



Medicare Part C Medical Coverage Policy

Orthotics: Knee Orthoses

Origination: July 9, 2014
Review Date: November 18, 2020
Next Review: November, 2022

******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: 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.

Certified Orthotist: 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.

Custom-fabricated Orthosis: 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.

Custom-fitted Orthotics: 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.

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

Knee extension contracture: Condition in which there is shortening of the muscles and/or tendons with the inability to bring the knee to eighty (80) degrees flexion or greater by passive range of motion.

Knee flexion contraction: Condition in which there is shortening of the muscles and/or tendons with the inability to bring the knee to zero (0) degrees extension or greater (i.e. hyperextension) by passive range of motion.

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) is 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 patient multiple times as prescribed during the day.

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.

POLICY STATEMENT

Coverage will be provided for Orthotics 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 decisions;
- 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)**

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

C. For Prefabricated Knee Orthoses (L1810, L1812, L1820, L1830-

L1833, L1836, L1843, L1845, L1847, L1848, L1850, L1851, L1852):

- a. Knee orthosis with joints, knee orthosis with condylar pads and joints with or without patellar control are covered when there is:
 - i. Documentation of weakness or deformity of the knee needing stabilization.
- b. Knee orthosis with locking knee joint or a rigid knee orthosis is covered for the following:
 - ii. Flexion or extension contractures of the knee with movement on passive range of motion of at least 10 degrees (i.e., a nonfixed contracture).
- c. Knee immobilizer without joints, a knee orthosis with adjustable knee joints, or a knee orthosis with an adjustable flexion and extension joint that provides both medial-lateral and rotation control is covered for the following:

- iii. Recent injury to or a surgical procedure on the knee(s).
 - d. Knee orthoses are covered for members who are ambulatory and has knee instability.
 - e. Knee orthosis, Swedish type, prefabricated is covered for members who are ambulatory and has knee instability due to genu recurvatum (hyperextended knee).
- D. For Custom Fabricated Knee Orthoses (L1834, L1840, L1844, L1846, L1860):**
- a. Covered when there is documentation of the need for customization or what the substantial modification adjustments are and why they were needed. Examples include but are not limited to:
 - 1. The member has a deformity of the leg or knee; **OR**
 - 2. The size of the calf or thigh requires customization; **OR**
 - 3. There is minimal muscle mass to suspend the orthosis.
 - b. For a custom fabricated knee immobilizer with or without adjustable flexion and extension joint is covered if 1 **and** 2 are met:
 - 1. The criteria for the prefabricated orthosis are met; **and**
 - 2. The criterion for custom fabricated orthosis is met.
 - c. A custom fabricated derotation knee orthosis is covered for instability due to internal ligamentous disruption of the knee.
 - d. Custom fabricated knee orthosis with a modified supracondylar prosthetic socket is covered for members who are ambulatory and have knee instability due to genu recurvatum(hyperextended knee).

WHEN COVERAGE WILL NOT BE APPROVED

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

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.

Custom fabricated knee orthosis are not reasonable and necessary in the treatment of knee contractures in cases where the member is nonambulatory.

PASS devices as described above, are not considered CPM devices, are considered "exercise equipment" and 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:

Heavy duty knee joint codes (L2385, L2395) are covered for member who weigh >300 pounds.

Concentric adjustable torsion style mechanisms used to assist knee joint extension (L2999) are covered for members **ONLY** when requiring knee extension assist in the absence of any co-existing joint contracture.

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.

References:

1. National Coverage Determination; Chapter 1, Part 4, viewed online at www.cms.gov; viewed on 11/5/2020.
2. Medicare Local Coverage Determination for Knee Orthoses – CGS Administrators (L33318); Effective date 10/01/2015; Accessed via <http://www.cgsmedicare.com/jc/index.html> 11/5/2020.
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 <https://cgsmedicare.com/jc/pubs/news/2019/07/cope13077.html> Viewed on 11/5/2020.
4. CGS online update; "Ankle-Foot Orthoses-Walking Boots-Coverage and Coding Issues- Revised; Effective Date is August 1, 2014; viewed online at <http://www.cgsmedicare.com/jc/index.html>; Viewed on 11/5/2020.
5. MLN Matters MM8531; CR 8531; see "Off the Shelf Orthotics" viewed online at www.cms.gov on 11/5/2020.

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 replaces the original Medical Coverage Policy: Orthotics created 7/2014. October 29, 2015 updated LCD due to ICD-10 update only.

Revision Date: August 23, 2017; No CMS updates. Minor Revisions only.

Revision Date: November 20, 2018: Alphabetized the Definition list, Indications for Coverage: Removed Section B. #3, and Section C: Removed Codes K0901, K0902 and added L1851, L1852.

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

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Revision Date: November 18, 2020; Annual Review; No CMS Updates. Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee: November 18, 2020

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator