



Medicare Part C Medical Coverage Policy

Orthotics: Ankle -Foot (AFO) and Knee-Ankle-Foot (KAFO) Orthoses

Origination: July 9, 2014

Review Date: August 16, 2023

Next Review: August 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services.******

DESCRIPTION OF PROCEDURE or SERVICE: An orthotic is a rigid or semi-rigid orthopedic appliance or device used to support, align, prevent, or correct deformities, protect body function, improve the function of movable body parts or to assist a dysfunctional joint. Orthotics may redirect, restrict, or prevent motion of an impaired body part. An orthotic must be used for therapeutic support, protection, restoration, or function of an impaired body part and be used in the treatment of an illness or injury.

Definitions:

Brace is a rigid and semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a disease or injured part of the body. Elastic devices, stockings, garter belts and other similar devices are not within the scope of a brace. An orthosis can be classified as either prefabricated (off-the-shelf or custom fitted) or custom-fabricated.

Off The Shelf (OTS) Orthotics: Prefabricated orthosis that may or may not be supplied as a kit and requires some assembly. OTS requires "Minimal Self Adjustment" for fitting. The item does not require trimming, bending, molding, assembling, or customizing to fit an individual by a certified orthotist or an individual with specialized training.

Custom-fitted Orthotic: This is a prefabricated device which is made for a specific member and involves cutting, bending, molding, or other mechanism which customizes the device to meet the member's specific needs. Custom devices require "substantial modification" at the time of delivery by a certified orthotist or individual with specialized training to obtain an individualized fit.

Custom-fabricated Orthosis: This is a device that is made for a specific member starting with basic materials including, but not limited to, plastic, metal, leather, or cloth. It can involve making an impression of a specific part of the body, obtaining detailed measurements of the member's torso, or creating a digital image of the member's torso

to create a positive model for the device. The orthosis is then individually fabricated and molded over the positive model.

Certified Orthotist: This is an individual who is certified by the American Board of Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

An individual who has specialized training may include an OT, PT, or other licensed person who can order orthotics and fit the orthotic within their regulated scope of practice.

Kits: A collection of components, materials and parts that require further assembly before the delivery of the final product.

Ankle flexion contracture: a condition in which there is shortening of the muscles and/or tendons that plantarflex the ankle with the inability to bring the ankle to zero (0) degrees by passive range of motion.

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

Plantar fasciitis: inflammation of the heel of the foot typically resulting from trauma to the deep tissue of the foot.

Mechanical Stretch Devices

1. Low loaded prolonged stretch devices (LLPS) are set to a level of tension by incorporating springs and permit resisted active and passive motion with a limited range.
 - a. Dynamic (spring loaded) splinting is a form of mechanical stretching that provides a constant low intensity force to the tissues and provides resistive and active motion with elastic traction within a prescribed range. These are sometimes used post operatively. Generally, these are used for the treatment of joint stiffness due to trauma and neurological disorders. Request may be for devices such as the Dynasplint, Ultraflex, Pro-glide or Advance Dynamic ROM. This type of device is generally used in the knee, elbow, wrist, or finger.
 - b. Static progressive stretch (Splinting) these are used to permanently lengthen shortened connective tissue. The patient can increase stretch in degrees, 3 to 4 times per day. (Includes Joint Active Systems (JAS) for the elbow, shoulder, ankle, knee, and wrist.)
2. Patient-actuated serial stretch (PASS) devices provide low to high level load to the joint using pneumatic or hydraulic systems that can be adjusted by the member multiple times as prescribed during the day.

POLICY STATEMENT

Coverage will be provided for Orthotics when it is determined to be medically necessary when the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

- A. Preauthorization by the Plan is required for any orthotic over \$1200.00;
- B. All orthotic devices should meet the following **general** criteria: **(1 or 2 and 3)**
 1. The support device (rigid or semi-rigid) must be for the treatment of an illness or injury, weak or deformed body member to improve the functioning of a malfunctioned body member; **OR**
 2. To restrict and eliminate motion in a diseased or injured body part; **and**
 3. Devices must be prescribed by a contracting Physician (applies to HMO members only);

AND

- C. Devices must meet the following criteria as given per Category:
 1. Spring-loaded orthotic devices and Static progressive stretch devices are covered if:
 - a. A member has failed conventional methods for restoring joint motion, such as exercise and physical therapy.
 2. Custom ankle-foot orthoses (AFO)/knee-ankle-foot orthoses (KAFO)
The member must meet the following medically necessary criteria:
 - A. **AFOs Not Used During Ambulation:**

- a. Static or dynamic (L4396, L4397) positioning AFO are covered if either all of i-iv **or** criterion v is met:
 - i. Plantar flexion contracture of the ankle with dorsiflexion on passive ROM testing of at least 10 degrees (pre-treatment passive ROM must be measured with a goniometer and documented in the medical record and there must be documentation of an appropriate stretching program carried out by professional staff or a caregiver); **AND**
 - ii. Reasonable expectation of the ability to correct the contracture **AND**
 - iii. The contracture is interfering or expected to interfere significantly with the member's functional abilities; **AND**
 - iv. Used as a component of a therapy program which includes active stretching of the involved muscles and/ or tendons **OR**
 - v. The member has plantar fasciitis.

- B. AFOs/KAFOs Used During Ambulation (L1900, L1902-L1990, L2106-L2116, L4350, L4360-L4361, L4386, L4387, L4631):**
 - a. Covered for ambulatory members with weakness or deformity of the foot and ankle, who:
 - i. Require stabilization for medical reasons, and
 - ii. Have the potential to benefit functionally.
 - b. KAFOs (L2000-L2038, L2126-L2136, L4370) are covered for ambulatory members for whom an AKO is covered (item A) **and** for whom additional knee stability is required.
 - c. AFOs **AND** KAFOs that are custom-fabricated are covered for ambulatory members when the coverage above (item a. and b.) is met, **and** ONE of the following criteria is met:
 - i. The member could not be fit with a prefabricated AFO; **or**
 - ii. The condition necessitating the orthosis is expected to be permanent (>6 months); **or**
 - iii. The ankle, knee or foot needs to be controlled in more than one plane; **or**
 - iv. The member has documented neurological, circulatory, or orthopedic compromise and customization is needed to prevent tissue damage; **or**
 - v. A healing fracture is not in normal anatomical position; **or**
 - vi. The concentric adjustable torsion mechanism (L2999) is covered to assist knee joint extension, and ankle joint plantar flexion or dorsiflexion **ONLY** in the absence of co-existing joint contracture.

WHEN COVERAGE WILL NOT BE APPROVED

If the criteria does not meet the guidelines as stated above.

- A static/dynamic AFO (L4396, L4397) and replacement interface(L4392) are not covered when used solely for the prevention or treatment of a heel pressure ulcer as they do not meet the definition of a brace.
- A foot drop splint/recumbent positioning device (L4398) and replacement interface (L4394) are not covered when used solely for the prevention or treatment of a pressure ulcer as they do not meet the definition. A foot drop splint/recumbent positioning device and replacement interface will be denied as not reasonable and necessary in a beneficiary with foot drop who is non-ambulatory because there are other more appropriate treatment modalities.
- A foot pressure off-loading/supportive device (A9283) and/or an inversion/eversion correction device (A9285) is not covered as it does not support a weak or deformed body member or restrict/eliminate motion in a diseased or injured body part (it does not meet the definition of a brace).
- Socks (L2840, L2850) used in conjunction with orthoses are not covered.
- Upgraded splints or orthotics for features beyond what is required for management of the patient's current medical condition.
- Over the counter support devices.
- Elastic support garments (e.g. made of material such as neoprene or spandex) do not meet the statutory definition of brace because they are not rigid or semi-rigid.
- **PASS** devices as described above, are not considered CPM devices, but are considered "exercise equipment" and are not covered.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: (Codes are too numerous to document)

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES:

Replacement for a customized orthotic is covered if the device is loose or irreparably damaged. Repairs are covered, if necessary, to make the orthotic functional. If the repair cost is more than the cost of replacement, then any excess amount is non-covered.

Concentric adjustable torsion style mechanisms (E1810 and/or E1815) used for the treatment of contractures, regardless of any co-existing condition(s) are covered.

References:

1. Medicare National Coverage Determinations Manual; Chapter 1, Part 4 section 280.1, viewed online at www.cms.gov; viewed on 07/20/23.
2. CGS: Local Coverage Determination: L33686; Ankle-Foot/ Knee Ankle-Foot Orthosis; Original Effective Date 10/1/2015. Also see related article; A52457; Viewed on 07/20/23, online at <http://www.cgsmedicare.com/jc/index.html>
3. CGS DME MAC; March 27, 2014, Correct Coding- Definitions Used for Off the Shelf versus Custom Fitted Prefabricated; Orthotics (Braces) Revised; viewed online at [Definitions Used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics \(Braces\) – Correct Coding - Revised \(cgsmedicare.com\)](http://www.cgsmedicare.com/jc/pubs/news/2020/10/cope19279.html); Viewed on 07/20/23.
4. CGS online update; "Ankle-Foot Orthoses-Walking Boots-Coverage and Coding Issues- Revised; Effective Date is August 1, 2014; viewed online at <https://cgsmedicare.com/jc/pubs/news/2020/10/cope19279.html>; Viewed on 07/20/23.
5. MLN Matters MM8531; CR 8531; see "Off the Shelf Orthotics" viewed online at www.cms.gov on 07/20/23.
6. Medicare Benefit Policy Manual Chapter 15 Section 130 viewed online at www.cms.gov; viewed on 07/20/23.

Policy Implementation/Update Information:

Origination Date: July, 2014; New Policy implemented due to updated LCDs and for staff clarity.

Revision Date: August 19, 2015; created a separate medical policy for Spinal Orthosis for clarification and ease of review for staff.

NOTE: This policy replaced the original Medical Coverage Policy: Orthotics created 7/2014.

Revision Date: October 21, 2015; minor revision to Indications For Coverage - removed reference to devices not to exceed 3 month rental based on no limitation noted in LCD; minor formatting updates.

Revision Date: August 23, 2017; No CMS Updates. Minor Revisions Only.

Revision Date: August 21, 2019; No CMS Updates. Minor Revisions Only.

Revision Date: April 22, 2020; Threshold increase for DME that requires PA, \$600 increased to \$1200.

Revision Date: August 18, 2021; Annual Review; No CMS Updates. Minor Revisions only.

Revision Date: August 16, 2023; Annual Review; No CMS Updates. Verbiage added to reflect LCD. Minor Revisions only.

Approval Dates:

Medical Coverage Policy Committee: August 16, 2023

Policy Owner: Beth Sell, BSN, RN, CCM, CPC-A
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