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Subject: Knee Braces

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

The three components common to most knee braces include a rigid shell, a hinge, and a strap system. The shell extends proximally and distally to a hinge that is centered on the knee axis of motion. The strapping system secures the brace to the leg.

Knee braces can be subdivided into four categories that are based on the intended use:

- 1. Prophylactic braces attempt to prevent or reduce the severity of knee ligament injuries. These braces are primarily designed to prevent injuries to the medial collateral ligament, which is among the most common athletic knee injury.
- 2. Rehabilitation braces allow protected motion of injured knees that have been treated operatively or non-operatively. These braces allow for controlled joint motion and typically consist of hinges that can be locked into place for the purpose of limiting range of motion. Rehabilitation braces are commonly used for 6 to 12 weeks after injury and are usually purchased off-the-shelf and are not custom-made.
- 3. Functional braces assist or provide stability for unstable knees during activities of daily living or sports and may be either "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.
- 4. <u>Unloader knee braces</u> are designed to reduce the pain and disability associated with osteoarthritis of the medial compartment of the knee by bracing the knee in the <u>valgus position</u> in order to unload the compressive forces on the medial compartment.

See the **DEFINITIONS** section of this policy for applicable descriptions.

POSITION STATEMENT:

Off-the-shelf (<u>custom-fitted</u>) functional knee braces **meet the definition of medical necessity** in members with knee instability due to injury (including members who have had surgery for the injury) or in members with painful osteoarthritis of the knee.

Examples of off-the-shelf (custom-fitted) functional knee braces may include:

Manufacturer	Brand Names
Bauerfeind	Moss Gen U Short
Bledsoe	Force I, Force 2, Force 3, Proshifter ACL, Proshifter Contact
Deroyal	Three-D
DonJoy	Gold Point, Legend, 4 Point Supersport, Playmaker, Monarch
Innovation	MVP
Medical Designs	Lorus
Mueller Sports	Magna-Lite Prefi t
Omni Scientific	Spectrum, OS-5
Orthomedics	Ecko II
Orthotech	Contender, Controller
Spademan	ACL Sport
Townsend	Off-shelf
Vixie Enterprise	MKS2 OTS
Zinco	Lehrman Multilig, MSO

Custom-made unloader knee braces **meet the definition of medical necessity** as a treatment for members with painful osteoarthritis involving the medial compartment of the knee.

Examples of unloader knee braces may include:

Manufacturer	Brand Names
Generation II	Unloader
Donjoy	Monarch
Orthotech	Montana

Replacement of a previously approved knee brace **meets the definition of medical necessity** under one of the following conditions:

- 1. The brace has exceeded its Reasonable Useful Lifetime (RUL); or
- 2. The brace is still within its RUL and documentation supports one or more of the following situations:
 - The brace has sustained irreparable damage not related to misuse;
 - There is significant wear that compromises the brace's functionality;
 - There has been a clinically relevant change in the member's condition, necessitating a different configuration; or
 - Growth-related changes require a new brace to ensure appropriate fit and therapeutic benefit.

Note: All requests must be supported by clinical documentation justifying the need for replacement.

Custom-made functional knee braces **do not meet the definition of medical necessity.** There is no data in the published peer-reviewed literature supporting custom-made functional knee braces offer any benefit over off-the-shelf braces in terms of activities of daily living (e.g., sporting activities). However, the medical necessity of a custom-made knee brace may be an individual consideration when: the member has met the criteria for an off the shelf (custom-fitted) knee brace and is unable to be fitted with a <u>prefabricated</u> brace as a result of any of the following: abnormal limb contour, (disproportionate size and shape) knee deformity, or large size, all of which would preclude the use of an off-the-shelf (custom-fitted) model. The following information may be required documentation to support medical necessity: Physician history and physical, physician operative reports and physician progress notes.

LOINC Codes:

Documentation	LOINC	LOINC	LOINC Time Frame Modifier Codes Narrative
Table	Codes	Time Frame	
		Modifier	
		Code	
Physician history	28626-0	18805-2	Include all data of the selected type that represents
and physical			observations made six months or fewer before starting
			date of service for the claim.
Attending physician	18741-9	18805-2	Include all data of the selected type that represents
progress note			observations made six months or fewer before starting
			date of service for the claim.
Physician operative	28573-4	18805-2	Include all data of the selected type that represents
note			observations made six months or fewer before starting
			date of service for the claim.

Examples of custom-made functional knee braces include:

Manufacturer	Brand Names
DonJoy	CE 2000, Defiance
Generation II	GII Sports Brace
Innovation Sports	CTI Classic, CTII Superlight, CTI Standard, CTI Pro Sport
Lennox Hill	Regular, Light, Spectralite
MedTechna	Can Am
Mueller Sports	Magnum Competition
Medicine	
Omni Scientific	Elite, TS-7
Orthotech	Oti Performer
Spademan	Custom
Sutter	Talon
Townsend Design	Air Custom, Original
Vixie Enterprise	MKS2 Custom, MKS2 PCL
Zimmer Sports	Caster I, Sports Caster II

Prophylactic and rehabilitative knee braces **do not meet the definition of medical necessity** and are generally considered contract exclusions.

BILLING/CODING INFORMATION:

HCPCS Coding:

There are a variety of HCPCS codes describing knee braces. While some describe knee braces according to their specific function, others describe knee braces according to their composition, which leads to overlapping of the HCPCS codes. Certain sports knee braces, such as the CTI or Defiance braces, could be accurately described by either code, and the choice of the code used probably depends on the level of reimbursement associated with each.

The following codes describe knee braces that **meet the definition of medical necessity** and are eligible for coverage:

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 joint, 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 orthotic, locking knee joint(s), positional orthotic, 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, pre-fabricated, item that has been trimmed, bent, molded,
	assembled, or otherwise customized to fit a specific patient by an individual with
	expertise
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, <u>custom fabricated</u>
L1845	Knee orthosis, double upright, thigh and calf, with adjustable flexion and extension
	joint, (unicentric or polycentric) medial-lateral and rotation control, custom fitted

	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

The following codes describe custom-made functional knee braces that **do not generally meet the definition of medical necessity** and therefore would not be eligible for coverage:

L1834	Knee orthosis (KO), without knee joint, rigid, custom fabricated
L1840	Knee orthotic (KO), derotation, medial-lateral, anterior cruciate ligament, custom
	fabricated
L1846	Knee orthotic, 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 (KO), modification of supracondylar prosthetic socket, custom
	fabricated (SK)

REIMBURSEMENT INFORMATION:

As with all covered orthotic devices, reimbursement for a knee brace is based on the lesser of either the established allowance or the actual cost shown on the invoice. Medically necessary additions to knee braces (e.g., L2395, L2397, L2820, and L2830) are separately reimbursable.

Replacement of a previously covered knee brace is limited to the following conditions:

- 1. Reasonable and useful lifetime (RUL) has been exceeded (see chart below) OR
- 2. When still within the RUL:
 - Irreparable damage
 - Wear
 - A change in the member's condition **OR**
 - When necessitated due to growth.

The following chart reflects the reasonable useful lifetime of prefabricated knee orthoses:

L1810	1 year
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L1812	1 year
L1820	1 year
L1821	1 year
L1830	1 year
L1831	2 years
L1832	2 years
L1833	2 years
L1836	3 years
L1843	3 years
L1845	3 years
L1850	2 years
L1851	3 years
L1852	3 years

Reimbursement for the repair is not to exceed the allowance for the cost of a new device.

Reimbursement for travel time and for professional services associated with preparation and fitting is included in the basic allowance for the orthotic device.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date and is located at cgsmedicare.com: Knee Orthosis (L33318).

The following DMERC Local Coverage article was reviewed on the last guideline reviewed date and is located at cgsmedicare.com: Knee Orthoses-Policy Article (A52465).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Custom-fabricated: see definition for "custom-made".

Custom fitted: see definition for "off-the-shelf".

Custom-made: generally describes a brace that is individually made according to precise measurements or molds/casts of an individual patient. Thus only the individual patient may use a custom-made brace.

According to the HCPCS codes, custom-made braces may also be described as custom-fabricated or molded to patient model.

Molded to patient model: see definition for "custom made".

Off-the-shelf (custom-fitted): knee braces that are described as "custom fitted." The braces are custom fitted only to the extent that the patient is fitted to a limited selection of sizes (i.e., small, medium, large, etc.). The brace may also be initially fitted by an orthotist, but this involves simple adjustments of the off-the-shelf braces.

Orthotist: someone skilled in the application of appliances or apparatus used to support, align, prevent, or correct deformities or improve function of movable parts of the body.

Unloader brace: designed to reduce pain and disability associated with osteoarthritis of the medial compartment of the knee by bracing the knee in a valgus position.

Prefabricated: see definition for "off-the-shelf".

Valgus position: bent outward.

RELATED GUIDELINES:

Orthotics, 09-L0000-03

OTHER:

None applicable.

REFERENCES:

- 1. American Academy of Orthopaedic Surgeons (AAOS). Treatment of Osteoarthritis of the Knee; Evidence-Based Guideline 2nd Edition, May 18, 2013. Accessed at aaos.org.
- CGS Administrators, LLC, Local Coverage Article: Knee Orthoses Policy Article (A52465); accessed at cgsmedicare.com.
- 3. CGS Administrators, LLC, Local Coverage Determination (LCD): Knee Orthoses (L33318); accessed at cgsmedicare.com.
- 4. Duivenvoorden T, Brouwer RW, et al. Braces and orthoses for treating osteoarthritis of the knee. Cochrane Database Syst Rev. 2015 Mar 16;(3):CD004020.
- 5. Kemker BP 3rd, Kankaria R, Patel N, Golladay G. Hip and Knee Bracing: Categorization, Treatment Algorithm, and Systematic Review. J Am Acad Orthop Surg Glob Res Rev. 2021 Jun 7;5(6):e20.00181-12.
- 6. U.S. Food and Drug Administration (FDA); accessed at fda.gov.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/23/25.

GUIDELINE UPDATE INFORMATION:

08/15/00	New Medical Coverage Guideline.
08/23/01	Reviewed – no changes.
03/15/03	Reviewed – added examples of the various types of braces; removed L1844 and L1880
	from the list of covered codes; and added L1836.
01/01/04	Annual HCPCS coding update.
02/15/04	Reviewed; deleted L1885; and added E1810.
05/15/05	Revision consisting of changing investigational statement for custom-made unloader
	knee braces to "medically necessary".
10/15/05	Revision consisting of addition of definition for "prefabricated".
01/01/06	Annual HCPCS coding update: revise L1832, L1843, L1844, L1845, and L1846.
05/15/07	Revision: deleted E1810 since this code is addressed in another MCG.
09/15/07	Reviewed; modified information regarding custom-made functional braces; updated
	coding section; reformatted guideline; updated references.
01/01/08	Annual HCPCS coding update: removed L1855, L1858, L1870, and L1880. Added
	statement regarding additions to knee braces.
01/01/10	Annual HCPCS coding update: removed L1800, L1815, and L1825.
12/15/10	Revisions; related ICD-10 codes added; formatting changes.
09/15/11	Revision; formatting changes.
01/01/14	Annual HCPCS coding update: added L1812 and L1833; revised L1810, L1820, L1830,
	L1832, L1836, L1843, L1845, L1847, and L1850. Updated Program Exceptions section.
08/21/14	Revision: updated Program Exceptions section.
08/15/15	Revision; Position statement, billing/coding, reimbursement information, program
	exception, and reference sections updated; formatting changes.
01/01/17	Annual CPT/HCPCS update.Added L1851 and L1852; deleted K0901 & K0902.
11/15/18	Review; Position statements maintained; code descriptors and references updated;
	formatting changes.
09/15/20	Review; Position statements maintained; codes L1851 & L1852 added to the <i>reasonable</i>
	useful lifetime of prefabricated knee orthoses chart; and references updated.
08/15/22	Review: Position statements maintained.
10/01/24	Quarterly CPT/HCPCS update. Code L1821 added; code L1820 revised.
11/15/24	Review: Prophylactic braces position statement updated to include "rehabilitative";
	references updated.
11/15/25	Review: Replacement position statement added, off-the-shelf position statement and
	description updated.