



Medical Policies

Medical Policies - DME

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Knee Braces

Number: DME103.002

Effective Date: 07-15-2018

Coverage:

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

A. Off-the-shelf (prefabricated) knee braces may be considered medically necessary for patients with knee instability due to injury or for patients with painful osteoarthritis of the medial compartment of the knee.

NOTE: According to the HCPCS codes, off the shelf models are described as prefabricated. 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 these off-the-shelf braces.

Off the shelf (prefabricated) knee braces include, but are not limited to:

Manufacturer	Brand Name
Bauerfeind	Moss Gen U Short
Bledsoe	Force I
	Force II
	Force III
	Proshifter ACL
	Proshifter Contract
Deroyal	Three-D
DonJoy	Gold Point
	Legend
	4 Point Supersport
	Playmaker
	Monarch
Innovation	MVP

Medical Designs	Lorus
Mueller Sports	Magna-Lite Prefit
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

B. Custom fabricated knee braces are considered not medically necessary (because of the availability of suitable off the shelf models).

EXCEPTION: Medical necessity of a custom fabricated knee brace may be an individual consideration in patients with abnormal limb contour, knee deformity, or large size, all of which would preclude the use of an off-the-shelf model.

NOTE: Clinical documentation should note that an effort to adjust a prefabricated brace was attempted prior to selecting a custom fabricated knee brace. For example, use of a pediatric sized knee brace for patients with small legs, the use of extra-long straps for patients with large limbs or addition of extension segments for tall patients. The request for a custom fabricated knee brace should include the patient's thigh measurement and the size of thigh the manufacturer's largest knee brace will fit.

NOTE #1: Custom fabricated describes a brace that is individually made according to precise measurements or mold/cast of an individual patient. Thus, only the individual patient should use a custom fabricated brace.

Custom fabricated functional knee braces include, but are not limited to:

Manufacturer	Brand Name
DonJoy	CE 2000
	Defiance
	Monarch
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 Medicine	Magnum Competition
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

C. Unloader off the shelf (prefabricated) knee braces may be considered medically necessary as a treatment for patients with painful osteoarthritis involving the medial compartment of the knee. Such off the shelf braces will require individual fitting. Off the shelf (prefabricated) Unloader knee braces include, but are not limited to the Generation II (Unloader express and Unloader Spirit).

Unloader custom fabricated knee braces are considered not medically necessary because of the availability of suitable off the shelf models. Custom Fabricated Unloader knee braces include, but are not limited to:

1. Generation II (Unloader Select, Unloader ADJ, Unloader Bi-Com),
2. DonJoy Monarch,
3. Align O.A. Knee Orthosis, and
4. Townsend Reliever.

D. Prophylactic knee braces are considered not medically necessary.

NOTE # 2 - Coverage of the Agilium Freestep Osteoarthritis device is defined in Medical Policy DME103.001 Orthotics.

Description:

Knee braces typically consist of three components: a superstructure (usually a rigid shell), a hinge, and a strap system. The superstructure

extends proximally to and distally from a hinge centered around the knee's axis of motion. The strapping system secures the brace to the limb. Knee braces can be subdivided into four categories that are based on their intended use:

- **Prophylactic braces** are those that 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 are among the most common athletic knee injury.
- **Rehabilitation braces** are designed to 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 to limit range of motion. Rehabilitation braces are commonly used for 6 to 12 weeks after injury. Rehabilitation braces are usually purchased off-the-shelf and not custom-made.
- **Functional braces** are designed to 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. Functional knee braces have also been used in patients with osteoarthritis in order to decrease the weight on painful joints.
- **Unloader knee braces** are specifically designed to reduce the pain and disability associated with osteoarthritis of the medial compartment of the knee by bracing the knee in the valgus position in order to unload the compressive forces on the medial compartment.

Rationale:

At the time this policy was created, no data in the published peer-reviewed literature showed that custom-made functional knee braces offered any benefit over off-the-shelf braces in terms of activities of daily living. Many of the custom-made functional knee braces were designed specifically for participation in elective sports and thus would be considered not medically necessary. (1,2) Research on unloader knee braces for osteoarthritis (OA) had focused on custom-made knee braces, and there were minimal data on off-the-shelf unloader knee braces, although several case series suggested that unloader knee braces were associated with a reduction in pain in patients with painful osteoarthritis of the medial compartment. (3) Relevant studies are described below, using the MEDLINE database.

Osteoarthritis (OA)

In 1999, Kirkley and colleagues reported on a controlled trial that randomly assigned 119 patients with medial compartment osteoarthritis to receive standard medical management, medical management plus a polychloroprene (Neoprene) sleeve, or medical management plus an unloader knee brace. (4) Compared to the control group, the unloader knee

brace group was associated with a significant improvement in quality of life (QOL) and function. In comparing the unloader knee brace with the Neoprene sleeve, there was a significant difference in functional outcomes favoring the unloader knee but no significant difference in terms of QOL measures.

In a 2005 Cochrane review of braces and orthoses for treating osteoarthritis of the knee, Brouwer et al. concluded that there was limited evidence in favor of an unloader knee brace. (5) In 2006, Brouwer and colleagues reported a randomized multicenter trial of 117 patients that compared off-the-shelf unloading braces and conservative therapy with conservative therapy alone for unicompartmental (valgus or varus) osteoarthritis of the knee. (6) The addition of a brace resulted in a slight increase in reported walking distances at 3, 6, and 12 months (effect size of 0.4), with trends for improvement in subjective pain (-0.63 on a 10-point visual analogue scale [VAS]) and knee function (3 points on a 100-point Hospital for Special Surgery score). QOL did not differ between the two groups. The authors noted that adherence to the brace was low, with 16 of 60 patients (27%) discontinuing by 3 months and another 9 (15%) stopping treatment by 12 months. Patient-reported reasons for discontinuing use of the unloading brace were lack of benefit and adverse effects (i.e., skin irritation, bad fit).

Another study from 2006 compared custom-made and off-the-shelf bracing for varus gonarthrosis. (7) Ten patients wore each type of brace for 4-5 weeks (approximately 9 hours per day) in a randomized order. Pain scores were reduced from 197 mm (500 mm maximum) to 71 mm with the custom brace and 120 mm with the off-the-shelf brace. Stiffness was reduced from 91 mm (200 mm maximum) to 36 mm with the custom brace and 63 mm with the off-the-shelf brace. Function was improved from 664 mm (1,700 mm maximum) to 248 mm with the custom brace, whereas the off-the-shelf brace did not significantly affect function. Kinematic analysis showed a reduction in peak knee adduction moments during gait and stair-stepping and reduced varus angulation by 1.5 degrees, compared with baseline with the custom brace. The off-the-shelf brace did not reduce the varus angle.

A French clinical practice guideline committee evaluated evidence on the use of braces in knee osteoarthritis in 2009. (8) The review found mainly low-quality evidence in support of valgus knee braces for symptomatic medial femoro-tibial osteoarthritis with short- and mid-term reduction of pain and disability. Adverse effects included venous thromboembolic events. No additional controlled trials were identified in a 2010 review of bracing in the management of knee osteoarthritis. (9)

A 2010 study compared use of insoles or off-the-shelf braces for medial knee osteoarthritis in a randomized trial of 91 patients with medial compartmental knee osteoarthritis. (10) Pain severity, measured by a 10-point VAS, improved by 0.9 in the insole group and 1.0 for the brace group in intent-to-treat analysis. Function on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) improved by 4.2 and 4.0 points, respectively, out of 100. There was no significant effect on the hip-knee-ankle angle for either device. Compliance was 45% for the brace group, with a mean wearing time of 39 hours (standard deviation [SD] 32 hours).

After 6 months of use, neither insoles nor off-the-shelf braces resulted in clinically significant changes in varus angle, pain, or function.

In 2011, Hunter et al. reported a randomized trial of patellofemoral bracing for the treatment of patellofemoral (PF) osteoarthritis. (11) Eighty subjects completed 6 weeks with a BioSkin Q Brace with the patellar realigning strap applied and 6 weeks with the realigning strap removed. There was a 6-week interval between the 2 conditions, and the order of treatment was randomized. They found no effect of treatment on VAS knee pain and no significant difference between the groups for WOMAC pain, function, or stiffness outcomes.

Ligamentous Instability of the Knee

Soma and colleagues compared the performance of custom-made and off-the-shelf functional knee braces from 4 manufacturers in 2004. (12) As a group, the custom-made knee braces restrained anterior displacement better than the off-the-shelf models by a mean difference of 0.84 mm. The clinical significance of this minimal but statistically significant difference is questionable.

A 2007 systematic review of 12 randomized controlled trials (RCTs) of bracing for rehabilitation following anterior cruciate ligament (ACL) reconstruction “found no evidence supporting the routine use of functional or rehabilitative bracing in a patient with a reconstructed ACL. In particular, no study demonstrated a clinically important finding of improved range of motion, decreased pain, improved graft stability, or decreased complications and reinjuries.” (13)

In 2008, Birmingham and colleagues reported an RCT that compared the use of an off-the-shelf functional knee brace or Neoprene sleeve beginning 6 weeks after ACL reconstruction. (14) Of 150 patients randomly assigned to a brace or sleeve after surgery, 127 (85%) completed 24-month follow-up. Compliance was similar for the 2 groups, and 3 patients from each group had graft failures and revision surgeries. Confidence in the knee was rated higher for the brace (70 vs. 55, respectively out of 100), as was the rating of help in returning to sport (66 vs. 53, respectively). No other outcome measures differed between the groups, including the ACL-quality-of-life questionnaire, highest activity level, satisfaction with the brace/sleeve, side-to-side laxity, or functional tests. As this report described evaluators as blinded to the patient's group allocation, it does not appear that the patients were wearing the brace or sleeve at the time of functional testing.

Patellofemoral Pain Syndrome

In 2008, Warden et al. reported a meta-analysis of 16 randomized or quasi-randomized studies assessing patellar taping or bracing effects on chronic knee pain. (15) Thirteen trials investigated taping or bracing for anterior knee pain, and 3 investigated taping for osteoarthritis. The authors concluded there was limited evidence to demonstrate the efficacy of patellar bracing. They reported high heterogeneity between study outcomes and significant publication bias in the studies.

Evidence of efficacy is limited for off-the-shelf bracing for osteoarthritis, ligamentous instability, or patellofemoral pain.

Practice Guidelines and Position Statements

The American Academy of Orthopaedic Surgeons (AAOS)

In the 2013 AAOS updated guideline addressing the nonarthroplasty treatment of osteoarthritis of the knee; the AAOS was unable to make a recommendation for or against the use of a brace with a varus- or valgus-directing force for patients with medial or lateral unicompartmental osteoarthritis of the knee, based on limited evidence for the effectiveness of knee braces. (19)

2015 Update

A search of peer reviewed literature through May 2015 identified no new clinical trial publications or any additional information that would change the coverage position of this medical policy.

2017 Update

UpToDate 2017

Knee braces - Valgus (or unloader) knee bracing has been used to shift the load from the medial compartment with intent to relieve pain and improve function in patients with medial tibiofemoral (TF) joint OA. Our approach is to use a brace, as an adjunct to the other core treatments, for patients who are amenable to this intervention and likely to comply with the treatment. Patients with medial TF OA who are more physically active and usually younger may experience greater improvements with unloader knee bracing.

In a meta-analysis of six randomized trials, use of a brace compared with standard care (no orthosis use) was associated with a moderate improvement in both pain and function, while overall small improvements in pain were found when valgus bracing was compared with an orthosis control group (neutral knee brace, neoprene knee sleeve, or insoles). There was great heterogeneity in the comparator and in the prescription of braces across the six studies included in the meta-analysis. In a randomized trial including 80 patients with medial knee OA comparing valgus bracing with a neutral brace, there was a small but statistically significant decrease in pain in the brace group. In general, up to 25 percent of patients experience minor complications of bracing such as slipping and poor fit. In addition, relatively low compliance rates (45 to 58 percent in parallel-group studies) may also hamper optimal results in clinical practice.

Patellofemoral (PF) taping and bracing, on the other hand, aim at reducing joint stress in patients with symptoms arising from the PF joint and presence of patellar malalignment. There is evidence that patellar taping markedly improves pain in the short term, while PF bracing seems a more appealing option for long-term use such as in patients with PF OA. However, a crossover trial did not find differences in pain reduction when PF OA participants wore a specific type of off-the-self brace with or without the realigning strap applied. On the other hand, another study found small improvement in pain in the group that wore the brace for a mean of 7.4

hours daily for six weeks compared with a no-brace control group. In addition, the brace group had greater reduction in PF bone marrow lesion volume, suggesting a potential structure-modifying effect. (18)

A search of peer reviewed literature through May 2017 identified no additional publications or information that would change the coverage position of this medical policy.

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
None
HCPCS Codes
L1810, L1812, L1820, L1830, L1831, L1832, L1833, L1834, L1836, L1840, L1843, L1844, L1845, L1846, L1847, L1848, [Deleted 1/2017: K0901, K0902]
ICD-9 Diagnosis Codes

Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

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1. Liu SH, Mirzayan R. Current review. Functional knee bracing. Clin Orthop Relat Res 1995; (317):273-81.
2. Beynnon BD, Pope MH, Wertheimer CM et al. The effect of functional knee-braces on strain on the anterior cruciate ligament in vivo. J Bone Joint Surg Am 1992; 74(9):1298-312.
3. Matsuno H, Kadowaki KM, Tsuji H. Generation II knee bracing for severe medial compartment osteoarthritis of the knee. Arch Phys Med Rehabil 1997; 78(7):745-9.
4. Kirkley A, Webster-Bogaert S, Litchfield R et al. The effect of bracing on varus gonarthrosis. J Bone Joint Surg Am 1999; 81(4):539-48.
5. Brouwer RW, Jakma TS, Verhagen AP et al. Braces and orthoses for treating osteoarthritis of the knee. Cochrane Database Syst Rev 2005; (1):CD004020.
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7. Draganich L, Reider B, Rimington T et al. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. J Bone Joint Surg Am 2006; 88(12):2645-52.
8. 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):629-36.

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10. 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):1926-32.

11. Hunter DJ, Harvey W, Gross KD et al. A randomized trial of patellofemoral bracing for treatment of patellofemoral osteoarthritis. Osteoarthritis Cartilage 2011 (in press).

12. Soma CA, Cawley PW, Liu S et al. Custom-fit versus premanufactured braces. Orthopedics 2004; 27(3):307-10.

13. Wright RW, Fetzner GB. Bracing after ACL reconstruction: a systematic review. Clin Orthop Relat Res 2007; 455:162-8.

14. Birmingham TB, Bryant DM, Giffin JR et al. A randomized controlled trial comparing the effectiveness of functional knee brace and neoprene sleeve use after anterior cruciate ligament reconstruction. Am J Sports Med 2008; 36(4):648-55.

15. 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.

16. Richmond J, Hunter D, Irrgang J et al. Treatment of osteoarthritis of the knee (nonarthroplasty). J Am Acad Orthop Surg 2009; 17(9):591-600.

17. Knee Braces-Archived. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (Archived May 2011) Durable Medical Equipment 1.03.02.

18. Alle Deveza, A., Bennell, K. Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 30, 2016.). Management of moderate to severe knee osteoarthritis. Available at <www.uptodate.com>.

19. Treatment of Knee Osteoarthritis: A Clinical Practice Guideline from the AAOS. Journal of the American Academy of Orthopaedic Surgeons, September 2013. Available at: <http://www.aaos.org>. Accessed May 2017.

Policy History:

Date	Reason
7/15/2018	Reviewed. No changes.

10/1/2017	Document updated with literature review. The following note was added as clarification for individual consideration of a custom fabricated knee brace as medically necessary: "Clinical documentation should note that an effort to adjust a prefabricated brace was attempted prior to selecting a custom fabricated knee brace. For example, use of a pediatric sized knee brace for patients with small legs, the use of extra-long straps for patients with large limbs or addition of extension segments for tall patients. The request for a custom fabricated knee brace should include the patient's thigh measurement and the size of thigh the manufacturer's largest knee brace will fit."
3/15/2016	Reviewed. No changes.
7/1/2015	Document updated with literature review. Coverage unchanged.
10/1/2014	Reviewed. No changes. CPT/HCPCS code(s) updated
10/15/2013	Document updated with literature review. Coverage unchanged.
10/1/2008	Revised/updated entire document.
4/1/2003	CPT/HCPCS code(s) updated
8/1/2002	Revised/updated entire document
1/1/2000	Revised/updated entire document
5/1/1996	Medical policy number changed
5/1/1990	New medical document

Archived Document(s):

Title:	Effective Date:	End Date:
Knee Braces	10-01-2017	07-14-2018
Knee Braces	03-15-2016	09-30-2017
Knee Braces	07-01-2015	03-14-2016
Knee Braces	10-01-2014	06-30-2015
Knee Braces	10-15-2013	09-30-2014
Knee Braces	10-01-2008	10-14-2013
Knee Braces	08-01-2002	09-30-2008

