



Medicare Part C Medical Coverage Policy

Orthotics: Lumbar Sacral Orthoses (LSO) and Thoracic Lumbar Sacral Orthoses (TLSO)

Origination: July 9, 2014

Review Date: August 18, 2021

Next Review: August, 2023

******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 diseased 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.

Lumbar Sacral Orthoses (LSO):

Designed to control gross movement of the trunk and motion of the vertebrae in one or more planes of motion, lateral/flexion, anterior flexion/posterior flexion, or axial rotation.

Thoracic Lumbar Sacral Orthoses (TLSO):

The posterior portion of the brace extends from the sacrococcygeal junction to just inferior to the scapular spine. The anterior portion of the orthosis at a minimum extends from the symphysis pubis to the xiphoid. These devices do not include elastic or equal shoulder straps or other strapping methods.

Off The Shelf (OTS) Orthotics: Prefabricated orthoses that may or may not be supplied as a kit and requires some assembly. OTS items require 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 Orthotics: 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 Orthotics: 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 are: A collection of components, materials and parts that require further assembly before the delivery of the final product.

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 have to be prescribed by a contracting Physician (applies to HMO members only);

AND

C. Spinal Orthoses must meet the following criteria:

1. A spinal orthosis (LSO or TLSO) is covered when medical necessity is met by one of the following::
 - a. To reduce pain by restricting mobility of the trunk; **or**
 - b. To facilitate healing following an injury to the spine or related soft tissues; **or**
 - c. To facilitate healing following a surgical procedure on the spine or related soft tissue; **or**
 - d. To support weak spinal muscles and/or a deformed spine.
 - e. The record documents what was done to individually fit the member and why the cutting, bending, molding, etc. was medically indicated.

WHEN COVERAGE WILL NOT BE APPROVED

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

A protective body sock (L0984) does not meet the definition of a brace and is not covered.

Brace sleeves used in conjunction with orthosis are not covered as they are not used to support a weak or deformed body member or to restrict or eliminate motion in a disease or injured body part. (i.e., it does not meet the definition of a brace).

Elastic support garments (made of neoprene or spandex) are not covered as they do not meet the definition of a brace since they are not rigid or semi-rigid devices.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

Medical Coverage Policy: 4

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.

References:

1. National Coverage Determination; Chapter 1, Part 4, viewed online at www.cms.gov; viewed on 07/24/19.
2. Medicare Local Coverage Determination for Spinal Orthoses: TLSO and LSO – CGA Administrator (L33790); Effective date 10/01/2015; Accessed via <http://www.cgsmedicare.com/jc/index.html> on 8/4/21.
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 <http://www.cgsmedicare.com/jc/pubs/news/2014/0314/cope25125.html>; Viewed on 04/14/2014, 8/4/21.
4. MLN Matters MM8531; CR 8531; see “Off the Shelf Orthotics” viewed online at www.cms.gov on 8/4/21.
5. Local Coverage Article: TLSO and LSO - Policy Article A52500- Effective Date 10/1/2015. Viewed online at www.cms.gov on 8/4/21.

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: 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.

Approval Dates:

Medical Coverage Policy Committee: August 18, 2021

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