



# Knee braces

Clinical Policy ID: CCP.1392

Recent review date: 8/2020

Next review date: 12/2021

Policy contains: Knee brace, knee orthotics, osteoarthritis.

*AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

## Coverage policy

Knee braces (orthoses) are clinically proven and, therefore, medically necessary for any of the following conditions:

- Prefabricated braces.
  - A flexion contracture (shortening of the muscles and/or tendons that limits knee extension to zero degrees extension) after injury, surgery, casting, or other immobilization.
  - An extension contracture (shortening of the muscles and/or tendons that limits knee flexion to 80 degrees by passive range of motion) after injury, surgery, casting, or other immobilization.
  - Weakness or deformity of the knee that requires stabilization.
  - Flexion or extension contractures with movement on passive range of motion testing of at least 10 degrees (brace has locking knee joint).
  - A recent injury or knee surgery (brace has a knee immobilizer without joints or with an adjustable flexion and extension joint that provides medial-lateral and rotation control).
  - A congenital or acquired hyperextended knee causing instability in ambulatory members.
  - Painful arthritis in the medial compartment of the knee (unloader braces).
- Custom fabricated braces.
  - A documented physical characteristic requiring use of a custom fabricated orthosis. These include, but are not limited to, deformity of the leg or knee, size of thigh and calf, and minimal

muscle mass upon which to suspend an orthosis. An adjustable flexion and extension joint may be required in some cases.

- Instability due to internal ligamentous disruption of the knee (derotation knee orthosis).
- Knee instability due to genu recurvatum/hyperextended knee for ambulatory members (custom fabricated knee orthosis with a modified supracondylar prosthetic socket) (Centers for Medicare & Medicaid Services, L33318, 2020).

### Limitations

Knee braces (orthoses) are not clinically proven/investigational, and therefore not medically necessary, for:

- Prefabricated braces for members with no documented criteria in (1) above.
- Custom fabricated braces for members with no documented criteria in (2) above.
- Molded-to-patient model braces.
- Prophylactic knee braces.
- Cases when the member is non-ambulatory.

### Alternative covered services

No alternative covered services were identified during the writing of this policy.

## Background

Knee braces are a type of durable medical equipment that are also known as orthotics. They are devices that range from a simple strap worn below the kneecap to an elaborate device that stretches from the thigh to the shin, with a hinge at the joint. Knee braces consist of a hinge centered around the knee's axis of motion, superstructure (shell that extends around the hinge), and strap system that secures the brace to the limb.

The purpose of a knee brace is to support a weak or deformed body part or restrict motion in a damaged body part. Braces can reduce pain or other impairment and prevent further injury and/or improve range of motion without causing further harm or damage.

Several types of knee braces are used for various reasons.

- A prefabricated model is purchased over the counter and fitted to individual body contours.
- A custom-made model is made for a specific individual by bending, cutting, sewing, or molding.
- A molded-to-patient model is manufactured by first creating a plaster cast impression, and molding the brace on to the model (Centers for Medicare & Medicaid Services, L33318, 2020).

Knee braces are used for various purposes, including:

- A functional brace stabilizes an unstable joint, often during elective activities, such as sports, and sometimes when osteoarthritis is present.
- An unloader brace shifts some weight in an osteoarthritic knee, reducing pain; osteoarthritis affects 9.3 Americans older than age 45 in the United States (Gohal, 2018).
- A rehabilitative brace moderates motion in a knee just after injury or surgery.
- A prophylactic brace is used to prevent or reduce injury severity, such as ligament tears (Paluska, 2000).

## Findings

For years, guidelines have been developed for knee brace use. An early set of recommendations by the American Academy of Family Physicians found no conclusive evidence that prophylactic knee braces were effective to prevent knee damage; that patellofemoral braces offer moderate improvement to anterior knee disorders; and functional braces have demonstrated ability to stabilize knees during rotational and anteroposterior forces (Paluska, 2000).

Many guidelines address only single purposes of knee braces; osteoarthritis is a common topic. A guideline from the French Physical Medicine and Rehabilitation Society found that while braces are not often prescribed for osteoarthritis of the knee, responses to valgus knee bracing remain inconsistent with considerable side effects (Beaudreuil, 2009). Unloading knee braces have been recommended to reduce knee pain, based on professional evidence (Rannou, 2010).

The Osteoarthritis Research Society International guideline recommended bracing for persons with knee osteoarthritis and mild-to-moderate varus/valgus instability, based on findings that knee braces can reduce pain and increase stability of the joint (Zhang, 2008).

The American College of Rheumatology did not make recommendations on wearing knee braces for osteoarthritis (Hochberg, 2012). The American Academy of Orthopaedic Surgeons (Brown, 2013) could not recommend for or against the use of valgus directing force knee braces for persons with osteoarthritis. The Academy did state that a hinged knee brace and/or unloading brace may be appropriate for reducing pain and increasing range of motion in knee osteoarthritis (Yates, 2014).

One clinical practice guideline recommended against the use of functional bracing for patients who had recently undergone anterior cruciate ligament reconstruction, instead giving highest recommendation instead to immediate knee mobilization and strength/neuromuscular training (Andrade, 2019).

A 2019 American College of Rheumatology/Arthritis Foundation guideline for managing osteoarthritis of the hand, hip, and knee included a provision conditionally supporting use of patellofemoral bracing for patellofemoral knee osteoarthritis (Kolasinski, 2020).

Numerous systematic reviews and meta-analyses have been conducted on effectiveness of knee braces. Articles mentioned below are all systematic reviews, unless meta-analysis is indicated.

### Comparing types of braces

- Studies (n = 24) of knee complications documented that static progressive stretch bracing given one to three sessions a day over seven to nine weeks had a significantly greater increase in range of motion (31 degrees) than did dynamic braces over six to eight weeks. Patients who had static progressive stretch bracing also had a superior increase in mean flexion (22 degrees) compared with that of patients who had dynamic knee bracing (seven degrees), leading authors to recommend it as a first-line recommendation for persons with knee pathology (Sodhi, 2017).

### Sports injuries – anterior cruciate ligament

- Early studies showed no benefit of wearing knee braces to the anterior cruciate ligament. A review (seven studies) on effects of prophylactic use of knee braces among college football players found injury risk declined in three and increased in four studies (Pietrosimone, 2008).

- A review of 70 randomized controlled trials determined that use of a knee brace, after reconstruction of the anterior cruciate ligament, does not affect the clinical outcome (Andersson, 2009).
- A review of six studies of rehabilitation after anterior cruciate ligament surgery concluded bracing was ineffective and no recommendation was made for its use. However, the review did find that accelerated and home-based rehabilitation, neuromuscular training programs, hyaluronic acid injection, and single (uninjured) leg cycling may be beneficial (Grant, 2013).
- A review of six analyses of prophylactic use of knee braces among U.S. football players showed a significant reduction in medial collateral ligament injuries in only one study, and thus authors did not recommend routine prophylactic use of braces (Salata, 2010).
- A systematic review of biomechanical and clinical evidence suggests functional bracing does not sufficiently restore normal biomechanics to the anterior cruciate ligament-deficient knee, protect the reconstructed ligament, and improve long-term patient outcomes, and that further improvements are needed in bracing technology (Smith, 2014).
- A review of 15 studies (only three randomized) of persons followed from 3 - 48 months after anterior cruciate ligament repair showed bracing significantly improved kinematics of the knee joint and improved gait kinetics, while decreasing quadriceps activation. Authors termed the effectiveness of this type of surgery to be “elusive” (Lowe, 2017), while another expert (after a review of 28 articles) declared that the literature does not support the use of braces after anterior cruciate ligament surgery (Rodriguez-Merchan, 2016).
- A systematic review/meta-analysis of seven studies (n = 440) of patients after anterior cruciate ligament reconstruction compared those given braces versus no braces. No significant differences were observed in International Knee Documentation Committee score, Lysholm score, Tegner score, side-to-side difference, single-leg hop test and Visual Analog Scale pain score (Yang, 2019).

#### Osteoarthritis

- In 25 studies of patients with varus and valgus knee osteoarthritis, Generation II knee braces, valgus knee braces, and functional off-loading knee braces were found to be effective in decreasing pain, joint stiffness, and drug dosage (Raja, 2011).
- A Cochrane review of 13 studies (n = 1,356) of knee braces and other conservative methods of treating medial compartment knee osteoarthritis revealed inconclusive benefits of bracing for pain, stiffness, function, and quality of life (Duivenvoorden, 2015).
- A meta-analysis of six studies documented persons with osteoarthritis using valgus braces to have a significant pain improvement ( $P = .001$ ) and function ( $P = .03$ ). Compared with a control group that did not use an orthosis, the valgus group had a significantly greater reduction in pain ( $P = .04$ ) and function ( $P = .04$ ) and a significant improvement ( $P = .01$ ) in pain compared with patients using a control orthosis (Moyer, 2015a).
- The same research team performed a meta-analysis of 17 studies, linking braces with a significant decrease in external knee adduction moment during walking, with a near-significant link to effect size and duration of brace use only, and with longer durations of brace use associated with smaller treatment effects on osteoarthritis (Moyer, 2015b).

- A review of 12 studies of persons with knee osteoarthritis determined knee braces decreased pain, and improved function, improved range of motion, and increased speed of walking and step length, along with a reducing the adduction moment applied to the knee (Mileki, 2016).
- A review found 20 of 24 articles addressing medial osteoarthritis revealed that valgus unloader braces significantly decrease the knee adduction moment (Petersen, 2016).
- A review of 31 studies (n = 619) typically found improved pain outcomes in osteoarthritis patients using valgus offloader braces, but variable results in functional outcomes and stiffness. Offloader bracing was more effective at reducing pain versus neutral braces or neoprene sleeves (Gohal, 2018).
- A review of 11 studies (n = 284), six randomized, documented significant improvement in pain ( $P = .007$ ) for persons with osteoarthritis wearing versus not wearing a soft brace. Those wearing a soft brace versus standard care showed significant improvements in pain reduction ( $P < .001$ ) and self-reported physical function ( $P = .006$ ) (Cudejko, 2018).
- A review of 30 studies (four of which addressed bracing) compared several treatments for pain in knee osteoarthritis. Bracing had a significant reduction standardized mean difference in pain of 1.34 – more effective than insoles (0.992) but less effective than transcutaneous electrical nerve stimulation (1.796) and neuromuscular electrical stimulation (1.924) (Cherian, 2016).
- A review of seven Japanese-language randomized trials found no conclusive evidence on effectiveness of any braces for patients with medial knee osteoarthritis (Mine, 2017).

#### Patellofemoral syndrome.

- A Cochrane review of five trials (n = 368) failed to produce helpful evidence on effectiveness of knee orthoses for treating patellofemoral syndrome. Very-low-quality evidence suggested that knee braces did not reduce knee pain or improve knee function in under three months in adults who were also undergoing an exercise program for treating the disorder (Smith, 2015).
- A meta-analysis of 37 trials on adults with patellofemoral pain found 80% did not show a clinically significant benefit. In the remaining seven studies, significant reductions in pain were documented for pulsed electromagnetic fields plus home exercise (-33.0), hip muscle strengthening (-65.0 and -32.0), weight-bearing exercise (-40.0), neuromuscular facilitation plus aerobic exercise and stretching (-60.1), postural stabilization (-24.4), and patellar bracing (-31.6) (Saltychev, 2018).

## References

On June 12, 2020, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “knee braces,” “orthoses,” and “orthotics.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Andersson D, Samuelsson K, Karlsson J. Treatment of anterior cruciate ligament injuries with special reference to surgical technique and rehabilitation: an assessment of randomized controlled trials. *Arthroscopy*. 2009;25(6):653-685. Doi: 10.1016/j.arthro.2009.04.066.

Andrade R, Pereira R, van Cingel R, Staal JB, Espregueira-Mendes J. How should clinicians rehabilitate patients after ACL reconstruction? A systematic review of clinical practice guidelines (CPGs) with a focus on quality appraisal (AGREE II). *Br J Sports Med*. 2019 Jun 7. pii: bjsports-2018-100310. Doi: 10.1136/bjsports-2018-100310.

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. Doi: 10.1016/j.jbspin.2009.02.002.

Brown GA. AAOS Clinical Practice Guideline: Treatment of Osteoarthritis of the Knee: Evidence-Based Guideline, 2nd Edition. *J Am Acad Orthop Surg*. 2013;21(9):577-579. Doi: 10.5435/JAAOS-21-09-577.

Centers for Medicare & Medicaid Services. Local Coverage Determination: Knee Orthoses (L33318). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33318&ver=47&SearchType=Advanced&CoverageSelection=Local&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=Knee+orthoses&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&>. Effective January 1, 2020. Accessed June 12, 2020.

Cherian JJ, Jauregui JJ, Leichliter AK, Elmallah RK, Bhave A, Mont MA. The effects of various physical non-operative modalities on the pain in osteoarthritis of the knee. *Bone Joint J*. 2016;98-B(1 Suppl A):89-94. Doi: 10.1302/0301-620X.98B1.36353.

Cudejko T, van der Esch M, van der Leeden M, et al. Effect of soft braces on pain and physical function in patients with knee osteoarthritis: Systematic review with meta-analyses. *Arch Phys Med Rehabil*. 2018;99(1):153-163. Doi: 10.1016/j.apmr.2017.04.029.

Duivenvoorden T, Brouwer RW, van Raaij TM, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM. Braces and orthoses for treating osteoarthritis of the knee. *Cochrane Database Syst Rev*. 2015;(3):CD004020. Doi: 10.1002/14651858.CD004020.pub3.

Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Rheumatol*. 2020;72(2):220-233. Doi: 10.1002/art.41142.

Gohal C, Shanmugarai A, Tate P, et al. Effectiveness of valgus offloading knee braces in the treatment of medial compartment knee osteoarthritis: A systematic review. *Sports Health*. 2018;10(6):500-514. Doi: 10.1177/1941738118763913.

Grant JA. Updating recommendations for rehabilitation after ACL reconstruction: a review. *Clin J Sport Med*. 2013;23(6):501-502. Doi: 10.1097/JSM.0000000000000044.

- Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. 2012;64(4):465-474. Doi: 10.1002/acr.21596.
- Lowe WR, Warth RJ, Davis EP, Bailey L. Functional bracing after anterior cruciate ligament reconstruction: A systematic review. *J Am Acad Orthop Surg*. 2017;25(3):239-249. Doi: 10.5435/JAAOS-D-15-00710.
- Mine K, Nakayama T, Milanese S, Grimmer K. The effectiveness of braces and orthoses for patients with knee osteoarthritis: A systematic review of Japanese-language randomised controlled trials. *Prosthet Orthot Int*. 2017;41(2):115-126. Doi: 10.1177/0309364616640926.
- Moyer RF, Birmingham TB, Bryant DM, Giffin JR, Marriott KA, Leitch KM. Valgus bracing for knee osteoarthritis: a meta-analysis of randomized trials. *Arthritis Care Res (Hoboken)*. 2015a;67(4):493-501. Doi: 10.1002/acr.22472.
- Moyer RF, Birmingham TB, Bryant DM, Giffin JR, Marriott KA, Leitch KM. Biomechanical effects of valgus knee bracing: a systematic review and meta-analysis. *Osteoarthritis Cartilage*. 2015b;23(2):178-188. Doi: 10.1016/j.joca.2014.11.018
- Paluska S, McKeag D. Knee braces: Current evidence and clinical recommendations for their use. *Am Fam Physician*. 2000;61(2):411-418. <https://www.ncbi.nlm.nih.gov/pubmed/10670507>. Accessed June 12, 2020.
- 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. Doi: 10.1007/s00402-015-2388-2.
- Pietrosimone BG, Grindstaff TL, Linens SW, Uczekai E, Hertel J. A systematic review of prophylactic braces in the prevention of knee ligament injuries in collegiate football players. *J Athl Train*. 2008;43(4):409-415. Doi: 10.4085/1062-6050-43.4.409.
- 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. Doi: 10.1097/PHM.0b013e318206386b.
- Rannou F, Poiraudou S, Beaudreuil J. Role of bracing in the management of knee osteoarthritis. *Curr Opin Rheumatol*. 2010;22(2):218-222. Doi: 10.1097/BOR.0b013e3182833619c4.
- Rodriguez-Merchan EC. Knee Bracing after anterior cruciate ligament reconstruction. *Orthopedics*. 2016 Jul 1;39(4):e602-609. Doi: 10.3928/01477447-20160513-04.
- Salata MJ, Gibbs AE, Sekiya JK. The effectiveness of prophylactic knee bracing in American football: a systematic review. *Sports Health*. 2010;2(5):375-379. Doi: 10.1177/1941738110378986.
- Saltychev M, Dutton RA, Laimi K, Beaupre GS, Virolainen P, Fredericson M. Effectiveness of conservative treatment for patellofemoral pain syndrome: A systematic review and meta-analysis. *J Rehabil Med*. 2018;50(5): 393-401. Doi: 10.2340/16501977-2295.



Smith SD, Laprade RF, Jansson KS, Aroen A, Wijdicks CA. Functional bracing of ACL injuries: current state and future directions. *Knee Surg Sports Traumatol Arthrosc.* 2014;22(5):1131-1141. Doi: 10.1007/s00167-013-2514-z.

Smith TO, Drew BT, Meek TH, Clark AB. Knee orthoses for treating patellofemoral pain syndrome. *Cochrane Database Syst Rev.* 2015 Dec 8;(12):CD010513. Doi: 10.1002/14651858.CD010513.pub2.

Sodhi N, Yao B, Khlopas A, et al. A case for the brace: A critical, comprehensive, and up-to-date review of static progressive stretch, dynamic, and turnbuckle braces for the management of elbow, knee, and shoulder pathology. *Surg Technol Int.* 2017;31:303-318. <https://www.ncbi.nlm.nih.gov/pubmed/29315452>. Accessed June 12, 2020.

Yang XG, Feng JT, He X, Wang F, Hu YC. The effect of knee bracing on the knee function and stability following anterior cruciate ligament reconstruction: A systematic review and meta-analysis of randomized controlled trials. *Orthop Traumatol Surg Res.* 2019;105(6):1107-1114. Doi: 10.1016/j.otsr.2019.04.015.

Yates AJ Jr, McGrory BJ, Starz TW, Vincent KR, McCardel B, Golightly YM. AAOS appropriate use criteria: optimizing the non-arthroplasty management of osteoarthritis of the knee. *J Am Acad Orthop Surg.* 2014;22(4):261-267. Doi: 10.5435/JAAOS-22-04-261.

Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage.* 2008;16(2):137-162. Doi: 10.1016/j.joca.2007.12.013.

## Policy updates

6/2018: initial review date and clinical policy effective date: 8/2018

8/2019: Policy references updated. Policy ID changed to CCP.1392.

8/2020: Two references added to this policy.