

Medical Policy



Blue Cross
Blue Shield
Blue Care Network
of Michigan

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of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Orthotic Devices

Description/Background

Orthotics are rigid or semi-rigid appliances used for the purpose of supporting or correcting a weak or deformed body part. They are also designed for restricting or eliminating motion in a diseased or injured part of the body.

An orthosis may be either prefabricated or custom fabricated. A prefabricated orthosis (off-the-shelf) is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (ie, custom fitted).

A custom fabricated orthosis (custom-made) is one that is designed for a specific individual. It may be required for fitting of an abnormal limb, contour, knee deformity or an unusual size. A custom orthosis may be necessary when a prefabricated orthosis cannot be adequately adjusted for the individual.

Regulatory Status

N/A

Medical Policy Statement

The safety and effectiveness of orthotics that are used to protect, restore, or improve all or part of an impaired body function, (eg braces, collars or supports) have been established.

Inclusionary and Exclusionary Guidelines

Guidelines are generally based on Medicare Part B and Blue Cross/Blue Care Network certificate language. Specific certificate language may vary.

The orthotic device must:

- Be prescribed by a qualified healthcare provider
- Meet the Medicare/CMS definition of an orthotic (essentially, that it is a rigid or semi-rigid appliance, often referred to as a brace, used for the purpose of supporting or correcting a weak or deformed body part).

Inclusions:

Orthotic devices may include, but are not limited to:

- Splints for spine, neck and shoulders
- Ankle-foot orthoses (AFO) and knee-ankle-foot orthoses (KAFO) for extremities
- Shoes designed for attachment to medically appropriate leg braces*
- Substitution of a somewhat different device required by change in medical condition, fit or function
- Cervical spine orthosis
- Cervical-Thoracic-Lumbar-Sacral orthosis
- Thoracic-Lumbar-Sacral orthosis (TLSO)
- Lumbar orthosis
- Lumbar-sacral orthosis (LSO)
- Sacroiliac orthosis

Exclusions:

Excluded orthotic devices and related services include, but are not limited to:

- Arch supports or supportive devices for the feet
- Dental appliances and bite splints
- Investigational, experimental or research devices or appliances
- Items excluded in individual certificates or riders
- Orthopedic or corrective shoes (except when either one or both are an integral part of a leg brace)*
- Orthotic devices used for participating in strenuous physical activity beyond normal activities of daily living
- Repair and replacement made necessary because of loss or damage caused by misuse or mistreatment
- Any item that is primarily made of elastic material, including, but not limited to:
 - Thoracic rib belt
 - Knee or knee cap orthosis, elastic, with or without stays or condylar pads, prefabricated
 - Ankle orthosis, elastic, prefabricated
 - Shoulder orthosis, elastic, prefabricated
 - Elbow orthosis, elastic, with or without stays, prefabricated
 - Wrist, hand or finger orthosis, elastic, prefabricated

*BCN Only. For Blue Cross members, see BCBSM policy *Orthopedic Footwear*.

Specific riders may apply and override exclusions.

Note: Check individual contract/certificate language regarding repair, replacement or adjustment of medically appropriate devices that is necessitated by wear, damage or medical condition changes.

While traveling: Orthotic devices are covered when the individual is traveling or staying at another location for a specified period of time. Check individual contract/certificate language, and any specific medical policy related to the item. Repair, replacement or adjustment are also covered as defined by the contract/certificate language and the applicable medical policy.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

Multiple codes: orthotics code range

K1015*

* Check member benefit. Certificate / benefit language may exclude coverage for this item.

Other codes (investigational, not medically necessary, etc.):

Multiple

Rationale

Current medical literature has demonstrated that the use of orthotic devices to restore or improve an impaired body function is both safe and effective. Effective April 01, 2009, CMS determined that elastic garments do not meet the statutory definition of a brace because they are not rigid or semi-rigid devices and therefore are not covered.

Government Regulations

National:

There is no national coverage determination (NCD) on this topic.

100-02 Medicare Benefit Policy Manual

Chapter 15 - Covered Medical and Other Health Services (Rev. 12532; Issued: 03-07-24)

130 Leg, Arm, Back and Neck Braces, Trusses and Artificial Legs, Arms and Eyes

(Rev 1, 10-01-03)

These appliances are covered under Part B when furnished incident to physicians' services or on a physician's order. A brace includes rigid and semi-rigid devices which are 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 stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Back braces include, but are not limited to, special corsets, e.g., sacroiliac, sacrolumbar, dorsolumbar corsets, and belts. A terminal device (e.g., hand or hook) is covered under this provision whether an artificial limb is required

by the patient. Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Adjustments to an artificial limb or other appliance required by wear or by a change in the patient's condition are covered when ordered by a physician.

Adjustments, repairs and replacements are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

140 - Therapeutic Shoes for Individuals with Diabetes

(Rev. 241, Issued: 02-02-18, Effective: 04-01-18, Implementation: 04-02-18)

Coverage of therapeutic shoes (depth or custom-molded) along with inserts for individuals with diabetes is available as of May 1, 1993. These diabetic shoes are covered if the requirements as specified in this section concerning certification and prescription are fulfilled. In addition, this benefit provides for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease. Each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected.

Therapeutic shoes for diabetics are not DME and are not considered DME nor orthotics, but a separate category of coverage under Medicare Part B.

[Refer to the full section for criteria related to the diabetic shoe benefit.]

Orthopedic shoes, as stated in the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices," generally are not covered. This exclusion does not apply to orthopedic shoes that are an integral part of a leg brace. In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately. Thus, the diabetic shoes may be covered if the requirements for this section are met, while the brace may be covered if the requirements of §130 are met.

Local:

Refer to CGS Administrators, LLC, JB DME, for the most current local coverage determinations and articles.

Ankle-Foot/Knee-Ankle-Foot Orthoses (L33686); original effective date for services performed on or after 10/01/15, revision effective date for services performed on or after 01/23/2024.

Ankle-Foot/Knee-Ankle-Foot Orthoses – Policy Article (A52457); original effective date 10/01/15, revision effective date 01/23/24.

Knee Orthoses (L33318); original effective date for services performed on or after 10/01/2015, revision effective date for services performed on or after 01/01/2020.

Knee Orthoses - Policy Article (A52465); original article effective date 10/01/2015, revision effective date 01/23/2024.

Orthopedic Footwear (L33641); original effective date for services performed on or after 10/01/15, revision effective date for services performed on or after 01/01/2020.

Orthopedic Footwear (A52481): original effective date 10/01/15, revision effective date 11/01/23.

Spinal Orthoses: TLSO and LSO (L33790): original effective date for services performed on or after 10/01/15, revision effective date for services performed on or after 01/01/2020.

Spinal Orthoses: TLSO and LSO - Policy Article (A52500): original effective date 10/01/15, revision effective date 01/23/2024.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Durable Medical Equipment
- Durable Medical Equipment, Prosthetics and Orthotics While Traveling (BCN Only)
- Orthopedic Footwear (BCBSM Only)
- Prosthetic Devices
- Therapeutic Shoes for Diabetics (BCBSM Only)
- Therapeutic Shoes for People with Diabetes (BCN Only - Retired)

References

1. CGS Administrators, LLC, Local Coverage Determination (LCD): Ankle-Foot/Knee-Foot Orthoses (L33686), original effective date 10/01/15, revision effective date 01/23/24.
2. CGS Administrators, LLC, Local Coverage Article: Ankle-Foot/Knee-Ankle-Foot Orthoses (A52457), original effective date 10/01/15, revision effective date 01/23/24.
3. CGS Administrators, LLC, Local Coverage Determination (LCD): Knee Orthoses (L33318), original effective date 10/01/15, revision effective date 1/1/20.
4. CGS Administrators, LLC, Local Coverage Article: Knee Orthoses (A52465), original date 10/01/15, revision effective date 01/23/2024.
5. CGS Administrators, LLC, Local Coverage Determination (LCD): Spinal Orthoses: TLSO and LSO (L33790), original effective date 10/01/15, revision effective date 1/1/20.
6. CGS Administrators, LLC, Local Coverage Article: Spinal Orthoses: TLSO and LSO (A52500), original effective date 10/01/15, revision effective date 01/23/2024.
7. CGS Administrators, LLC, Local Coverage Determination (LCD): Orthopedic Footwear (L33641), original effective date 10/01/15, revision effective date 1/1/20.
8. CGS Administrators, LLC, Local Coverage Article: Orthopedic Footwear (A52481), original effective date 10/01/15, revision effective date 11/01/23.
9. Centers for Medicare & Medicaid Services, Medicare Benefit Policy Manual 100-02, Chapter 15 – Covered Medical and Other Health Services, Section 130. Available online at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf> Accessed 5/22/24.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/22/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|------------------------------|-----------------------------|---------------------------|---|
| 6/13/02 | 6/13/02 | 6/13/02 | Joint policy established |
| 2/28/05 | 2/28/05 | 2/8/06 | Routine maintenance |
| 1/1/07 | 11/1/06 | 11/19/06 | Routine maintenance |
| 9/1/08 | 7/3/08 | 7/3/08 | Routine maintenance |
| 3/1/10 | 3/1/10 | 12/8/09 | Routine maintenance, added elastic garments to the exclusion list |
| 11/1/11 | 8/16/11 | 8/16/11 | Routine maintenance |
| 11/1/12 | 8/21/12 | 8/21/12 | Routine maintenance |
| 3/1/14 | 12/10/13 | 1/6/14 | Routine maintenance |
| 11/1/15 | 8/24/15 | 9/14/15 | Routine maintenance |
| 11/1/16 | 8/16/16 | 8/16/16 | <ul style="list-style-type: none"> • Routine maintenance • Moved codes L0450, L0454, L0621, L0625 & L0628 from investigational to established • Added LCD & LCA Orthopedic Footwear • Added * to Inclusion/Exclusion related to shoes as BCN Only. For BCBSM, refer to BCBSM Only policy <i>Orthopedic Footwear</i> |
| 11/1/17 | 8/15/17 | 8/15/17 | <ul style="list-style-type: none"> • Routine maintenance |
| 11/1/18 | 8/21/18 | 8/21/18 | Routine maintenance |
| 11/1/19 | 8/20/19 | | Routine maintenance |
| 11/1/20 | 8/18/20 | | Routine maintenance |
| 11/1/21 | 8/17/21 | | Routine maintenance. Streamlined inclusion language; added coverage while traveling Added code K1015 |
| 11/1/22 | 8/16/22 | | Routine maintenance (ls) |
| 11/1/23 | 8/15/23 | | Routine maintenance (jf) Vendor Managed: Northwood Removed reference 1 |
| 11/1/24 | 8/20/24 | | Routine maintenance (jf) Vendor Managed:NA |

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| | | | <ul style="list-style-type: none">• 2024 Code Update add L1320 as payable effective 4/1/24 (codes listed on this policy is within the multiple code range) |
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Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE

POLICY: ORTHOTIC DEVICES

I. Coverage Determination:

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| Commercial HMO (includes Self-Funded groups unless otherwise specified) | <p>Covered; policy and certificate guidelines apply.</p> <p>Spinal Garments:</p> <ul style="list-style-type: none"> ▪ Spinal garments made primarily of elastic material are not covered. ▪ Spinal garments made primarily of nonelastic material (eg, cotton or nylon) or have rigid posterior panels are covered. |
| BCNA (Medicare Advantage) | <p>Covered; policy and certificate guidelines apply.</p> <p>Spinal Garments:</p> <ul style="list-style-type: none"> ▪ Spinal garments made primarily of elastic material are not covered. ▪ Spinal garments made primarily of nonelastic material (eg, cotton or nylon) or have rigid posterior panels are covered. |
| BCN65 (Medicare Complementary) | <p>Coinsurance covered if primary Medicare covers the service.</p> |

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.