Anthem

Clinical UM Guideline

Subject: Custom-made Knee Braces
Guideline #: CG-OR-PR-03
Status: Reviewed
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Description

This document addresses the intended use of custom-made (that is, custom fabricated, custom molded) functional and unloader knee braces. This document does not address custom-fitted, prefabricated knee braces.

Note: Please refer to the following document for additional information concerning knee braces:

- CG-OR-PR-02 Prefabricated and Prophylactic Knee Braces

Clinical Indications

Medically Necessary:

A. Custom-made (custom fabricated, custom molded) unloader knee braces are considered**medically necessary** as an alternative to a prefabricated (custom-fitted) knee brace for the treatment of unicompartmental osteoarthritis with or without valgus/varus deformity, when **any** of the following criteria are met:
   1. Individual is a candidate for high tibial osteotomy or total knee arthroplasty (replacement) and may elect non-surgical treatment; **or**
   2. To predict the success of high tibial osteotomy versus total knee arthroplasty;**or**
   3. Individual has severe patellofemoral arthrosis in conjunction with medial or lateral compartment arthrosis.

B. Custom-made (custom fabricated, custom molded) functional knee braces may be**medically necessary** as an alternative to a prefabricated (custom-fitted) knee brace when the individual meets **any** of the following criteria, including but not limited to:
   1. Abnormal limb contour (disproportionate size of thigh and calf);**or**
   2. Knee deformity that interferes with fitting (valgus or varus limb);**or**
   3. Minimal muscle mass upon which to suspend an orthosis.

Not Medically Necessary:

Custom-made (custom molded, custom fabricated) knee braces, functional or unloader, are considered**not medically necessary** when the above criteria are not met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
L1834	Knee orthosis; without knee joint, rigid, custom fabricated
L1840	Knee orthosis; derotation, medial-lateral, anterior cruciate ligament, custom fabricated
L1844	Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment; custom fabricated
L1846	Knee orthosis; double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated
L1860	Knee orthosis; modification of supracondylar prosthetic socket, custom fabricated (SK)
L2861	Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each [when specified as knee]

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

***Note:** The code L1844 may be used either for a medically necessary custom-made unloader knee brace (only considered medically necessary in members with osteoarthritis) or it may be used to describe either a non-covered custom-made functional or rehabilitation (used in a postoperative setting) knee brace.

Discussion/General Information

Knee braces can be subdivided into four categories based on their intended use: prophylactic braces, rehabilitation braces, functional braces, and unloader knee braces. One category of braces, unloader knee braces, is specifically designed to provide pain relief in arthritic knees. Unloader knee braces, also referred to as off-loader knee braces, are typically custom-made (custom fabricated, custom molded) and are considered for individuals who are unable to be fitted with a prefabricated (off-the-shelf) knee brace.

The United States Food and Drug Administration (FDA, 2022) defines a brace as “device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement.” Knee braces are classified as a Class 1 device by the FDA and are exempt from a premarket notification application

(PMA) requirement prior to marketing any device.

Individuals with osteoarthritis of the knee with varus or valgus deformity often develop increased pain in the affected compartment due to increased mechanical loading. Unloader knee braces are designed and constructed to reduce the asymmetric loading in such knees. In order to decrease the weight on a painful knee joint, an unloader knee brace is designed to provide stability during activities of daily living. There is biomechanical data demonstrating reduction in adduction movement in varus knees when the appropriate unloader brace is used. In a systematic review of the literature, Raja and Dewan (2011) identified the existence of a number of high-quality clinical studies that recommend the use of an unloader knee brace as conservative management in the relief of signs and symptoms associated with medial compartment knee osteoarthritis.

Functional knee braces are defined as braces designed to assist or provide stability for the anterior cruciate ligament (ACL) or other ligament deficient knees, and provide protection for the ACL or other ligaments after knee repairs or reconstructions. Functional knee braces are worn throughout the day for unstable knees during activities of daily living or sports and may be either prefabricated (off-the-shelf) or custom-made. Derotation braces are typically used after injuries to ligaments and have medial and lateral bars with varying hinge and strap designs. These derotation braces are designed to permit significant motion and in many instances the braces are worn only during elective activities, such as sports. Braces made of graphite, titanium, or other lightweight materials are specifically designed for high-performance sports. Functional knee braces have also been used in individuals with osteoarthritis in order to decrease the weight on painful joints. Custom-made functional knee braces may be prescribed as an alternative to a prefabricated, custom-fitted knee brace when an individual has a deformity of the knee or leg that interferes with fitting, such as a disproportionate thigh and calf; or minimal muscle mass upon which to suspend an orthosis. Height (exceptionally tall or short stature) or weight (obesity) alone are insufficient reasons for a custom-made functional knee brace. These individuals can be fitted with a prefabricated (custom-fitted) knee brace with the following adjustments: extensions for an unusually tall person, a pediatric model for a person of short stature, or extra-large straps for an obese person.

Custom-made (custom molded, custom fabricated) unloader knee braces are fabricated specifically for an individual. These braces generally use basic materials, including, but not limited to, plastic, metal, leather, or cloth in the form of sheets or bars. Fabrication involves substantial work such as cutting, bending, molding, or sewing and may involve the incorporation of some prefabricated components. Constructing a custom-made knee brace involves much more work than a predominantly prefabricated item. A molded-to-member-model orthosis is a particular type of custom-made orthosis in which an impression of the specific body part is made by means of a plaster cast or computer aided design/computer aided manufacturing (CAD-CAM) technology. This impression is then used to make a positive model of plaster or other material of the body part. The orthosis is then molded on this positive model.

Definitions

Cartilage: A cellular tissue in adults that is specific to joints. A tough, fibrous material with high collagen content, such as found in the meniscus of the knee.

Instability: Looseness, unsteadiness, or an inability to withstand normal physiologic loading without mechanical deformation.

Knee brace: A limb orthosis or device intended for medical purposes that is worn on the lower extremity to support, to correct, or to prevent deformities, or to align body structures for functional improvement.

Ligament: A collagenous tissue that connects two bones to stabilize a joint.

Meniscus: A soft-tissue structure that lines some joints and provides load distribution, shock absorption, and lubrication.

Osteoarthritis (OA): A deterioration of the weight bearing surface distinguished by destruction of the hyaline cartilage and narrowing at the joint space.

Osteotomy: A surgical procedure in which bone is cut and realigned.

Unicompartmental osteoarthritis of the knee: A condition characterized by degenerative articular cartilage in the medial or lateral aspect of the tibiofemoral joint; may be associated with meniscal disruption, ligamentous instability, and malalignment.

Valgus deformity: Angulation of a distal bone away from the midline in relation to its proximal partner; also referred to as “bow-legged.”

Varus deformity: Angulation of a distal bone toward the midline in relation to its proximal partner; also referred to as “knock-kneed.”

References

Peer Reviewed Publications:

1. Beaudreuil J, Bendaya S, Faucher M, et al. Clinical practice guidelines for rest orthosis, knee sleeves, and unloading knee braces in knee osteoarthritis. Joint Bone Spine. 2009; 76(6):629-636.
2. Brouwer RW, van Raaij TM, Verharr JA, et al. Brace treatment for osteoarthritis of the knee: a prospective randomized multi-centre trial. Osteoarthritis Cartilage. 2006; 14(8):777-783.
3. Draper, ER, Cable, JM, Sanchez-Ballester, J, et al. Improvement in function after valgus bracing of the knee. An analysis of gait symmetry. J Bone Joint Surg Br. 2000; 82(7):10011005.
4. Duivenvoorden T, van Raaij TM, Horemans HL, et al. Do laterally wedged insoles or valgus braces unload the medial compartment of the knee in patients with osteoarthritis? Clin Orthop Relat Res. 2015; 473(1):265-274.
5. Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. J Knee Surg. 2002; 15(3):155-158, discussion 159.
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7. Paluska S, McKeag D. Knee braces: current evidence and clinical recommendations for their use. Am Fam Physician. 2000; 61(2):411-418, 423-424.
8. Petersen W, Ellermann A, Zantop T, et al. Biomechanical effect of unloader braces for medial osteoarthritis of the knee: a systematic review (CRD 42015026136). Arch Orthop Trauma Surg. 2016; 136(5):649-656.
9. Raja K, Dewan N. Efficacy of knee braces and foot orthoses in conservative management of knee osteoarthritis: a systematic review. Am J Phys Med Rehabil. 2011; 90(3):247-262.
10. Rannou F, Poiraudeau S, Beaudreuil J. Role of bracing in the management of knee osteoarthritis. Curr Opin Rheumatol. 2010; 22(2):218-222.
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12. Smith SD, Laprade RF, Jansson KS, et al. Functional bracing of ACL injuries: current state and future directions. Knee Surg Sports Traumatol Arthrosc. 2014; 22(5):1131-1141.
13. van Raaij TM, Reijman M, Brouwer RW, et al. Medial knee osteoarthritis treated by insoles or braces: a randomized trial. Clin Orthop Relat Res. 2010; 468(7):1926-1932.

14. Warden SJ, Hinman RS, Watson MA Jr, et al. Patellar taping and bracing for the treatment of chronic knee pain: a systematic review and meta-analysis. Arthritis Rheum. 2008; 59(1):73-83.
15. Wright, FW, Fetzer, GB. Bracing after ACL reconstruction: a systematic review. Clin Orthop Relat Res. 2007; 455:162-168.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Orthopaedic Surgeons (AAOS). Clinical Practice Guideline Management of osteoarthritis of the knee (non-arthroplasty). August 31, 2021. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf. Accessed on September 19, 2023.
2. Duivenvoorden T, Brouwer RW, van Raaij TM, et al. Braces and orthoses for treating osteoarthritis of the knee. Cochrane Database Syst Rev. 2015;(3):CD004020.
3. U.S. Food and Drug Administration (FDA). CFR - Code of Federal Regulations Title 21. Current as of June 2023. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=890.3475. Accessed on September 19, 2023.

Websites for Additional Information

1. National Institutes of Health (NIH): MedlinePlus. Knee braces-unloading. Updated on 07/28/2021. Available at: http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000372.htm. Accessed on September 19, 2022.

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History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information and References sections.
Reviewed	11/10/2022	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	11/11/2021	MPTAC review. Updated References section.
Reviewed	11/05/2020	MPTAC review. Updated Table 1 in Discussion/General Information section. Updated References section. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated References section.
Reviewed	01/24/2019	MPTAC review.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion/General Information, References, and Websites sections.
Reviewed	05/04/2017	MPTAC review. Updated References section.
Reviewed	05/05/2016	MPTAC review. Updated Description, Table 2 and References section. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Discussion/General Information, References and Websites sections.
Reviewed	05/15/2014	MPTAC review. Updated References section.
Reviewed	05/09/2013	MPTAC review. Updated Table 2, References and Index.
Reviewed	05/10/2012	MPTAC review. Updated Discussion, Product Table and References.
Reviewed	05/19/2011	MPTAC review. Updated Product Table, Definitions, Coding and References.
Reviewed	05/13/2010	MPTAC review. Updated Discussion and References.
	01/01/2010	Updated Coding section with 01/01/2010 HCPCS changes.
Reviewed	08/27/2009	MPTAC review. Updated Product Table and References.
Revised	08/28/2008	MPTAC review. Revised medically necessary Clinical Indications to address custom-made functional knee braces as an alternative to prefabricated knee braces when specific criteria are met. Clarified not medically necessary statement to include “functional or unloader” to describe the custom-made knee braces that are not medically necessary when criteria are not met. Updated Discussion, Coding and References.
New	05/15/2008	MPTAC review. Archived CG-DME-02, addressing custom-made knees braces as a separate and new clinical UM guideline. Clarified Clinical Indications. Revised the Discussion, Definitions (AAOS), and Index. References and Product Table updated.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/28/2005	DME.021	Knee Braces
WellPoint Health Networks, Inc.	09/23/2004	9.07.02	Knee Braces

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guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.