Knee Orthoses (Braces), Ankle-Foot-Orthoses, and Knee-Ankle-Foot-Orthoses

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.

An ankle-foot orthosis is a device that provides stability to the ankle and support to the foot. A knee-ankle-foot orthosis may be used when the knee requires extra stability and both the ankle and foot require stability and support.

This policy describes when knee braces, ankle-foot, and knee-ankle-foot orthoses are considered medically necessary.

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.
**Note:** Coverage for a knee brace or ankle/knee orthosis is subject to the terms, conditions, and limitations of the Durable Medical Equipment benefit. Please refer to the applicable benefit plan document to determine availability and terms, conditions and limitations of coverage.

## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Type of Orthosis</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>
<tr>
<td></td>
<td>• The patient has painful osteoarthritis involving the medial compartment of the knee (causing a varus deformity) or the lateral compartment of the knee (causing a valgus deformity).</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>• A prefabricated brace was tried and did not fit due to one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Abnormal limb contour (disproportionate size of thigh and/or calf) exists that interferes with fitting of the brace</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>o Knee deformity (eg valgus, varus deformity) is present that interferes with fitting of the brace</td>
</tr>
<tr>
<td></td>
<td>▪ varus = knee joint is outward compared to the foot</td>
</tr>
<tr>
<td></td>
<td>▪ valgus = knee joint is inward compared to the foot</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>o Minimal muscle mass upon which to suspend an orthosis interferes with fitting of the brace</td>
</tr>
<tr>
<td></td>
<td><strong>Custom-made unloader knee braces are considered not medically necessary when:</strong></td>
</tr>
<tr>
<td></td>
<td>• A prefabricated unloader knee brace can be custom fit and adjusted for the patient.</td>
</tr>
<tr>
<td></td>
<td><strong>Custom-made unloader knee braces for any condition other</strong></td>
</tr>
<tr>
<td>Type of Orthosis</td>
<td>Coverage Criteria</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Prefabricated unloader knee brace (off-the-shelf, ready-made, custom-fitted) | **Prefabricated unloader knee braces may be considered medically necessary** for patients with painful osteoarthritis of the medial or lateral compartment of the knee.  

Prefabricated unloader knee braces for any condition other than osteoarthritis is considered a contractual 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. |

| Functional Knee Brace                   | Prefabricated functional knee braces may be considered medically necessary when all of the following criteria are met:  

- 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. |

<p>| Custom-made functional                  | Custom-made functional knee braces may be considered |</p>
<table>
<thead>
<tr>
<th>Type of Orthosis</th>
<th>Coverage Criteria</th>
</tr>
</thead>
</table>
| knee brace             | 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:  
\>
  - Abnormal limb contour (disproportionate size of thigh and/or calf) exists that interferes with fitting of the brace  
\>
  OR  
\>
  - Knee deformity is present that interferes with fitting such as contracture or genu varum/valgum (bow legged/knocked kneed)  
\>
  OR  
\>
  - Minimal muscle mass upon which to suspend an orthosis interferes with the fitting of the brace  
\>
  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.  
\>
  Custom-made functional knee braces that do not meet the above criteria are considered a contractual exclusion because it is considered a “special or extra cost convenience feature” under the durable medical equipment/medical supplies benefit in most contracts. |

<table>
<thead>
<tr>
<th>Prophylactic Knee Brace</th>
<th></th>
</tr>
</thead>
</table>
| Prophylactic knee braces (custom or prefabricated) | Prophylactic knee braces are considered not medically necessary for all indications.  
\>
  - 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.) |

<table>
<thead>
<tr>
<th>Ankle-Foot-Orthoses/Knee-Ankle-Foot-Orthoses</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefabricated ankle-foot orthoses, Knee-ankle-foot orthoses</td>
<td>Prefabricated ankle-foot-orthoses (AFOs) may be considered medically necessary for ambulatory individuals with weakness or deformity of the foot and ankle who require stabilization for medical reasons and are expected to have improved function with use of the device.</td>
</tr>
<tr>
<td>Type of Orthosis</td>
<td>Coverage Criteria</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Prefabricated knee-ankle-foot-orthoses (KAFOs)</strong> are considered medically</td>
<td>necessary for ambulatory individuals who meet criteria for an ankle-foot orthosis and require additional knee stability. Pre-fabricated AFOs and KAFOs that do not meet these criteria are considered not medically necessary.</td>
</tr>
</tbody>
</table>
| **Custom made AFOs or KAFOs (custom-fabricated, custom molded)**              | Custom-made AFOs and KAFOs that are “molded-to-patient-model” for an ambulatory individual who meets the above medical necessity criteria for a prefabricated AFO or KAFO are considered medically necessary when ANY of the following criteria are met:  
  • The individual could not be fit with a prefabricated AFO  
  • The condition necessitating the orthosis is expected to be permanent or of long-standing duration (>6 months)  
  • The individual has a documented neurological, circulatory, or orthopedic status that requires custom fabrication to prevent tissue injury  
  • There is a need to control the knee, ankle, or foot in more than one plane  
  • The individual has a healing fracture that lacks normal anatomical integrity or anthropometric proportions  

| **Documentation Requirements**                                                | The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:                                                                                                                   |
|                                                                              | **Unloader custom made knee braces (custom fabricated, custom molded):**  
  • Patient has painful osteoarthritis involving the medial compartment of the knee (causing a varus deformity) or the lateral compartment of the knee (causing a valgus deformity)  

  **AND**  
  • Patient has tried and did not fit a premade unloader brace even after adjustment, because of:  
    o An unusual leg shape or size |
**Documentation Requirements**

- A knee deformity
  - **OR**
  - There is not enough muscle to allow a premade brace to fit correctly

**Prefabricated unloader knee brace (off-the-shelf, ready-made, custom-fitted):**
- Documentation that patient has painful osteoarthritis of the medial or lateral compartment of the knee

**Prefabricated functional knee brace (off-the-shelf, ready-made, custom-fitted):**
Clinical documentation that the patient is able to walk and:
- Physical exam shows patient’s knee is unstable due to a knee injury
  - **OR**
  - Knee is unstable because of recent knee surgery
  - **OR**
  - Knee instability due to a knee deformity such as contracture or genu varum/valgum (bow legged/ knocked kneed) is present

**Custom-made functional knee brace:**
- Patient has tried and did not fit a premade functional brace even after adjustment because of:
  - An unusual leg shape or size
  - A knee deformity is present that interferes with fitting such as contracture or genu varum/valgum (bow legged/ knocked kneed)
  - **OR**
  - There is not enough muscle to allow a premade brace to fit correctly

**Prefabricated ankle-foot orthoses (AFOs):**
Clinical documentation:
- That the patient is able to walk and has weakness or deformity of the foot and ankle needing stabilization
  - **AND**
  - Documentation of expected improved function with the use of the orthosis

**Prefabricated knee-ankle-foot-orthoses (KAFOs):**
Documentation Requirements

- All of the above documentation under AFOs and additional documentation of knee instability

Custom-fabricated AFOs or KAFOs:

- All of the above documentation under AFOs and KAFOs and ANY of the following:
  - Patient could not be fit with a prefabricated AFO
  - Patient’s condition requires permanent or long-duration (>6months) use of orthosis
  - Patient has neurological, circulatory, or orthopedic status that requires custom fabrication to prevent tissue injury
  - There is a need to control the knee, ankle, or foot in more than one plane
  - Patient has a healing fracture that lacks normal anatomical integrity or anthropometric proportions

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
<table>
<thead>
<tr>
<th>Code</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>L1860</td>
<td>Knee orthotic (KO), modification of supracondylar prosthetic socket, custom fabricated (SK)</td>
</tr>
<tr>
<td>L1945</td>
<td>Ankle-foot orthotic (AFO), plastic, rigid anterior tibial section (floor reaction), custom fabricated</td>
</tr>
<tr>
<td>L2755</td>
<td>Addition to lower extremity orthotic, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthotic only</td>
</tr>
</tbody>
</table>

**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**

Custom 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.
Definition of Terms

**Ankle-foot-orthoses (AFOs):** These extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle. These features distinguish them from foot orthoses which are shoe inserts that do not extend above the ankle.

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

**Knee-ankle-foot-orthoses (KAFOs):** An orthosis designed to control knee and ankle motion that extends from the upper portion of the thigh, crossing the knee and ankle and ending at the toes.

**Orthosis (brace):** A rigid or semi-rigid device that is used for the purpose of supporting a weak or deformed body part, or for restricting or eliminating motion in a diseased or injured part of the body. An orthosis can be either prefabricated or custom-fabricated.

**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).
Description

*Knee Orthoses*

Knee injury, knee surgery, or osteoarthritis may result in a knee that is unstable. A knee brace is an orthosis or orthopedic appliance used to provide support and motion control during functional activity. A brace supports or holds in correct position any movable part of the body that allows for motion of that part. It must be rigid or semirigid and support a weak or deformed body part or restrict or eliminate motion in a diseased or injured part of the body. It provides support and counterforce on the limb on which it is being used.

Background

Knee braces may be custom made or available off-the-shelf in a variety of sizes. Knee braces may be intended for rehabilitation, to reduce pain, or to prevent injury in either stable or unstable knees.

Knee braces typically consist of 3 components:

- A superstructure (usually a rigid shell),
- A hinge
- A strap system

The superstructure extends proximally and distally to a hinge centered on the knee axis of motion. The strapping system secures the brace to the limb.

There are different kinds of knee braces which may be used for different types of clinical situations. They are classified by the type of manufacturing process and categorized according to their intended use.

Manufacturing Classification

Prefabricated knee braces also known as off-the-shelf braces, are manufactured in standard sizes and require only minimal adjustments. These braces come in a selection of sizes (small, medium, large, extra-large) and only require measurements and a sizing chart for fitting. A prefabricated knee brace may be modified, by an individual with expertise, with minimal adjustments that have been assembled, bent, trimmed, molded, or otherwise customized to fit
the specific person. These minimal adjustments are custom fitted which should not be confused with custom fabricated (custom made).

**Custom-made knee braces**, also known as custom molded or custom fabricated braces, are fabricated specifically for an individual. These braces generally use materials such as, plastic, metal, leather, or cloth in the form of sheets or bars. Fabrication involves substantial work such as cutting, bending, molding, or sewing and may involve the incorporation of some prefabricated components. Constructing a custom-made knee brace involves more than trimming, bending, or other modifications to a substantially prefabricated item. A molded-to-member-model orthosis is a particular type of custom-made orthosis in which an impression of the specific body part is made by means of a plaster cast or computer aided design/computer aided manufacturing (CAD-CAM) technology. This impression is then used to make a positive model of plaster or other material of the body part. The orthosis is then molded on this positive model.

Studies comparing prefabricated and custom braces have found few significant clinical differences between the two types of braces. There is not significant evidence available that the use of custom braces over prefabricated braces are more effective.

**Categories of Knee Braces**

**Prophylactic** knee 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 is the area of the most common athletic knee injuries. However, no conclusive evidence support their effectiveness and they are not recommended for regular use.

**Rehabilitation** knee braces are designed to allow protected motion of injured knees that have been treated operatively or nonoperatively. 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 are not custom-made.

**Functional** knee 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 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 to unload the compressive forces on the medial compartment. In other words, 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 (see examples below).

Custom-Made Unloader Knee Braces

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bledsoe Brace Systems (Grand Prairie, TX)</td>
<td>Axion OA-Custom (Axion series), OA A1R-Custom, Thruster RLF, Z-12 OA</td>
</tr>
<tr>
<td>DeRoyal® Industries (Powell, TN)</td>
<td>Custom Knee Braces, OA Knee Brace</td>
</tr>
<tr>
<td>DonJoy/dj Orthopedics (Vista, CA)</td>
<td>OA Defiance®</td>
</tr>
<tr>
<td>Össur Americas (Foothill Ranch, CA)</td>
<td>CTi® OA models (Pro Sport, Standard, Vapor®), Custom OA Unloader® models</td>
</tr>
<tr>
<td></td>
<td>(ADJ®, LP®, One®, Select®, XT®)</td>
</tr>
<tr>
<td>Townsend Design (Bakersfield, CA)</td>
<td>Polio &amp; Trigger series, Premier &amp; Reliever series (Custom-fabricated models for severe osteoarthritis)</td>
</tr>
</tbody>
</table>

Note: Not intended to be a complete list of devices.

Off-the-Shelf (prefabricated) Bracing

Manufacturers offer different sizes of off-the-shelf braces. Sizing is determined by taking a measurement of the thigh, circumferentially, six inches (15 cm) above mid-patella or knee cap. See below, an example of one company’s measurements.

<table>
<thead>
<tr>
<th>Size</th>
<th>Measurement 1</th>
<th>Measurement 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>XS</td>
<td>33 – 39 cm</td>
<td>13” - 15 ½”</td>
</tr>
<tr>
<td>S</td>
<td>39 – 47 cm</td>
<td>15 ½” - 18½”</td>
</tr>
<tr>
<td>M</td>
<td>47 – 53 cm</td>
<td>18½” - 21”</td>
</tr>
<tr>
<td>L</td>
<td>53 – 60 cm</td>
<td>21” - 23½”</td>
</tr>
<tr>
<td>XL</td>
<td>60 – 67 cm</td>
<td>23½” - 26½”</td>
</tr>
<tr>
<td>XXL</td>
<td>67 – 75 cm</td>
<td>26½” - 29½”</td>
</tr>
<tr>
<td>XXXL</td>
<td>75 – 81,25 cm</td>
<td>29½” - 32”</td>
</tr>
</tbody>
</table>
Terminology and Coding Information

In general, the term “custom-made” describes a brace that is made for one patient according to precise measurements or molds/casts of the individual patient. Thus, a custom-made brace is only used by one specific patient. According to the HCPCS codes, the following terms describe “custom-made” braces:

- Custom fabricated; or
- Molded-to-patient model

According to the HCPCS codes, off-the-shelf knee brace models are described as “custom fitted”. These braces are prefabricated or mass-produced and come pre-sized, ie, small, medium, large, etc. The brace can be modified easily to meet the patient's rehabilitation need without the wait for a custom-made brace that requires special molds/casts and detailed fitting. The orthotist may provide the initial functional assessment and fit, as well as make simple adjustments to the off-the-shelf brace(s) to enable same day use, in many cases.

Ankle-Foot-Orthoses and Knee-Ankle-Foot-Orthoses

Ankle-foot-orthoses and knee-ankle-foot-orthoses are orthopedic appliances used to support, align, prevent or correct deformities. Some are rigid (static) and are used to support weakened or paralyzed body parts in a particular position while others are dynamic and are used to allow body motion for optimal function. These orthoses can either be prefabricated or custom-fabricated, which also includes a molded-to-patient model orthosis which is a special type of custom-fabricated orthosis for which an impression of the specific body part is made. The impression is then used to make a specific patient model. The orthosis is then molded from the patient-specific model. Likewise, a digital image of the patient’s affected body part may be made using Computer-Aided-Design-Computer-Aid Manufacturing (CAD-CAM) systems software. This technology creates a computerized model and direct milling equipment then carves the model, which is an exact replica of the affected body part. The carved model is then individually fabricated and molded over the positive model of the patient.

Lower limb orthoses are classified according to their anatomic location, for example, foot orthoses, ankle orthoses, ankle-foot-orthoses (AFOs), knee-ankle-foot-orthoses (KAFOs). Foot orthoses are devices that are placed in shoes; ankle orthoses are devices used to support and
immobilize the ankle. AFOs have both a shoe and ankle component and KAFOs contain shoe, ankle and knee components.

AFOs extend above the ankle to the top of the calf. They are commonly used to treat disorders of ankle dorsiflexion (upward motion), plantar flexion (downward motion), inversion and eversion (turning inward or outward), spastic displegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia associated with cerebral infarction.

A KAFO is an AFO with metal uprights, a mechanical knee joint, and two thigh bands. They are used in individuals who require additional support to the knee for stability.

The Intrepid Dynamic Exoskeleton Orthosis (IDEO) is a custom fabricated, dynamic response carbon fiber AFO that is reported to stabilize ankle support while reducing forefoot abduction or adduction. It was developed for military individuals who suffered massive tissue, nerve, and bone damage to enable them to return to high-level physical function capabilities to the injured ankle. The carbon fiber posterior strut is dynamic as it stores energy and returns the energy stored during the stance phase of gait to help power push-off to aid in ambulation. The IDEO is custom molded out of lightweight black carbon that includes a foot plate and a strut that runs up the back of the calf to a cuff that is situated just below the knee. This adaptation reportedly provides injury-specific deflection, energy storage and power, all while maintaining control and minimizing pain.

The ExoSym™ kinetic orthosis (a hybrid prosthetic-orthotic device) was designed by the same prosthetist who designed the Intrepid Dynamic Exoskeletal Orthosis (IDEO) for the military (a U.S Army medical facility product), and who is now designing for civilians to restore high-level activity and function to patients with severe lower-extremity conditions or injuries. The device has been used to treat patients with ankle fusions, partial-foot amputations, fractures, tarsal coalitions and other lower extremity dysfunctions. The ExoSym™ is lighter, thinner and stronger than the IDEO. The ExoSym™ is custom-made for each individual’s needs with reported optimal alignment, positioning, off-loading, and control. The device is provided as part of a care program which takes place at a specially designed facility where a training regimen and ongoing adjustments can be made as the patient progresses through 8 visits of rehabilitation.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS provided a 2013 clinical practice guideline 2nd edition update 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 valgus-directing force brace (medial compartment unloader) for patients with symptomatic osteoarthritis of the knee, based on limited evidence for the effectiveness of knee braces.\textsuperscript{4,6}

The AAOS published clinical practice guideline in 2014\textsuperscript{31-33} 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.

\textit{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.\textsuperscript{34,35}

\textit{The Osteoarthritis Research Society International (OARSI)}

The OARSI treatment guidelines from 2014 recommend the following: We recommend use of biomechanical interventions as directed by an appropriate specialist. One review suggested that knee braces and foot orthoses were effective in decreasing pain, joint stiffness, and drug dosage and also improved physical function, with insignificant adverse events.\textsuperscript{37}


29. Smith TO, Davies L. A systematic review of bracing following reconstruction of the anterior cruciate ligament. Physiotherapy 2008;94(1):1-10


History

<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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</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>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 &quot;When the patient's clinical condition meets the requirement for an off-the-shelf (prefabricated) knee brace but the patient</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>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>
<td></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 title, as they apply to the entire section, “Custom-made Knee Brace/Knee Orthosis (L1834, L1840, L1844, L1846, L1860)” – not just to unloader knee braces as had been previously listed.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>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.</td>
</tr>
<tr>
<td>06/01/17</td>
<td>Annual review, approved May 23, 2017. No changes to policy statement. Coverage criteria clarified with grammatical corrections.</td>
</tr>
<tr>
<td>10/01/18</td>
<td>Annual Review, approved September 11, 2018. Policy title changed from “Knee Braces” to “Knee Orthoses, Ankle-Foot and Knee-Ankle-Foot Orthoses”. Policy statement added: Custom AFOs and KFOs are considered medically necessary when criteria are met and not medically necessary when criteria are not met. References 33, 37-41</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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</tbody>
</table>

**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). ©2019 Premera All Rights Reserved.

**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5952. TTY 800-537-5357
Email AppealsDepartmentInquiries@Premera.com

You can also 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.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

Office for Civil Rights Complaint Portal, available at
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).


Cushite (Oromo): Daytoy a Pakdaar ket Naglaan iti Napateg nga Impomasion. Daytoy a pakdaar mabalin nga adda ket naglaan iti napateg nga impomasion maipanggep iti aplikaysyon wone coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaar. Mabalin nga adda radda ngu aramnidee nga adda sakkay dagiti partikul a naituding a dafun nga alaw tapo mapatalignayeyo ti coverage ti salun-ayyo wenno tulong kadagiti gastos. Adda karbenganyo a mongala iti daytoy nga impomasion ken tulong iti bukodyo a pagsasao nga awan ti bayadando. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

To ogłoszenie zawiera ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Polskiego Funduszu Oszczędności Pracy oraz Polskiej Kasy Chorych. Informacje zawarte w tym ogłoszeniu oraz w Publicznych Finansach są ważnymi informacjami dla osób korzystających z tych usług. Ostatnia aktualizacja na ten dzień to 2022-12-31. (TTY: 800-842-5357)

Premera Blue Cross

Polski (Polish):

To ogłoszenie zawiera ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Polskiego Funduszu Oszczędności Pracy oraz Polskiej Kasy Chorych. Informacje zawarte w tym ogłoszeniu oraz w Publicznych Finansach są ważnymi informacjami dla osób korzystających z tych usług. Ostatnia aktualizacja na ten dzień to 2022-12-31. (TTY: 800-842-5357)

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357)

Română (Romanian):


Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется привести к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357)

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357)

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hỗ trợ bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện những hành động sau khi nhận được thông báo này để đủ điều bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357)