

Corporate Medical Policy

Orthotics

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Description of Procedure or Service

An orthotic (orthosis) is a rigid or semi-rigid orthopedic appliance or device that is used to support, align, prevent or correct deformities, protect a body function, improve the function of movable body parts or to assist a dysfunctional joint. Orthotics may also 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. Examples of orthotic devices include, but are not limited to the following:

- splints for extremities
- braces for leg, arm, neck, back, and shoulder
- trusses
- corsets for back problems or following a surgical procedure
- foot orthotics which are custom molded
- Patient-controlled serial stretch devices such as the ERMI Flexionater®, ERMI Extensionater®, the Elite Seat®
- Spring-loaded orthotic devices, also referred to as dynamic splinting systems and low-load prolonged-duration stretch, such as Dynasplint®, EMPI Advance®, LMB Proglide™, SaeboFlex™, and Ultraflex™
- Static progressive stretch devices or Joint Active Systems (JAS) Splints such as JAS Elbow, JAS Shoulder, JAS Ankle, JAS Toe, JAS Knee, JAS Wrist, and JAS Pronation-Supination

Related Policies

Chiropractic Services

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for an Orthotic device when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Some BCBSNC Plan Contracts specifically exclude Orthotic Devices from coverage.

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Some BCBSNC Plan Contracts have limitations on Foot Orthotics. Please refer to the member's benefit booklet for availability of benefits.

Please refer to the member's benefit booklet for "Professional Services", "Orthotic Devices", and "Durable Medical Equipment."

When Orthotics are covered

Orthotics are considered medically necessary when **both** of the following criteria are met:

1. The orthotic device is medically necessary to support or aid in the treatment of an illness or injury; and
2. It is prescribed by a qualified physician.

Spring-loaded orthotic devices are eligible for coverage when the patient is not responding favorably to conventional methods for restoring joint motion such as exercise and/or physical therapy.

Static progressive stretch devices are eligible for coverage when the patient is not responding favorably to conventional methods for restoring joint motion such as exercise and/or physical therapy.

Continued coverage for orthotic devices is eligible when significant measurable improvement in joint range of motion is being made while using the device, but not to exceed three months (see "When Not Covered" section below.)

All medically necessary supplies, adjustments, repairs or replacement of covered orthotic devices are eligible for coverage. Replacement of the orthotic is generally provided under the following conditions:

- after the device's normal life span; or
- following malfunction of the device; or
- for growth adjustments.

Custom Foot Orthotics are considered medically necessary when **all** of the following criteria are met:

1. the custom foot orthotics are prescribed by a qualified physician; and
2. the orthotic device is medically necessary to support or aid in the treatment of an illness of injury, as described below:
 - a. When there is a primary diagnosis of foot pain or a primary diagnosis of a foot condition (e.g., plantar fasciitis, pes planus, pes cavus) provided that:
 - i. Documented objective clinical findings clearly link the prescription of custom foot orthotics to the primary diagnosis and/or chief complaint;
AND
 - ii. The prescription of custom foot orthotics is consistent with the goals of the treatment plan.
 - b. In the absence of a primary diagnosis of foot pain or a foot condition as described above, custom foot orthotics may be medically necessary when provided concurrent with Chiropractic Manipulative Therapy, provided
 - i. Documented objective clinical findings clearly link the prescription of custom foot orthotics to the primary diagnosis and/or chief complaint;
AND

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- ii. The prescription of custom foot orthotics is consistent with the goals of the treatment plan.
3. The clinical record provides evidence the foot orthotics have been customized from a mold or scan of the patient's foot.
4. There is clear, clinical documentation indicating non-custom foot orthotics are not appropriate for the condition or injury.

Replacement of Custom Foot Orthotics

Medically necessary replacement of custom foot orthotics is generally provided under the following conditions:

- Following malfunction of the device; or
- after the device's normal life span, provided there are objective clinical findings clearly linking the replacement of custom foot orthotics to the patient's current primary diagnosis and/or chief complaint; or
- for growth adjustments, provided there are objective clinical findings clearly linking the replacement of custom foot orthotics to the patient's current primary diagnosis and/or chief complaint.

When Orthotics are not covered

Orthotics are considered to be **not medically necessary** under the following circumstances:

1. Orthotics that are not prescribed by a qualified physician are not covered.
2. Spring-loaded orthotics and static progressive stretch devices are not covered when conventional methods of treating a stiff or contracted joint have not been attempted.
3. Spring-loaded orthotics and static progressive stretch devices are not covered for longer than 3 months of use.
4. Upgraded splints or orthotics may not be medically necessary. (Upgrades include, but are not limited to: decorative items; functionality or features beyond what is required for management of the patient's current medical condition.)
5. Over the counter support devices are not eligible for coverage.
6. Elastic stockings and garter belts are not eligible for coverage.
7. Orthopedic shoes are not eligible for coverage unless one or both shoes are an integral part of a leg brace.
8. Orthotic devices are not covered for sport-related activities (example: a knee brace to prevent injury to the knees while playing football). However, an orthotic would be covered for the treatment of the initial, acute, sports-related injury.
9. Foot orthotics are considered not medically necessary when the criteria listed above have not been met.
10. Thoracic-lumbo-sacral orthotics incorporating pneumatic inflation are considered investigational.
11. Patient-controlled serial stretch devices, such as the ERMI Flexionater® and the ERMI Extensionater® are considered not medical necessary.

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12. Custom made orthotic devices are not medically necessary unless there is clinical documentation indicating that a non-custom made orthotic device is not appropriate for the condition or diagnosis.

Policy Guidelines

Some BCBSNC Plan contracts specifically exclude coverage for Orthotic Devices. Specific contracts must be reviewed before determining coverage eligibility.

For chiropractors who are specifically trained in the fitting and management of orthotics, the prescribing of foot orthotics is within their scope of practice.

Low-load Prolonged-duration Stretch/Spring-loaded Devices

Dynamic splinting systems or spring-loaded devices are designed to provide low-load prolonged stretch while patients are asleep or at rest. Dynamic splinting units (for both extension as well as flexion) are available for many joints, including elbow, wrist, fingers, knee, ankle and toes. These devices are being marketed as a treatment of joint stiffness due to immobilization or limited range of motion subsequent to fractures, dislocations, tendon and ligament repairs, joint arthroplasties, burns, arthritis, hemophilia, tendon releases, head trauma, spinal cord injuries, cerebral palsy (CP), multiple sclerosis, and other traumatic and non-traumatic disorders. Dynamic splinting is usually prescribed in the post-operative period for the prevention or treatment of motion stiffness/loss in the knee, elbow, wrist or finger. It is not generally used in other joints such as the hip, ankle or foot.

Patient-controlled Serial Stretch Devices

The shoulder flexionator (ERMI Shoulder Flexionator) is designed to isolate and treat decreased glenohumeral abduction and external rotation. The device is intended to address the needs of patients with excessive scar tissue. The knee/ankle flexionator (ERMI Knee/Ankle Flexionator) is a self-contained device that facilitates recovery from decreased range of motion of the knee and/or ankle joints. The knee flexionator is designed to address the needs of patients with arthrofibrosis (excessive scar tissue within and around a joint.)

Static Progressive Stretch Devices

JAS splints use static progressive stretch to permanently lengthen shortened connective tissues. Typically, the patient sets the device angle at the beginning of the session, and every several minutes the angle is increased. A typical session lasts 30 minutes, and sessions may be repeated up to 3 times per day. JAS systems are designed to simulate manual therapy.

Thoracic-lumbo-sacral Orthotics

The absence of controlled studies of thoracic-lumbo-sacral orthotics with pneumatics precludes any conclusions regarding effectiveness for the treatment of low back pain; the device is considered investigational.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: L3020, L3030, L0112-L4398, L4631, L5961 L3660, L3670, L3675, L0455, L0457, L0467, L0469, L0641, L0642, L0643, L0648, L0649, L0650, L0651, L1812, L1833, L1848, L1851, L1852, L3678, L3761, L3809, L3916, L3918, L3924, L3930, L4361, L4387, L4397, E1800, E1801, E1802, E1805, E1806, E1810, E1811, E1812, E1815, E1816, E1818, E1821, E1825, E1830, E1831, E1840, E1841, 97760, 97762

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BCBSNC 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.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 11/30/96

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Advisory Panel - 9/2000

Medical Policy Advisory Group - 9/14/2000

BCBSA Medical Policy Reference Manual, 2/15/2002; 1.04.02

Specialty Matched Consultant Advisory Panel - 8/2002

BCBSA Medical Policy Reference Manual, 7/12/02; 1.03.01 and 7/12/02; 1.03.02

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.03, 11/8/12

Health Technology Inquiry Service (HTIS). Custom Foot Orthotics for Adults with Foot Conditions: A Review of the Clinical and Cost Effectiveness Health Technology Assessment (HTA). Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); June 21, 2012. Retrieved from <http://www.cadth.ca/media/pdf/htis/june-2012/RC0363%20Orthotics%20Final.pdf>

Food and Drug Administration (FDA) Clinical Trial #00220935. A randomized, controlled trial of treatment for disc herniation with radiating leg pain. Retrieved from <http://www.clinicaltrials.gov/ct/show/NCT00220935>

Duerinck S, Swinnen E, Beyl P, et al. The added value of an actuated ankle-foot orthosis to restore normal gait function in patients with spinal cord injury: A systematic review. J Rehabil Med. 2012;44(4):299-309. Retrieved from <http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-0958>

Larson D, Jerosch-Herold C. Clinical effectiveness of post-operative splinting after surgical release of Dupuytren's contracture: a systematic review. BMC Musculoskelet Disord. 2008 Jul 21;9:104. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2518149/>

Specialty Matched Consultant Advisory Panel review 2/2013

Medical Director review 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.03, 11/14/13

Papotto BA, Mills T. Treatment of severe flexion deficits following total knee arthroplasty: a randomized clinical trial. Orthop Nurs. 2012 Jan-Feb;31(1):29-34

Stephenson JJ, Quimbo RA, Gu T. Knee-attributable medical costs and risk of re-surgery among patients utilizing non-surgical treatment options for knee arthrofibrosis in a managed care population. Curr Med Res Opin. 2010 May;26(5):1109-18.

Specialty Matched Consultant Advisory Panel review 2/2014

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Medical Director review 3/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.05, 1/15/15

Specialty Matched Consultant Advisory Panel review 2/2015

Specialty Matched Consultant Advisory Panel review 2/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.05, 7/14/2016

Specialty Matched Consultant Advisory Panel review 2/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.05, 3/9/2017

Specialty Matched Consultant Advisory Panel review 2/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.05, 3/8/2018

Specialty Matched Consultant Advisory Panel review 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.05, 3/14/2019

Specialty Matched Consultant Advisory Panel review 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.05, 3/12/2020

Specialty Matched Consultant Advisory Panel review 2/2021

Policy Implementation/Update Information

6/90	Original Policy
8/99	Reformatted, Medical Term Definitions added.
12/99	Medical Policy Advisory Group
7/00	Information added regarding foot orthotics.
8/00	System coding changes.
9/00	Specialty Matched Consultant Advisory Panel review. Medical Policy Advisory Group review. Approved. No change in criteria. Typographical errors corrected. System coding changes.
01/01	Changed Date of Next Review to 9/2002
4/01	Added information indicating that the only foot orthotics covered are those which are made from corrected custom molds of the patient's feet.
1/02	Removed statement saying that arch supports are not covered. Coding changes.
2/02	Corrected implementation information for 1/02. Revised "When Orthotics are Covered" to state "the orthotic was prescribed by a qualified provider" Removed the following statement "the mold has had corrections made to it before the orthotic is fabricated to accommodate the condition being treated."

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- 5/02 Revised policy under when it is not covered to include thoracic-lumbo-sacral orthosis incorporating pneumatic inflation is investigational. Format changes. Codes E1800-E1840, K0112-K0116, L5999, L7499, and L8239 added to Billing and Coding section.
- 8/02 Specialty Matched Consultant Advisory Panel meeting 8/14/2002. No changes.
- 11/02 Policy revised to include covered and not covered indications for the Dynasplints/JAS Splints. Individual policy for Dynasplint will no longer be maintained. Added words to the Policy Key Word section.
- 12/02 Code E0830 added to Billing and Coding section. System coding changes.
- 9/03 Policy status changed to: "Active policy, no longer scheduled for routine literature review".
- 4/04 Benefits Application and Billing/Coding sections updated for consistency. Individual codes listed for code ranges E1800-E1840 and K0114-K0116 under Billing/Coding section. Added codes, K0628, K0629, K0630, K0631, K0632, K0633, K0634, K0635, K0636, K0637, K0638, K0639, K0640, K0641, K0642, K0643, K0644, K0645, K0646, K0647, K0648, and K0649 to policy.
- 8/12/04 Codes K0618 and K0619 added to Billing/Coding section.
- 2/3/05 First quarter 2005 HCPCS codes L1932, L2005, L2232, and L4002 added to Billing/Coding section in policy. Policy number added in key word section.
- 4/07/05 New HCPCS code S8434, effective 4/1/05, added to Billing/Coding section of policy.
- 5/19/05 Removed codes: K0114, K0115 and K0116 from Billing/Coding section due to deletion from HCPCS 2005.
- 4/10/06 Updated Billing/Coding section to reflect 2006 HCPCS code changes.
- 4/9/07 Statement added to When Orthotics are Covered section that reads: Continued coverage for spring-loaded orthotic devices is eligible when significant measurable improvement in joint range of motion is being made while using the device. Updated Billing/Coding section to reflect 2007 HCPCS codes changes. (adn)
- 6/22/10 Policy Number(s) removed (amw)
- 10/12/10 Added codes E1800, E1802, E1805, E1806, E1810, E1811, E1812, E1815, E1816, E1818, E1821, E1824, E1825, E1830, E1840, E1841 to Billing/Coding section. Added the following statements to the When not covered section: "Patient-actuated serial stretch (PASS) devices such as the ERMI Flexionater® or ERMI Extensionater® are considered not medically necessary. Custom made orthotic devices are not medically necessary unless there is clinical documentation indicating that a non-custom made orthotic device is not appropriate for the condition or diagnosis." Added the following statement to the Benefits Application section: "Please refer to the member's benefit booklet for "Professional Services", "Orthotic Devices", and "Durable Medical Equipment." (mco)
- 1/4/11 Added codes E1831, L5961 and L4631 to Billing/Coding section to reflect 2011 HCPCS code changes. L3672 and L3673 will no longer be valid HCPCS codes effective 1/01/11. (mco)

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- 5/24/11 Removed reference to “dynasplints” in policy. (btw)
- 10/25/11 Revised (i.e, JAS splints) to read (e.g., JAS splints) throughout the policy. Description section reformatted. Medical Director review 10/2011. (mco)
- 1/29/13 Policy returned to active status and will undergo scheduled review. References updated. No changes to Policy Statements. (mco)
- 5/14/13 Specialty Matched Consultant Advisory Panel review. Medical Director review. References updated. Policy Guidelines updated. Deleted code E1824 and added E1801 to Billing/Coding section. Removed references to JAS splints as spring-loaded devices. Added product information for Low-load Prolonged-duration Stretch/Spring-loaded Devices, Static Progressive Stretch Devices and Patient-actuated Serial Stretch (PASS) Devices in the Description section and the Policy Guidelines section. Added the following statements to the “When Covered” section: “Static progressive stretch devices are eligible for coverage when the patient is not responding favorably to conventional methods for restoring joint motion such as exercise and/or physical therapy. Continued coverage for orthotic devices is eligible when significant measurable improvement in joint range of motion is being made while using the device, but not to exceed three months (see “When Not Covered” section below.)” Revised the following statements to the “When not Covered” section: “2.Spring-loaded orthotics and static progressive stretch devices are not covered when conventional methods of treating a stiff or contracted joint have not been attempted. 3.Spring -loaded orthotics and static progressive stretch devices are not covered for longer than 3 months of use.” (mco)
- 5/28/13 Added CPT codes 97760 and 97762 to Billing/Coding section. (mco)
- 12/31/13 L0455, L0457, L0467, L0469, L0641, L0642, L0643, L0648, L0649, L0650, L0651, L1812, L1833, L1848, L3678, L3809, L3916, L3918, L3924, L3930, L4361, L4387, L4397 added to Billing/Coding section. (mco)
- 4/15/14 References updated. Specialty Matched Consultant Advisory Panel review 2/2014. Medical Director review 3/2014. (mco)
- 4/28/15 Reference added. Specialty Matched Consultant Advisory Panel review 2/25/2015. (sk)
- 4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)
- 9/30/16 Reference added. Patient-actuated serial stretch devices changed to patient-controlled serial stretch devices throughout document. (sk)
- 12/30/16 Codes L1851 and L1852 added to Billing/Coding section. (sk)
- 3/31/17 Specialty Matched Consultant Advisory Panel review 2/22/2017. (sk)
- 5/26/17 Reference added. (sk)
- 12/29/17 Code L3761 added to Billing/Coding section for effective date 1/1/2018. (sk)
- 4/27/18 Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)
- 8/24/18 Reference added. (sk)

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- 10/26/18 Related policy added. Clarification added to When Covered section regarding coverage and replacement of custom foot orthotics. L3020 and L3030 added to Billing/Coding section. (sk)
- 2/25/20 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)
- 2/9/21 References added. Specialty Matched Consultant Advisory Panel review 2/18/2020. (sk)
- 3/9/21 Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.