

Subject: Prefabricated and Prophylactic Knee Braces
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Description

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

Note: 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**

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Prefabricated and Prophylactic Knee Braces

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:

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:

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HCPGs

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, includes fitting and adjustment
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
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

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Prefabricated and Prophylactic Knee Braces

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.

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 1 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:

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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 reduce 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. Functional knee braces have also been used in individuals with osteoarthritis in order to decrease the weight on painful joints.

The American Academy of Orthopaedic Surgeons (AAOS) 2014 guidelines on the management of ACL injuries do not support the routine use of functional knee bracing following isolated ACL reconstruction noting there is no demonstrated efficacy (moderate recommendation). 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 bracing. No specific functional brace has been validated as a means of effectively

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Prefabricated and Prophylactic Knee Braces

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.

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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Clinical UM Guideline

CG-OR-PR-02

Prefabricated and Prophylactic Knee Braces

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
Fillauer LLC (Chattanooga, TN)	OAK™ series Comfil® TFC, Kydex®, ABS
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

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Manufacturer	Brand Name
	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 , Sulistab Genu , Sport Series , TS ROM 1200/1600 , UniReliever
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.

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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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Prefabricated and Prophylactic Knee Braces

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Accessed on January 16, 2020January 18, 2021.

Index

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	02/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion and References sections. Reformatted Coding section.
Reviewed	02/20/2020	Medical Policy & Technology Assessment Committee (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.

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Reviewed	10/01/2014 05/15/2014	Updated Coding section with 10/01/2014 HCPCS changes. MPTAC review. Updated Description, Discussion, Table 2, and Reference sections.
Reviewed	01/01/2014 05/09/2013	Updated Coding section with 01/01/2014 HCPCS changes. 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.
Reviewed	01/01/2010 05/21/2009	Updated Coding section with 01/01/2010 HCPCS changes; removed HCPCS L1800, L1815, L1825 deleted 12/31/2009. 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.
Revised	01/01/2008 05/17/2007	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. 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.

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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

CHANGES

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