a)

Therapeutic radiology port films are radiographs taken at regular intervals to verify correct positioning of all treatment machine portals on individuals undergoing external-beam radiation therapy.

The Company covers therapeutic radiology port films alone and/or in conjunction with other radiology services, including other radiation therapy services. Therefore, therapeutic radiology port films are eligible for separate reimbursement from other reported services.

In geographical areas with a Capitated Outpatient Radiology Program, therapeutic radiology services are exclusions to the capitation program and eligible for fee-for-service reimbursement.

Experimental/Investigational Policy

Serodiagnosis of Inflammatory Bowel Disease (06.02.17a)

NOT COVERED: CONSIDERED EXPERIMENTAL/ INVESTIGATIONAL

Inflammatory bowel disease (IBD) is a chronic, inflammatory disorder of the gastrointestinal tract of unknown etiology. IBD falls into two major categories: ulcerative colitis (UC) and Crohn's disease (CD), both of which present with abdominal pain and diarrhea. A definitive diagnosis can usually be established with a combination of endoscopic, radiographic, and histologic criteria. However, in 10 to 15 percent of the cases, a distinction between UC and CD is not definitive.

Serodiagnosis is defined as the diagnosis of disease based on antigen-antibody reactions in the blood serum, or other serum fluids in the body (serologic tests). Anti-neutrophilic cytoplasmic antibodies (ANCA) and anti-Saccharomyces cytoplasmic antibodies (ASCA) are two serum antibodies that have been associated with IBD and can potentially be used in diagnostic tests. Although ANCA and ASCA are present in individuals with CD and UC, the tests used to detect these antibodies have low sensitivities, and neither test is completely specific for the disease. Currently, the efficacy of serodiagnosis cannot be established by review of the available established literature.

Serodiagnosis of IBD 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

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

