

Prostheses and Orthotics/Orthoses

This addresses the Policy on Prostheses and Orthotics. Coverage depends on Plan coverage. See Explanation of Coverage (EOC). All Prostheses and Orthotics requests are subject to medical necessity review.

PROSTHESIS: Is an artificial device which replaces all or portion of a part of the human body. These devices are necessary because a part of the body is permanently damaged, is absent or is malfunctioning. A prosthesis is an artificial replacement for a missing body part, or a device designed to improve a specific body function.

Types of Prostheses: Internal and External.

Examples of internal prostheses are: implanted pacemakers, contact lenses after cataract surgery, breast prostheses, surgically implanted hip joints, etc.

Examples of external prostheses are: artificial limbs, artificial eyes, visual aids (excluding eyewear) to assist the visually impaired with proper dosing of insulin, etc.

Replacement of Prosthetic Devices:

Prosthetic devices will be replaced for the following reasons: a) when it is no longer functional, b) due to a reasonable wear and tear, c) per regulatory requirement, and d) as medically necessary and prescribed by a licensed practitioner. However, repair or replacement for loss or misuse is not covered.

Coverage: Prosthetics are covered when provided by a provider authorized by the Plan.

Examples of Prosthetics that the Plan covers:

- Initial and subsequent prosthetic devices and installation accessories to restore a method of speaking incident to a laryngectomy
- Prosthetic devices to restore and achieve symmetry incident to mastectomy.
- Intraocular lenses after cataract surgery
- Breast prosthesis post mastectomy
- Visual aids (excluding eyewear) to assist the visually impaired with proper dosing of insulin
- Fitting, repair, replacement and maintenance of prosthetic device.
- Eye glasses or contact lenses post cataract surgery.
- Non-prescription (over the counter) prosthetics that can be purchased without a licensed provider's prescription specifically provided under Home Health Care Services or Hospice Care. Under Hospice Care, prosthetics are covered to the extent reasonable and necessary for the palliation and management of terminal illness and related conditions.

Exclusions:

- Prosthetic services are not covered when provided for other than medical necessity (e.g. for cosmetic purposes)
- Dental appliances

- Electronic voice producing machines not related to laryngectomy
- More than one device for the same body part
- Eye glasses or contact lenses not related to cataract surgery
- Prosthetics that can be purchased over the counter at a retail store.
- Non-prescription (over the counter) prosthetics that can be purchased without a licensed provider's prescription

There are situations when over the counter prosthetics (when written as a prescription by the doctor) may be covered as medically necessary. This will require medical necessity review and approval by the Plan's Medical Director.

ORTHOTICS/ORTHOSES: Orthotics are usually rigid or semi-rigid supports, splints or braces for the support of weak or ineffective joints or muscles. Their purpose is to protect, restore or improve function. They are also used restrict or eliminate motion in a disease or injured part of the body.

Definitions:

Prefabricated (over the counter/non-prescription)):

A prefabricated (off-the-shelf) orthotic is one that is manufactured in quantity without a specific patient in mind. A prefabricated orthotic may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom fitted). An orthotic that is assembled from prefabricated components is considered prefabricated. Any orthotic that does not meet the definition of a custom fabricated (custom-made) orthotic is considered prefabricated.

Custom-made or Custom –Fabricated: A custom fabricated (custom-made) orthotic is one that is individually made for a specific patient starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item. A molded-to-patient-model orthotic is a particular type of custom fabricated orthotic in which an impression of the specific body part is made (by means of a plaster cast, CAD-CAM technology, etc.) and this impression is then used to make a positive model (of plaster or other material) of the body part. The orthotic is then molded on this positive model.

Ankle-Foot Orthoses (AFOs) and Knee Ankle Foot Orthoses (KAFOs): A system of standard terminology has been developed to describe orthoses. The system uses the first letter of each joint that the orthosis crosses in correct sequence, with the letter "O" for orthosis at the end. Thus, the more common orthoses would be named AFO (ankle-foot orthosis), KAFO (knee-ankle-foot orthosis), and KO (knee orthosis). A properly written orthotic prescription does not just state the name of the orthosis; it also is necessary to state the desired function to be obtained, the specific material from which the device is to be made, and the specific design and construction that is to be employed.

Cast Braces: Hinged polypropylene cast braces consisting of a foot section with heel stabilizer, a lateral ankle extension and an articulating ankle joint joining the two. An example is the Sarmiento cast brace, which is removable and fits in the patient's shoe.

Examples of Orthotics are: an orthotic brace for the treatment of scoliosis, wrist splints, shoe inserts or cam walkers.

Coverage: Orthotics are covered based on medical necessity when provided by a provider authorized by the Plan.

Examples of Orthotics that the Plan covers:

- Therapeutic footwear, corrective shoes, shoe inserts, arch supports and foot orthotics for members with diabetes or plantar fasciitis. (See Foot Orthotic Policy for details regarding coverage for therapeutic shoes for diabetics).
- Special footwear for foot disfigurement including, but not limited to, disfigurement from cerebral palsy, arthritis, polio, spina bifida, diabetes, and foot disfigurement caused by accident or developmental disability and congenital foot deformities. Therapeutic shoes if they are an integral part of a covered leg brace and are medically necessary for the proper functioning of the brace. (See Foot Orthotic Policy for details).
- Podiatric devices to prevent or treat diabetes related complications
- Custom made orthotics when there is clinical documentation indicating that a non-custom made (pre-fabricated) orthotic is not appropriate for the condition or diagnosis.
- Fitting, repair, replacement, and maintenance.
- Non-prescription (over the counter) orthotics that can be purchased without a licensed provider's prescription specifically provided under Home Health Care Services or Hospice Care. Under Hospice Care, orthotics are covered to the extent reasonable and necessary for the palliation and management of terminal illness and related conditions.
- Orthotics required post-operatively when prescribed within six (6) weeks of surgery.
- Rehabilitative foot orthotics prescribed following foot surgery or trauma when part of post-surgical or casting care.
- Orthotics, including rigid ankle casts, prescribed to stabilize a fracture, dislocation or ligament tear.
- Unna Boots for ankle sprains with accompanying ulcerative skin changes.
- Ankle Contracture Splints and Foot Drop Splints for *Non-ambulatory* persons:
 - Ankle contracture splints: are medically necessary if *all* of the following criteria are met:
 - a. The member has a plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a non-fixed contracture), *and*
 - b. There is a reasonable expectation of the ability to correct the contracture, as evidenced by recent onset or relation to recent surgical procedure *and*
 - c. The contracture is interfering or expected to interfere significantly with the member's functional abilities, *and*
 - d. The ankle contracture splint is used as a component of a therapy program that includes passive stretching of the involved muscles and/or tendons.

If an ankle contracture splint is used for the treatment of a plantar flexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record. There must be documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home).

If an ankle contracture splint is considered medically necessary, a replacement interface is also considered medically necessary DME as long as the member continues to meet medical necessity criteria for the splint. Up to one replacement interface per six months is considered medically necessary.

- AFOs in *ambulatory* members: For weakness or deformity of the foot and ankle, which require stabilization for medical reasons, and have the potential to benefit functionally. Members prescribed

custom-made “molded-to-patient-model” AFOs must also meet the criteria set forth in section below.

- KAFOs in *ambulatory* members: For ambulatory members for whom an ankle-foot orthosis is covered and for whom additional knee stability is required. Members prescribed custom-made “molded-to-patient model” KAFOs must also meet the criteria set forth below
- Molded-to-patient model AFOs and KAFOs in *ambulatory* members: Custom-made AFOs and KAFOs that are “molded-to-patient-model” are considered medically necessary DME for ambulatory members when the basic medical necessity criteria listed above are met and one or more of the following criteria is met:
 - i. The member could not be fit with a prefabricated (over the counter/non-prescription) AFO; *or*
 - ii. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); *or*
 - iii. There is a need to control the knee, ankle or foot in more than one plane; *or*
 - iv. The member has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; *or*
 - v. The member has a healing fracture that lacks normal anatomical integrity or anthropometric proportions.

Exclusions:

- Orthotics (other than those covered above) not made to fit the member’s body (i.e. prefabricated). Foot orthotics (whether or not custom fit) that are not incorporated into a cast, splint, brace or strapping of the foot unless for diabetes or plantar fasciitis.
- Corrective orthopedic shoes, shoe inserts, arch supports, foot orthotics, therapeutic footwear or other supportive devices of the feet unless for diabetes or plantar fasciitis.
- Non-rigid devices such as elastic knee supports, corsets, elastic stockings, and garter belts
- Non-prescription (over the counter) orthotics that can be purchased without a licensed provider’s prescription such as wrist supports, back supports.
- Prescription Orthotics (other than those covered above) that can be purchased at a retail store, on-line or at a specialty store such as a back brace, boot walker or knee braces.
- Orthotics that are to be used for sports-related activities intended to prevent injury or re-injury related directly to the risks of engaging in said sport (for example, a knee brace to prevent injury to the knee while playing football) even in post-operative cases. Prophylactic orthotics used to prevent injury in a previously uninjured body part.
- Rigid or semi-rigid ankle casts to treated ankle sprains, for chronically unstable ankles, for prophylaxis or when used to prevent re-injury (considered experimental and investigational)
- Cast braces (no benefit over other forms of treatment)
- Unna Boots used after ankle fracture or when used in chronically unstable ankles or to prevent re-injury.
- Stabilizing shoes for ankle injuries, acute or chronic (considered experimental and investigational)
- Ankle tapes and wrapping as these items are not reusable.
- AFOs, KAFOs and any related addition when used solely for the treatment of edema and/or for the prevention or treatment of a heel pressure ulcer in ambulatory patients Additions to AFOs or KAFOs if either the base orthosis is not medically necessary or the specific addition is not medically necessary
- Socks used in conjunction with orthoses as they do not meet the contractual definition of durability.
- An ankle contracture splint and replacement for the following indications:
 - a. Fixed contractures;
 - b. Members with foot drop but without an ankle flexion contracture.
 - c. When used solely for the prevention or treatment of a heel or forefoot pressure ulcer.

- d. A component of an ankle contracture splint that is used to address positioning of the knee or hip is considered experimental and investigational because the effectiveness of this type of component is not established
- Foot drop splint/ recumbent positioning device: when used solely for the prevention or treatment of a heel pressure ulcer. Duplicate orthotics for the same part of the body.

Replacement of Orthotics:

Orthotics will be replaced for the following reasons: a) due to reasonable wear and tear, and b) as medically necessary and prescribed by a licensed practitioner.

A. Attachment: None

B. Author/Reviewer: Albert Reeves, MD Date: July 2010

Committee Review: UM on 8/11/11; QA on 8/23/11

C. Reviewed/No Changes: Albert Reeves, MD Date: 4-17-12

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E. Reviewed/No Changes: Catherine Sanders, MD

Committee Review: UM on 2/13/14; QA on 2/25/14

F. Reviewed/With Changes: Catherine Sanders, MD

Committee Review: UM on 08/14/14; QA on 09/02/14

F. References:

1. American Diabetes Association. Clinical Practice Recommendations 1991-1992. "Self-Monitoring of Blood Glucose." *Diabetes Care*. April 2, 1992; Supplement 2: Volume 15.
2. Department of Health and Human Services. Food and Drug Administration. 21 CFR, Part 882. Docket No. 98N-0513. "Medical Devices; Neurological Devices; Classification of Cranial Orthosis." *Federal Register*. July 30, 1998; 63(146)
3. Hay, William, et al., ed.; *Current Pediatric Diagnosis & Treatment*. Twelfth edition. Norwalk, Connecticut: Appleton & Lange, 1995.
4. Medicare coverage Guidelines
5. Medicare Carriers Manual, Section 22100.1
6. Moss, David S., et al. "Diagnosis and Management of the Misshapen Head in the Neonate" *Pediatric Review*. Spring 1993;4:4-7
7. Tarpy, Stephen P., et al. "Long-term Oxygen Therapy." *The New England Journal of Medicine*. September 14, 1995;333(11):710-714.
8. U.S. Department of Health and Human Services, Health Care Financing Administration. Self-contained pacemaker monitors. Medicare Coverage Issues Manual §60-7. Baltimore, MD: HCFA, 2000.
9. U.S. Department of Health and Human Services, Health Care Financing Administration. Cardiac pacemaker evaluation services. Medicare Coverage Issues Manual §50-1. Baltimore, MD: HCFA, 2000.
10. U.S. Department of Health and Human Services, Health Care Financing Administration. Durable medical equipment reference list. Medicare Coverage Issues Manual §60-9. Baltimore, MD: HCFA, 2000.
11. Emergency Care Research Institute (ECRI). Pacemakers, cardiac, implantable. In: *Healthcare Product Comparison System*, Hospital Edition. Plymouth Meeting, PA: ECRI, 1999.
12. American College of Surgeons. Statement on indications for the use of permanently implanted cardiac pacemakers. *Bull Am Coll Surg*. 1996;81(2):40.

