MEDICAL POLICY – 1.03.501
Knee Braces

Effective Date: June 1, 2017
Last Revised: May 23, 2017
Replaces: 1.03.02

RELATED MEDICAL POLICIES:
1.01.529 Durable Medical Equipment
7.01.15 Meniscal Allograft and Other Meniscus Implants
7.01.549 Knee Arthroscopy in Adults

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Knee braces are devices worn to support the knee joint. They are made by combining pieces of metal, foam, plastic, elastic materials and straps. The typical knee brace parts can be combined such that most people will get a comfortable fit. In rare cases, a custom-built brace might be needed if the knee and leg have an unusual shape.

An injury, knee surgery or severe arthritis of the knee may be reasons why a knee brace might be used. A knee brace may be useful when the knee is unstable or “gives out”. Special knee braces, called “unloader braces,” may help decrease pain for people who have severe arthritis. Knee braces that are worn to protect the knee and prevent injuries during sports/athletic activities are not covered by medical insurance. This policy describes the type of knee braces that are covered by the plan, as well as the type of knee braces that need to be approved before they are covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Type of Brace</th>
<th>Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unloader Knee Brace</strong></td>
<td><strong>Custom-made unloader knee braces may be considered medically necessary when all of the following criteria are met:</strong></td>
</tr>
</tbody>
</table>

- **Custom-made knee braces (custom fabricated, custom molded)**

  **Note:** These braces must be designed and fit by a board certified prosthetist/orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and prosthetics, Ins., or by the Board for Orthotist/Prosthetist Certification.

- **Custom-made unloader knee braces are considered not medically necessary when:**

  - A prefabricated unloader knee brace can be custom fit and adjusted for the patient.

- **Custom-made unloader knee braces for any condition other than osteoarthritis is considered a contract exclusion because it is considered a “special or extra cost convenience feature” under the durable medical equipment/medical supplies benefit in most contracts.**

  **Note:** Clinical notes should document that an effort to adjust a prefabricated brace was made. 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 knee brace request should include the patient’s thigh measurement and the size of thigh the manufacturer’s largest knee brace will fit.
<table>
<thead>
<tr>
<th>Type of Brace</th>
<th>Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefabricated unloader knee brace</td>
<td>Prefabricated unloader knee braces may be considered medically necessary for patients with painful osteoarthritis of the medial or lateral compartment of the knee.</td>
</tr>
<tr>
<td><strong>(off-the-shelf, ready-made, custom-fitted)</strong></td>
<td>Prefabricated unloader knee braces for any condition other than osteoarthritis is considered a contract exclusion because it is considered a “special or extra cost convenience feature” under the durable medical equipment/medical supplies benefit in most contracts.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Functional Knee Brace</th>
<th>Prefabricated functional knee braces may be considered medically necessary when all of the following criteria are met:</th>
</tr>
</thead>
</table>
| **Prefabricated functional knee brace (off-the-shelf, ready-made, custom-fitted)** | • The patient is ambulatory  
**AND has one of the following:**  
• Knee instability due to a knee injury (fracture, ligament tear) is documented on a physical exam  
**OR**  
• Knee instability due to recent knee surgery (rehab braces are used short-term, usually 6-12 weeks after surgery)  
**OR**  
• Knee instability due to a knee deformity such as contracture or genu varum/valgum (bow legged/ knocked kneed) is present  

Prefabricated functional knee braces are considered not medically necessary when criteria are not met. |

<table>
<thead>
<tr>
<th>Custom-made functional knee brace</th>
<th>Custom-made functional knee braces may be considered medically necessary when the criteria are met for a prefabricated functional brace, but a prefabricated functional brace was tried and did not fit due to one of the following:</th>
</tr>
</thead>
</table>
| **Note:** These braces must be designed and fit by a board certified prosthetist/orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is certified by the | • Abnormal limb contour that interferes with fitting (disproportionate size of thigh and/or calf)  
**OR**  
• Knee deformity is present that interferes with fitting such as contracture or genu varum/valgum (bow legged/ knocked kneed)  
**OR**  
• The knee anatomy has minimal muscle mass that interferes |
<table>
<thead>
<tr>
<th>Type of Brace</th>
<th>Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Board for Certification in Orthotics and prosthetics, Ins., or by the Board for Orthotist/Prosthetist Certification.</td>
<td>with fitting</td>
</tr>
<tr>
<td>Note:</td>
<td>Clinical notes should document that an effort to adjust a prefabricated brace was made. 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 knee brace request should include the patient’s thigh measurement and the size of thigh the manufacturer’s largest knee brace will fit.</td>
</tr>
<tr>
<td>Custom-made functional knee braces that do not meet the above criteria are considered a contract exclusion because it is considered a “special or extra cost convenience feature” under the durable medical equipment/medical supplies benefit in most contracts.</td>
<td></td>
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</tbody>
</table>

### Prophylactic Knee Brace

<table>
<thead>
<tr>
<th>Prophylactic knee braces (custom or prefabricated)</th>
<th>Prophylactic knee braces are considered not medically necessary for all indications.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prophylactic knee braces are frequently used for sport or recreational activities to prevent an injury. (Using a brace for this indication has not been proven in the literature.)</td>
<td></td>
</tr>
</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1834</td>
<td>Knee orthotic (KO), without knee joint, rigid, custom fabricated</td>
</tr>
<tr>
<td>L1840</td>
<td>Knee orthotic (KO), derotation, medial-lateral, anterior cruciate ligament, custom fabricated</td>
</tr>
<tr>
<td>L1844</td>
<td>Knee orthotic (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, custom fabricated</td>
</tr>
<tr>
<td>L1846</td>
<td>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</td>
</tr>
<tr>
<td>L1847</td>
<td>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</td>
</tr>
</tbody>
</table>
L1860  Knee orthotic (KO), modification of supracondylar prosthetic socket, custom fabricated (SK)

**Notes:** Skin protectors like brace sleeves are considered medically necessary supplies when used in conjunction with knee braces/knee orthoses.

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**Related Information**

**Definition of Terms**

**Custom-made knee brace:** Braces built for one patient according to precise measurements or molds/casts of the individual. A custom-made brace is used by only one specific patient and will not be useful to another patient. The certified orthotist provides the initial functional assessment and fit and builds the knee brace, which may include custom fabrication of parts.

**Functional knee braces/orthosis:** A type of knee brace used for knee instability. Examples of when this type of brace may be used are after knee injury, repairs, or reconstructions. Functional knee braces are worn during the day to stabilize and restrain the knee joint to prevent abnormal movement (rotation) during activities of daily living or sports. These knee braces are commonly used for a long time and may be either prefabricated/off-the-shelf, or in rare cases they may be custom-made.

**Instability:** An unsteadiness when bearing weight on the knee joint without an actual giving way, or causing an unexpected fall.

**Osteoarthritis (OA):** Also known as degenerative joint disease (DJD), OA in the knee happens due to overuse or injury of the joint. This overuse or injury breaks down the tissues (cartilage) that cushion the ends of the bones which make up the knee joint. These bones are the thigh bone or femur, the shin bone or tibia, and the knee cap or patella. The breakdown is usually on one side or the other where the bones come together. The breakdown of one side of the joint causes the knee to shift toward the opposite side, either towards the inside or the outside of the leg. That is, if the breakdown is on the inside of the knee joint, the knee shifts to the outside causing a bowlegged appearance. The deformity causes pain and affects the ability to move the knee joint and to walk.

**Over-the-counter (OTC) knee braces:** Elastic sleeve-like garments that provide minimal rigid supports to protect the knee and are usually made of neoprene or spandex. These elastic knee
sleeve supports are available without a prescription at many retail outlets. These items do not meet the definition of durable medical equipment (DME).

**Pre-fabricated/Off-the-shelf knee brace:** Braces that are mass-produced and come pre-sized in small, medium, large, etc. The certified orthotist provides the initial functional assessment and fit, as well as makes substantial modifications for a customized fit, without having to wait for a custom-made brace.

**Prophylactic knee braces/orthosis:** A type of brace used to protect uninjured knees from ligament injuries. These braces are primarily used in recreational or organized sports to prevent injury from occurring. However, no conclusive evidence supports their effectiveness and they are not recommended for regular use.

**Unloader knee braces:** A type of knee brace used to treat patients with painful osteoarthritis. These braces shift (unload) the body weight onto a different part of the knee than where the arthritis is located, for example, from the medial compartment to the lateral compartment.

**Documentation**

Clinical information to document the medical condition that requires the use of a knee brace may be requested. Information in the clinical record should include:

- A physical examination and an objective description of the knee joint instability
- A statement that the patient can walk (is ambulatory)
- The medical condition that indicates why use of a brace will benefit the patient
- Report from any imaging studies that were done
- Information about attempts to adjust a prefabricated brace to fit the patient. For example:
  - Use of pediatric knee orthoses in individuals with small limbs
  - Use of straps with additional length for individuals with larger limbs
  - Use of extensions for very tall individuals
  - The patient’s thigh measurement that exceeds the size of thigh the manufacturer’s largest prefabricated brace is designed to fit
Evidence Review

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS provided a 2009 clinical practice guideline on the non-surgical 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.

The AAOS published clinical practice guideline in 2014 on the management of anterior cruciate ligament injuries that includes these recommendations:

- ACL prophylactic braces: Limited evidence does not support prescribing prophylactic knee braces to prevent ACL injury because they do not reduce the risk for ACL injury.

- ACL post-op functional braces: Moderate evidence does not support the routine use of functional knee bracing after isolated ACL reconstruction because there is no demonstrated efficacy.

The American Academy of Orthopaedic Surgeons and the American Academy of Pediatrics

The AAOS and AAP have determined that prophylactic knee braces lack sufficient evidence of effectiveness in reducing the frequency or severity of knee ligament injuries. A prophylactic knee brace may offer a subjective sense of protection, but it is unable to protect the medial collateral ligament (MCL) during a direct lateral impact. Researchers have found that prophylactic brace usage is less important in MCL injury prevention than strength training, conditioning, technique refinement, and flexibility. The regular use of a prophylactic knee brace at any level of athletic competition is not currently recommended.

The Osteoarthritis Research Society International (OARSI)
The OARSI treatment guidelines from 2008 recommend the following: “In patients with knee OA and mild/moderate varus or valgus instability, a knee brace can reduce pain, improve stability and diminish the risk of falling.” This guideline is based in part on the Brower study in which there was a small but significant effect with unloading knee braces for patients with mild or moderate varus or valgus instability. In this study, the patients had medial or lateral osteoarthritis and the unloading knee brace was adapted to each kind of compartment. A slightly better effect was shown for the varus group.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/25/98</td>
<td>Add to Durable Medical Equipment Section - New Policy</td>
</tr>
<tr>
<td>11/05/99</td>
<td>Replace Policy - Description revised.</td>
</tr>
<tr>
<td>09/11/01</td>
<td>Replace Policy - Scheduled update</td>
</tr>
<tr>
<td>10/09/01</td>
<td>Replace Policy - HCPCS codes added; reviewed by Care Management staff.</td>
</tr>
<tr>
<td>05/14/02</td>
<td>Replace Policy - Benefits Application Section updated.</td>
</tr>
<tr>
<td>10/08/02</td>
<td>Replace Policy - Policy reviewed; policy statement unchanged. Additional references added.</td>
</tr>
<tr>
<td>12/10/02</td>
<td>Replace Policy - Policy reviewed; reimbursement for custom brace language updated.</td>
</tr>
<tr>
<td>12/09/03</td>
<td>Replace Policy - Policy reviewed; policy statement added concerning elective sports braces. Additional references and HCPC codes added.</td>
</tr>
<tr>
<td>01/01/04</td>
<td>Replace Policy - HCPC code update only.</td>
</tr>
<tr>
<td>07/13/04</td>
<td>Replace Policy - Policy reviewed; policy statement unchanged. Tables, Rationale and References updated.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.1.03.100. No date changes.</td>
</tr>
<tr>
<td>09/14/04</td>
<td>Replace Policy - Policy reviewed; policy statement unchanged. Benefit Application and Rationale updated.</td>
</tr>
<tr>
<td>09/13/05</td>
<td>Replace Policy - Policy statement revised to indicate that custom knee braces not meeting criteria are considered an extra cost convenience feature excluded under most contract provisions. Rationale and References updated.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/23/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>09/12/06</td>
<td>Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.</td>
</tr>
<tr>
<td>08/14/07</td>
<td>Replace Policy - Policy updated with literature review; references added. No change in policy statement.</td>
</tr>
<tr>
<td>08/12/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>New BC - Policy updated with literature search and converted to BC version. Replaces PR.1.03.500. Policy statement reworded but essentially unchanged.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>09/14/10</td>
<td>New PR Policy - Policy updated with literature search; references added and reordered. Policy statements changed to allow unloader bracing for “lateral” compartment of knee, in addition to medial. A new PR policy has been developed to replace BC.1.03.02</td>
</tr>
<tr>
<td>07/12/11</td>
<td>Replace Policy - Policy updated with literature review; reference added. 2011 update added to osteoarthritis section. No change to the policy statement.</td>
</tr>
<tr>
<td>07/20/12</td>
<td>Replace policy. No change in policy statement.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Removed Policy guideline stating “When the patient’s clinical condition meets the requirement for an off-the-shelf (prefabricated) knee brace but the patient prefers a custom knee brace, payment for the most common type of off-the-shelf knee brace (L1845) may be allowed toward that purchase”. Moved codes from benefit application to Policy Guidelines following the descriptions of the types of knee braces. A review of the literature through August 2013 did not prompt any additions to the references. Policy statement unchanged.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Annual Review. Policy statements extensively revised. Functional knee braces for knee instability due to injury or surgery, previously considered medically necessary is now considered not medically necessary. Added references 18-27. Coding update: ICD diagnosis codes removed; HCPCS codes L1810-L1812 (these apply to a separate medical policy) and L1820-32, 34-36 removed as they do not apply to this policy.</td>
</tr>
<tr>
<td>07/24/14</td>
<td>Update Related Policies. Change title to 7.01.549.</td>
</tr>
<tr>
<td>08/18/14</td>
<td>Coding update. HCPCS codes L1844 and L1846 reversed in coding table within Policy Guidelines section. In the previous version; they have been corrected.</td>
</tr>
<tr>
<td>11/10/14</td>
<td>Interim review. Clarifications to policy statements: Custom made contract exclusion policy statement split into two. Prophylactic policy statement reworded. HCPC codes added to policy statements. Manufacturing and classification of knee braces definitions added to policy guidelines section. HCPCS code E1810 removed; it relates to another policy (1.01.514).</td>
</tr>
<tr>
<td>03/11/15</td>
<td>Update Related Policies. Add 1.01.529.</td>
</tr>
<tr>
<td>03/24/15</td>
<td>Update Related Policies. Change title to 7.01.549.</td>
</tr>
<tr>
<td>05/27/15</td>
<td>Annual Review. Added an off the shelf knee brace sizing chart to the Policy Guidelines section.</td>
</tr>
<tr>
<td>04/01/16</td>
<td>Annual Review, approved March 8, 2016. Added Definition of Terms to Policy Guidelines. CPT code L1850 removed from policy – these are not covered under the benefit and are out of the scope of the policy.</td>
</tr>
<tr>
<td>04/14/16</td>
<td>Coding Update. Removed prefabricated codes from policy.</td>
</tr>
<tr>
<td>05/15/16</td>
<td>Formatting edit. Moved the codes listed within the policy section to the main header</td>
</tr>
</tbody>
</table>
### Date | Comments
---|---
11/01/16 | Interim update, approved October 11, 2016. Policy updated with review through September 2016, references added. Policy statements revised for clarity and usability. All tables of braces types and sizing were deleted. Policy moved into new template.
06/01/17 | Annual review, approved May 23, 2017. No changes to policy statement. Coverage criteria clarified with grammatical corrections.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

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  • Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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