

Clinical UM Guideline

Subject: Prefabricated and Prophylactic Knee Braces
Guideline #: CG-OR-PR-02
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Description

This document addresses the intended use of prefabricated functional or rehabilitation knee braces and prophylactic knee braces.

Note: This document does not address the use of unloader knee braces. Please refer to the following document for additional information concerning knee braces:

- CG-OR-PR-03 Custom-made Knee Braces

Clinical Indications

Medically Necessary:

Prefabricated functional or rehabilitation knee braces are considered **medically necessary** for individuals when **any** of the following criteria are met:

1. Documented anterior or posterior cruciate ligament tears or functional instability episodes due to cruciate ligament insufficiency when non-surgical treatment is elected; **or**
2. Grade II or III medial collateral or lateral collateral ligament sprain to support ambulation when the use of a hinged brace allows for controlled joint motion; **or**
3. Posterior cruciate or posterior lateral reconstruction, including reconstruction after knee dislocation; **or**
4. Recent surgery for anterior cruciate ligament repair in the post-operative recovery phase; **or**
5. Recent surgery for meniscal cartilage repair in the post-operative recovery phase; **or**
6. Major ligament and bony reconstruction above the knee such as patella or quadriceps tendon repair, medial and lateral collateral ligament repair; **or**
7. Major fractures requiring early post-injury or post-operative motion such as patella fractures or tibial plateau fractures; **or**
8. Osteoarthritis of the knee (unicompartmental) who meet **any** of the following:
 - a. High tibial osteotomy or total knee arthroplasty (replacement) candidate that may elect non-surgical treatment; **or**
 - b. To predict the success of high tibial osteotomy versus total knee arthroplasty; **or**
 - c. Severe patellofemoral arthrosis in conjunction with medial or lateral compartment arthrosis.

Not Medically Necessary:

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Prefabricated functional or rehabilitation knee braces are considered **not medically necessary** for individuals who are status post knee surgery when the criteria are not met, including, but not limited to total knee arthroplasty (unless there is documented ligament insufficiency).

Prefabricated functional or rehabilitation knee braces are considered **not medically necessary** for non-surgical indications when the criteria are not met.

Prophylactic knee braces are considered **not medically necessary** for all indications.

Note: Individuals with height (tall or short stature) or weight (obesity) variations can be fitted with a prefabricated (custom-fitted) knee brace with **any** of the following adjustments:

- extra-large straps for an obese person
- a pediatric model for a person of short stature
- extensions for an unusually tall person

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 for functional or rehabilitation braces:

HCPCS

L1810	Knee orthosis, elastic with joints, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1812	Knee orthosis, elastic with joints, prefabricated, off-the-shelf
L1820	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1821	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf
L1830	Knee orthosis, immobilizer, canvas longitudinal, prefabricated, off-the-shelf
L1831	Knee orthosis, locking knee joint(s), positional orthosis, prefabricated, includes fitting and adjustment
L1832	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf

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L1836	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
L1843	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; prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1845	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; prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1847	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1848	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf
L1850	Knee orthosis, Swedish type, prefabricated, off-the-shelf
L1851	Knee orthosis (KO), 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, prefabricated, off-the-shelf
L1852	Knee orthosis (KO), 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, prefabricated, off-the-shelf

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met for functional or rehabilitation braces, or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Prefabricated knee braces, also known as off-the-shelf knee braces, are manufactured in standard sizes and require only minimal adjustments. These braces are custom-fitted to the extent that the individual is fitted to a limited selection of sizes (that is, small, medium, large, extra-large) and only require measurements and a sizing chart for fitting. A prefabricated knee brace may be modified by an individual with expertise with minimal adjustments that have been assembled, bent, trimmed, molded, or otherwise customized to fit the specific person. A custom-fitted, prefabricated knee brace should not be confused with a custom-made knee brace.

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The U.S. Food and Drug Administration (FDA) 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 I device by the FDA and are exempt from a premarket notification application (PMA) requirement prior to marketing any device.

Knee braces can be subdivided into four categories based on their intended use: prophylactic braces, rehabilitation braces, functional braces, and unloader knee braces. With the exception of unloader (custom-made) knee braces (see CG-OR-PR-03 Custom-made Knee Braces); these categories are defined as follows:

Prophylactic knee braces

Prophylactic braces are designed to prevent or reduce the severity of ligament injuries in a relatively *normal* (stable) knee. These injuries, primarily to the medial collateral ligament (MCL), are among the most common athletic knee injuries. There is a lack of evidence to support that the use of prophylactic braces reduces the incidence or severity of injuries of ligaments of the knee.

Rehabilitation knee braces

Rehabilitation braces are designed to allow protected and controlled motion of the *injured* knee treated operatively or non-operatively. These braces allow for controlled joint motion and typically consist of hinges that can be locked into place to limit range of motion. Rehabilitation braces are commonly used for 6 to 12 weeks following an injury. Rehabilitation braces are usually purchased prefabricated (off-the-shelf) and can be ordered either as small, medium, or large, or by a size chart. Most rehabilitation knee braces can be adjusted within each size to allow for edema or atrophy, and are not custom-made.

Functional knee braces

Functional braces are 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 speed; 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.

The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines on the management of ACL injuries do not support the routine use of functional knee bracing following isolated ACL reconstruction, stating, “Functional knee braces are not recommended for routine use in patients who have received isolated primary ACL reconstruction, as they confer no clinical benefit”. This recommendation is limited, based on strong strength of evidence. They also state, “Prophylactic bracing is not a preferred option to prevent ACL injury,” citing low strength of evidence. Lowe (2017) published a systematic review evaluating the efficacy of functional knee braces following ACL reconstruction. The authors note that there is limited evidence supporting the use of functional

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bracing. No specific functional brace has been validated as a means of effectively reducing the risk of re-injury following ACL reconstruction. The authors note that further studies are needed to clarify the role of functional knee braces following ACL reconstruction. In another systematic review, Marois and colleagues (2021) investigated whether the use of a knee brace when returning to sports could prevent a second injury after ACL reconstruction. The authors noted that there were no trends indicating a protective effect of knee braces against re-tear after ACL reconstruction due to a limited amount of included studies (n=3) and heterogeneity in their methods and outcomes.

Functional knee braces have also been used in individuals with osteoarthritis in order to decrease the weight on painful joints. The 2021 AAOS guidelines on the management of osteoarthritis of the knee indicate that “brace treatment could be used to improve function, pain, and quality of life in patients with knee osteoarthritis” (moderate recommendation). Alfatafta and colleagues (2021) published a systematic review aimed at evaluating the effects of using a knee valgus brace on pain and activity levels in individuals with medial compartment knee osteoarthritis. They found that while using a knee valgus brace was effective at reducing pain and improving activity level, most studies evaluated the impact of the brace for less than 6 months. The authors note there is a need for further studies to evaluate the long-term impact of the knee valgus brace and the identification of individuals who would likely benefit from its use.

Table 1. Prefabricated (Off-the-shelf, Custom-fitted) Knee Braces (Not intended to be a complete list of devices.)

Manufacturer	Brand Name
Advanced Orthopaedics (Philadelphia, PA)	ACL Knee Brace, Advanced Hinged Range of Motion, Airprene Hinged, Cobra Unloaded Knee, Deluxe Hinged, F.M. Hinged, Min-Knee Hinged Knee Brace, TM Wrap-Around Hinged Knee Brace, Wrap-Around Hinged Knee Brace
Bauerfeind USA, Inc. (Marietta, GA)	MOS Genu [®] , SecuTec [®] Genu, SofTec [®] series
Bledsoe Brace Systems (Grand Prairie, TX)	Aligner, Axiom series, Crossover series, Extender Plus, G3, Jet, Lever Lock, Merit, Merit OR, OA Impulse, Original Knee Brace, Primas, Revolution 3, Thruster, Z-12, Z-13, 20.50
Comfy Splints (Lenjoy Medical Engineering, Inc, Gardena, CA)	Comfy [™] and Comfyprene [™] series
DeRoyal [®] Industries (Powell, TN)	Deluxe Hinged, Flexgard [™] , Functional ACL, Hypercontrol [®] , M.3 or M.4 [®] S Functional Knee Brace, OA Upright series, Slimline series, Transition series, Warrior [®] series

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Manufacturer	Brand Name
DonJoy/dj Orthopedics DJO, LLC (Vista, CA)	4TITUDE™, A22 Custom, ACL Everyday, Armor series, Competitor, Defiance series, Drytex™ Hinged Knee models, ELS, Female Fource, Fource Point™, OA FullForce, Hinged Lateral J, IROM Playmaker, Legend, OA Adjuster, OA Assist, OA Everyday, OA FullForce, OA Nano™, Playmaker models, TROM models (cool, Rehab, telescoping, with or without shells), TROM models, X-Act ROM
Mueller Sports Medicine, Inc. (Prairie du Sac, WI)	Hg80® Hinged Knee Brace, Hg80® Knee Stabilizer, Mueller® Green Adjustable Hinged Knee, MuellerHinge™ 2100, PRO LEVEL™ Hinged Knee Brace Deluxe
Ortho Innovations (Tempe, Arizona)	Mackie Hinge Knee Brace
Össur Americas (Foothill Ranch, CA)	Aspire®, C180 (various models), CTi® Series, Edge/Edge Lite, Extreme®, Flex® OTS, Flex Sport™, GII Unloader Express®, Innovator DLX®/DLX®+, Morph, Oasys® Carticare, MVP® Contour OTS, OAJ®, OASYS® OTS, Paradigm® OTS, PCL Opposition, Rebound® Cartilage series, Rehab, Sentry™, Trainer OA, Trainer OTS, Unloader® ADJ, Unloader Express®, Unloader One® Plus, Unloader® Select, Unloader Spirit®
Ottobock (Duderstadt, Germany)	Agilium Reactive, Patella Pro
Thuasne (Levallois-Perret, France)	Action Reliever, Active Reliever, Air Townsend, Air Townsend Lite, Bold, Dynamic Reliever, EXOGUARD, Genu Dynastab, Genu Ligaflex®, Genu Ligaflex® ROM, Genu PRO ACTIV®, Genuextrem, Ligastrap Genu, Motocross Series, Patella Reliever, Pediatric Air Townsend, Premier Reliever, Premier Reliever One, Premier Series, Rebel Ligament, Rebel Lite, Rebel Lock, Rebel Pro, Rebel Reliever, Reliever, Reliever Air, Reliever Air Lite, Reliever One, ROMX, Safe Limb, Silistab Genu, Sport Series, TS ROM 1200/1600, UniReliever

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Manufacturer	Brand Name
Townsend Design (Bakersfield, CA)	Active Reliever, Air Lite, Air Townsend, BOLD, Full Shell, Premier Series, Rebel Series, Reliever Series ROM Post Operative Knee Braces, SoftForce, Sport Series

Definitions

Anterior cruciate ligament (ACL) tear: An acute knee injury that occurs when the foot is planted, the knee is flexed, and a valgus force is applied to the knee with the lower leg in external rotation; commonly occurs in sports that require twisting, jumping, and pivoting.

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.

Medial collateral ligament (MCL) injury: An acute knee injury that is the result of a blow to the lateral side of the knee when the foot is planted; a commonly occurring sports-related injury.

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.

Sprain: A partial or complete tear of a ligament.

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Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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Prefabricated and Prophylactic Knee Braces

[idx?SID=b605863996f45e7e5675f4d69a8a9f26&mc=true&tpl=/ecfrbrowse/Title21/21cfr890_main_02.tpl](https://www.cms.gov/medicare/coverage/dmcs/medicare-coverage-database/details/idx?SID=b605863996f45e7e5675f4d69a8a9f26&mc=true&tpl=/ecfrbrowse/Title21/21cfr890_main_02.tpl).
Accessed on January 24, 2025.

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Functional Knee Braces
Prophylactic Knee Braces
Rehabilitation Knee Braces

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/20/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
	10/01/2024	Updated Coding section with 10/01/2024 CPT changes; revised descriptor for L1820 and added L1821.
Reviewed	02/15/2024	MPTAC review. Updated References section.
Reviewed	02/16/2023	MPTAC review. Updated Discussion and References sections.
Reviewed	02/17/2022	MPTAC review. Updated Discussion and References sections.
Reviewed	02/11/2021	MPTAC review. Updated Discussion and References sections. Reformatted Coding section.
Reviewed	02/20/2020	MPTAC review. Updated Discussion and References sections.
Reviewed	03/21/2019	MPTAC review. Updated References section.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date”. Updated Discussion and References sections.
Revised	05/04/2017	MPTAC review. Made minor typographical edits to Clinical Indications section. Updated Table 2.
	01/01/2017	Updated Coding section with 01/01/2017 HCPCS changes; removed codes K0901, K0902 deleted 12/31/2016.
Reviewed	05/05/2016	MPTAC review. Updated Table 2, Discussion and References sections. Removed ICD-9 codes from Coding section.
Revised	05/07/2015	MPTAC review. Updated Clinical Indications with format changes and minor revisions to the not medically necessary statements and the Note. Updated References section.
	10/01/2014	Updated Coding section with 10/01/2014 HCPCS changes.
Reviewed	05/15/2014	MPTAC review. Updated Description, Discussion, Table 2, and Reference sections.
	01/01/2014	Updated Coding section with 01/01/2014 HCPCS changes.

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Prefabricated and Prophylactic Knee Braces

Reviewed	05/09/2013	MPTAC review. Updated Table 2, References, and Index.
Reviewed	05/10/2012	MPTAC review. Updated Discussion and References.
Reviewed	05/19/2011	MPTAC review. Updated Product Table, Definitions, Coding and References.
Revised	05/13/2010	MPTAC review. Clarified and reformatted Clinical Indications. Revised medically necessary indication for a prefabricated functional or rehabilitation knee brace for patellar fractures, expanding criteria to include patellar fractures that do not require surgical intervention. Updated Discussion, Product Tables and References.
	01/01/2010	Updated Coding section with 01/01/2010 HCPCS changes; removed HCPCS L1800, L1815, L1825 deleted 12/31/2009.
Reviewed	05/21/2009	MPTAC review. Updated References and Product Tables.
Revised	05/15/2008	MPTAC review. Archived document CG-DME-02, split and renamed into two separate orthotic documents: Prefabricated and Prophylactic Knee Braces (CG-OR-PR-02) and Custom-made Knee Braces (CG-OR-PR-03). Updated Tables, Coding, Discussion, and Reference sections. Revised and added AAOS definitions.
	01/01/2008	Updated Coding section with 01/01/2008 HCPCS changes; removed HCPCS codes L1855, L1858, L1870, L1880 deleted 12/31/2007. Removed Coding discussion from Definitions section.
Revised	05/17/2007	MPTAC review. Clinical indications clarified. References updated.
Reviewed	03/08/2007	MPTAC review. Clinical indications clarified. Discussion, Definitions, Coding and References updated.
Revised	03/23/2006	MPTAC review. The wording of the criteria under 1-d was changed to eliminate the time frame of 6 weeks. References and Coding updated.
	11/17/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/28/05	DME 021	Knee Braces
WellPoint Health Networks, Inc.	09/23/04	9.07.02	Knee Braces

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