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| Department: | Medical Management | Original Approval: | 10/18/2017 |
| Policy #: | MM158 | Last Approval: | 09/06/2019 |
| Title: | Foot Orthoses, Ankle Foot Orthoses, and Ankle Knee Orthoses | | |
| Approved By: | UM Medical Subcommittee | | |

REQUIRED DOCUMENTATION

Chart notes detailing the symptoms, other treatments and devices the patient has tried and the outcome, physical examination, imaging studies if applicable, assessment and plan, rationale for the request.

POLICY:

This policy applies to Apple Health and Medicare members. There are no restrictions based on age for Apple Health members or Medicare members.

DEFINITIONS:

Orthotics - is a [medical specialty](#) that focuses on the design and application of orthoses. Patients frequently refer to foot orthoses as “orthotics”.

Orthosis (brace) - a rigid and semi-rigid device which is used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a disease or injured part of the body. An orthosis can be classified as either prefabricated (off-the-shelf), custom fitted, or custom-fabricated.

Prefabricated Orthosis (Off-the-shelf) - Require minimal self-adjustment not requiring a not require expertise of a certified orthotist or an individual who has equivalent specialized training for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, and molding, assembling, or customizing to fit an individual.

Custom-fitted Orthosis - Requires substantial modification for fitting at the time of delivery in order to provide an individualized fit, i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified, resulting in alterations beyond minimal self-adjustment. Requires expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthosis to fit the item to the individual.

Custom-fabricated Orthosis – Individually made for specific member starting with basic materials including, but not limited to, plastic, metal, leather, or cloth. The orthosis is then individually fabricated and molded over the positive model.

Foot Orthoses – Devices inserted into shoes to provide support for the foot by redistributing ground reaction forces acting on the foot joints while standing, walking or running. They may be either pre- pre-fabricated or custom made according to a cast or impression of the foot.

Ankle Foot Orthosis (AFO)- A brace, usually made of plastic, that is worn on the lower leg and foot to support the ankle, hold the foot and ankle in the correct position

Knee Ankle Foot Orthosis (KAFO) -Long leg orthosis that spans the knee, ankle, and foot to stabilize the involved joints and assist the muscles of the lower extremity

Foot drop –Weakness and/or lack of use of the muscles that dorsiflex the ankle, but there is the ability to bring the ankle to zero (0) degrees by passive range of motion.

INDICATIONS/CRITERIA:

A. AFOs NOT USED DURING AMBULATION:

Prefabricated or custom fitted static or dynamic positioning ankle-foot orthosis (L4396 or L4397 and replacement interface (L4392) is medically necessary if either all of criteria 1 - 6 or criterion 7 is met:

1. Plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture)
2. The pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record
3. Reasonable expectation of the ability to correct the contracture; and,
4. Contracture is interfering or expected to interfere significantly with the member's functional abilities
5. Used as a component of a therapy program, this includes active stretching of the involved muscles and/or tendons
6. There must be documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home)
7. The member has plantar fasciitis

The following devices are not considered medically necessary:

1. Static or dynamic positioning ankle-foot orthosis due to lack of established efficacy for the following conditions:
 - a. Fixed plantar flexion contracture of the ankle
 - b. Foot drop without an ankle flexion contracture
2. A component of a static/dynamic AFO that is used to address positioning of the knee or hip, due to lack of established efficacy
3. Replacement interfaces (L4392) in excess of one per six months
4. Foot drop splint/recumbent positioning device (L4398) or replacement interface (L4394) in a member with foot drop who is non-ambulatory, because there are other more appropriate treatment modalities

B. DEVICES (ORTHOTICS, AFO AND KAFO) USED DURING AMBULATION:

Orthotics:

Foot insert removable, molded to patient model, (L3000), Berkeley shell, is medically necessary if one of the following criteria is met:

1. Required to prevent or correct pronation
2. Required to promote proper foot alignment due to pronation
3. For ankle stability as required due to an existing medical condition such as hypotonia, Cerebral Palsy, etc.
4. For treatment of Hallux Valgus (Bunions)

Foot insert, removable, formed to patient foot (L3030) is medically necessary if one of the following criteria is met:

1. Severe arthritis with pain
2. Flat feet or pes planus with pain
3. Valgus or Varus deformity with pain
4. Plantar fasciitis with pain
5. Pronation

Ankle-foot orthoses (AFO) described by codes L1900, L1902-L1990, L2106-L2116, L4350, L4360, L4361, L4386, L4387 and L4631 are medically necessary for ambulatory members with weakness or deformity of the foot and ankle, who meet all the following criteria:

1. Require stabilization for medical reasons
2. Have the potential to benefit functionally

Knee-ankle-foot orthoses (KAFO) described by codes L2000-L2038, L2126-L2136, and L4370 are medically necessary for ambulatory members who meet criteria for an ankle-foot orthosis and for whom additional knee stability is required.

Custom-fabricated AFOs and KAFOs are medically necessary for ambulatory members when the appropriate criteria listed above for either AFO or KAFO and one of the following criteria are met:

1. The member could not be fit with a prefabricated AFO or KAFO; or,
2. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or,
3. There is a need to control the knee, ankle or foot in more than one plane; or,
4. The member has a documented neurological, circulatory, or orthopedic status that requires custom fabricating to prevent tissue injury; or,
5. The member has a healing fracture which lacks normal anatomical integrity or anthropometric proportions

Concentric adjustable torsion style mechanisms require different CPT codes depending on presence or absence of a joint contracture:

1. Coded as L2999 and medically necessary when used to assist knee or ankle joint extension members who require joint extension assist in the absence of any co-existing joint contracture
2. Coded as E1810 for knee and E1815 for ankle and medically necessary when used for the treatment of contractures

The following devices are not considered medically necessary:

1. Custom fabricated orthosis provided without both basic coverage criteria and the additional criteria 1-5 for a custom fabricated orthosis being met
2. L coded additions to AFOs and KAFOs (L2180-L2550, L2750-L2768, L2780-L2830) are not medically necessary if either the base orthosis is not medically necessary, or the specific addition is not medically necessary

Replacements:

Replacement of durable components is expected to occur no more than once every 12 months. Replacement of soft interface components can be provided every 6 months, without regard to whether the original item is worn out.

SPECIAL CONSIDERATIONS FOR CHILDREN:

Orthotics, Ankle Foot Orthoses, and Knee Ankle Foot Orthoses

The coverage of Orthoses requires accommodation for rapid growth of the patient, particularly under the age of 5, for example:

1. Bilateral Ponseti braces (AFOs) are expected to be replaced every 3 months in the first year and every 4-6 months in the second through fourth years of treatment of congenital clubfoot (talipes equinovarus). Detailed on the following reference:
http://globalhelp.org/publications/books/help_cfponseti.pdf
2. Other Orthotics, AFOs or KAFOs might need to be replaced more frequently than once every 12 months for a child who is demonstrating rapid growth.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

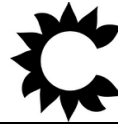
| PRODUCT LINE | LINK TO CERTIFICATE OF COVERAGE |
|-------------------------|---|
| MEDICARE ADVANTAGE | http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides |
| WASHINGTON APPLE HEALTH | http://chpw.org/our-plans/apple-health/ |
| INTEGRATED MANAGED CARE | http://chpw.org/our-plans/apple-health/ |

Citations & References

| | | |
|--------------------|--|--|
| CFR | | |
| WAC | WAC 182- 543-1000 | |
| RCW | | |
| Contract Citation | <input checked="" type="checkbox"/> WAH | 1.55 Durable Medical Equipment |
| | <input checked="" type="checkbox"/> FIMC | |
| | <input checked="" type="checkbox"/> MA | Local Coverage Determination (LCD): Ankle-Foot/Knee-Ankle-Foot ORTHOSIS (L33686) Local Coverage Determination (LCD): ORTHOPEDIC FOOTWEAR (L33641) |
| Other Requirements | | |
| NCQA Elements | | |

Revision History

| Revision Date | Revision Description | Revision Made By |
|---------------|---|-------------------|
| 10/16/2017 | Policy Creation | LuAnn Chen, MD |
| 10/18/2017 | Approval | MMLT |
| 03/27/2018 | Changed from UM432 to MM158 | Cindy Bush |
| 09/06/2018 | Clarified that there is no restriction based on age. Added HCA criteria for custom orthotics | LuAnn Chen, MD |
| 10/12/18 | Added definitions and updated formatting | Yves Houghton, RN |
| 10/18/2018 | Approval | UM Subcommittee |



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|------------|---|-------------------------|
| 09/03/2019 | Changed name of policy to include orthotics. Grammatical edits. Clarified that this policy applies to AH and MA members and that there are no restrictions based on age. Edited required documentation. Established medical necessity criteria and removed most references to coverage. Added LCD links under Contract Citations. | LuAnn Chen, MD |
| 09/06/2019 | Approval | UM Medical Subcommittee |