Prior Authorization Review Panel  
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
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<tr>
<td>Policy Number: CCP.1392</td>
<td>Effective Date: August 1, 2018</td>
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<tr>
<td></td>
<td>Revision Date: September 10, 2019</td>
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<tr>
<td>Policy Name: Knee braces</td>
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Type of Submission – Check all that apply:

- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions
- [ ] Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Please see revisions below using tracked changes.

Name of Authorized Individual (Please type or print): William D. Burnham, MD

Signature of Authorized Individual: [Signature]

[Signature]
ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania, AmeriHealth Caritas Northeast and Keystone First has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania, AmeriHealth Caritas Northeast and Keystone First's 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 Pennsylvania, AmeriHealth Caritas Northeast and Keystone First 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 Pennsylvania, AmeriHealth Caritas Northeast and Keystone First's 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 Pennsylvania, AmeriHealth Caritas Northeast and Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania, AmeriHealth Caritas Northeast and Keystone First's clinical policies will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania, AmeriHealth Caritas Northeast and Keystone First's 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:

1. 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).

2. 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, 2019).

Limitations:

We consider the use of knee braces (orthoses) to be investigational/experimental, 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.

Alternative covered services:

None.

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, 2019).
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).

**Searches**

We searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane library.

We conducted searches on June 20, 2019. Search terms were: “knee braces,” “orthoses,” and “orthotics.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**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 in the last decade 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 (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 mobilisation and strength/neuromuscular training (Andrade, 2019).

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 three to 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).

### 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, but improved function, improved range of motion, and increased speed of walking and step length, along with a reduction in 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 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 percent 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).

Policy updates:

The policy number was changed from CP#14.02.16 to CCP.1392 in June 2019.

A total of one guideline/other was added to, and one guideline/other and one peer-reviewed reference removed from this policy in June 2019.

References
Professional society guidelines/other:


Peer-reviewed references:


**Centers for Medicare & Medicaid National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

L33318 Knee orthoses.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>L1810-L1860</td>
<td>Knee orthotics</td>
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<td>L2000-L2038</td>
<td>Knee-Ankle-Foot Orthotic (KAFO) - Or Any Combination</td>
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<td>L2387</td>
<td>Addition to lower extremity, polycentric knee joint, for custom fabricated knee ankle foot orthosis, each joint</td>
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<td>Unspecified subluxation and dislocation of knee</td>
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**Appendix**

No additional information was identified for this section during the writing of this policy.