LifeWise
Health Plan of Washington

MEDICAL POLICY – 1.03.501

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

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RELATED MEDICAL POLICIES:

1.01.529	Durable Medical Equipment
7.01.15	Meniscal Allograft and Other Meniscal Implants
7.01.549	Knee Arthroscopy in Adults

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | 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.

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 custom 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

Type of Orthosis	Coverage Criteria
Unloader Knee Brace	

Custom-made unloader knee brace (HCPCS L1844)	**Custom-made unloader knee braces may be considered medically necessary when all of the following criteria are met:**
	• The individual 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
	• A prefabricated 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 (e.g. valgus, varus deformity) is present that interferes with fitting of the brace
	  ▪ Varus = knee joint is outward compared to the foot
	  ▪ Valgus = knee joint is inward compared to the foot)
	  OR
	  ○ Minimal muscle mass upon which to suspend an orthosis interferes with fitting of the brace
	
	Custom-made unloader knee braces are considered not medically necessary when:
	• A prefabricated unloader knee brace can be custom fit and adjusted for the individual.
	
	Custom-made unloader knee braces for any condition other than osteoarthritis is considered a contractual exclusion because it is considered a "special or extra cost convenience

Type of Orthosis	Coverage Criteria
	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 individuals with small legs, the use of extra-long straps for individuals with large limbs or addition of extension segments for tall individuals. The knee brace request should include the individual's thigh measurement and the size of thigh the manufacturer's largest knee brace will fit.
Functional Knee Brace	
Custom-made functional knee brace	**Custom-made functional knee braces may be considered medically necessary when one of the following criteria are met:** • Knee instability due to a knee injury (fracture, ligament tear) is documented on a physical exam **OR** • Knee instability due to recent knee surgery (rehabilitation 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 **AND** • A prefabricated 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 individuals with small legs, the use of extra-long straps for individuals with large limbs or addition of extension segments for tall individuals. The knee brace request should include the individual's thigh measurement and the size of thigh the manufacturer's largest knee brace will fit.

Type of Orthosis	Coverage Criteria
	Custom-made functional knee braces are considered not medically necessary when: • A prefabricated functional knee brace can be custom fit and adjusted for the individual. **Custom-made functional knee braces for other conditions than those noted above 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.**
Prophylactic Knee Brace	
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 before or after surgery. (Using a brace for this indication has not been proven in the clinical literature.)
Ankle-Foot-Orthoses/Knee-Ankle-Foot-Orthoses	
Custom made AFOs or KAFOs (custom-fabricated, custom molded)	**Custom-made AFOs and KAFOs that are "molded-to-patient-model" for an ambulatory individual are considered medically necessary when ANY of the following criteria are met:** • The individual could not be fit with a prefabricated AFO or KAFO • 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 **Custom-made AFOs and KAFOs that do not meet the above criteria are considered not medically necessary**

Documentation Requirements

The individual'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):

- Individual 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

- Individual has tried and did not fit a premade unloader brace even after adjustment, because of:
  - An unusual leg shape or size
  - A knee deformity

  OR
  - There is not enough muscle to allow a premade brace to fit correctly

Custom-made functional knee brace:

- Individual 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

Custom-fabricated AFOs or KAFOs:

- All of the above documentation under AFOs and KAFOs and ANY of the following:
  - Individual could not be fit with a prefabricated AFO
  - Individual's condition requires permanent or -duration of (>6months) use of orthosis
  - Individual 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
  - Individual 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 individual can walk (is ambulatory)
- The medical condition that indicates why use of a brace will benefit the individual
- Report from any imaging studies that were done
- Information about attempts to adjust a prefabricated brace to fit the individual. 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 individual's thigh measurement that exceeds the size of thigh the manufacturer's largest prefabricated brace is designed to fit

Coding

Code	Description
HCPCS	
L1834	Knee orthosis (KO), without knee joint, rigid, custom fabricated
L1840	Knee orthosis (KO), derotation, medial-lateral, anterior cruciate ligament, custom fabricated
L1844	Knee orthosis (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
L1846	Knee orthosis, 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
L1860	Knee orthosis (KO), modification of supracondylar prosthetic socket, custom fabricated (SK)

Code	Description
L1945	Ankle-foot orthosis (AFO), plastic, rigid anterior tibial section (floor reaction), custom fabricated
L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthotic only

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

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 kneecap 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 support 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).

Evidence Review

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 supports 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 individuals 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

Manufacturer	Brand Name
Bledsoe Brace Systems (Grand Prairie, TX)	Axion OA-Custom (Axion series), OA AIR-Custom, Thruster RLF, Z-12 OA
DeRoyal Industries (Powell, TN)	Custom Knee Braces, OA Knee Brace
DonJoy/dj Orthopedics (Vista, CA)	OA Defiance
Össur Americas (Foothill Ranch, CA)	CTi OA models (Pro Sport, Standard, Vapor), Custom OA Unloader models (ADJ, LP, One, Select, XT)

Manufacturer	Brand Name
Townsend Design (Bakersfield, CA)	Polio & Trigger series, Premier & Reliever series (Custom-fabricated models for severe osteoarthritis)

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

Off-the-Shelf (prefabricated) Brace Sizing Chart

Circumference measurements should be taken at knee center, 6" (15cm) above knee center and 6" (15cm) below knee center. An abnormal contour exists when either the calf or thigh measurements do not fall within the same category (i.e., the calf is in the small category but the thigh is in the medium category).

Size	Thigh	Knee Center	Calf
XS (X=1)	13" - 15 ½" (33 – 39 cm)	12"-13" (30.5-33 cm)	10"-12" (25.5-30.5 cm)
S (X=2)	15 ½" – 18½" (39 - 47 cm)	13"-14" (33-35.5 cm)	12"-14" (30-35.5 cm)
M (X=3)	18½" – 21" (47 - 53.25 cm)	14"-15" (35.5-38 cm)	14"-16" (35.5-40.5 cm)
L (X=4)	21" – 23½" (53.25 - 59.5 cm)	15"-17" (38-43 cm)	16"-18" (40.5-47 cm)
XL (X=5)	23½" – 26½" (59.5 - 67.25 cm)	17"-19" (43-48.25 cm)	18"-20" (47-50.75 cm)
XXL (X=6)	26½" – 29½" (67.25 - 75 cm)	19"-21" (48.25-53.25 cm)	20"-22" (50.75-56 cm)
XXXL (X=7)	29½" – 32" (75 - 81.25 cm)	21"-23" (53.25-58.5 cm)	22"-24" (56-61 cm)

Source: DJO Global, Donjoy (Specifications), Off-The-Shelf Knee Brace Sizing Chart. **https://www.djoglobal.com/sites/default/files/DonJoy%20Preferred%20Products%20Catalog.pdf** . Accessed April 1, 2024.

Terminology and Coding Information

In general, the term "custom-made" describes a brace that is made for one individual according to precise measurements or molds/casts of the individual patient. Thus, a custom-made brace is only used by one specific individual. 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, i.e., small, medium, large, etc. The brace can be modified easily to meet the individual'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 individual model. The orthosis is then molded from the patient-specific model. Likewise, a digital image of the individual'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 individual.

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 diplegia 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 individuals with severe lower-extremity conditions or injuries. The device has been used to treat individuals 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 individual 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.[45] The AAOS was unable to make a recommendation for or against the use of a valgus-directing force brace (medial compartment unloader) for individuals with symptomatic osteoarthritis of the knee, based on limited evidence for the effectiveness of knee braces.[4,6]

In 2021, the AAOS published in their evidence-based clinical practice guideline on management of osteoarthritis of the knee (non-arthroplasty) the recommendation that brace treatment could improve function, pain, and quality of life in individuals with knee osteoarthritis.

The AAOS published a clinical practice guideline in 2014[46] 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.[38,46]

American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee

In 2019, the ACR and AF strongly recommended tibiofemoral knee braces for the management of knee osteoarthritis in whom disease in one or both knees is causing a sufficiently large impact on ambulation, joint stability, or pain to warrant use of an assistive device…[59]

National Institute for Health and Care Excellence (NICE)

In 2022, NICE[41] changed their clinical guideline on osteoarthritis to a NICE guideline with the following recommendation for non-pharmacological management devices: to consider walking aids for individuals with lower limb osteoarthritis and to not routinely offer insoles, braces, tape, splints or supports to individuals with osteoarthritis unless there is joint instability or abnormal biomechanical loading where therapeutic exercise has been ineffective and the addition of an aid or device is likely to improve movement and function.

The Osteoarthritis Research Society International (OARSI)

The OARSI treatment guidelines from 2014 recommended 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."[47]

The OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis in 2019 gave a ≥ 75% "in favor" and > 50% "conditional" recommendation for non-pharmacologic treatment for knee osteoarthritis such as aquatic exercise, gait aids, and self-management programs.[58]

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History

Date	Comments
06/25/98	Add to Durable Medical Equipment Section - New Policy
11/05/99	Replace Policy - Description revised.
09/11/01	Replace Policy - Scheduled update
10/09/01	Replace Policy - HCPCS codes added; reviewed by Care Management staff.
05/14/02	Replace Policy - Benefits Application Section updated.
10/08/02	Replace Policy - Policy reviewed; policy statement unchanged. Additional references added.
12/10/02	Replace Policy - Policy reviewed; reimbursement for custom brace language updated.
12/09/03	Replace Policy - Policy reviewed; policy statement added concerning elective sports braces. Additional references and HCPC codes added.
01/01/04	Replace Policy - HCPC code update only.
07/13/04	Replace Policy - Policy reviewed; policy statement unchanged. Tables, Rationale and References updated.
09/01/04	Replace Policy - Policy renumbered from PR.1.03.100. No date changes.
09/14/04	Replace Policy - Policy reviewed; policy statement unchanged. Benefit Application and Rationale updated.

Date	Comments
09/13/05	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.
02/06/06	Codes updated - No other changes.
06/23/06	Update Scope and Disclaimer - No other changes.
09/12/06	Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.
08/14/07	Replace Policy - Policy updated with literature review; references added. No change in policy statement.
08/12/08	Replace Policy - Policy updated with literature search; no change to the policy statement.
08/11/09	New BC - Policy updated with literature search and converted to BC version. Replaces PR.1.03.500. Policy statement reworded but essentially unchanged.
09/14/10	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
07/12/11	Replace Policy - Policy updated with literature review; reference added. 2011 update added to osteoarthritis section. No change to the policy statement.
07/20/12	Replace policy. No change in policy statement.
07/24/13	Replace policy. Policy reviewed. Minor edits for readability. A review of the literature through April 2013 did not prompt any additions to the references. Policy statement unchanged.
10/14/13	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.
05/12/14	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.
07/24/14	Update Related Policies. Change title to 7.01.549.
08/18/14	Coding update. HCPCS codes L1844 and L1846 reversed in coding table within Policy Guidelines section. In the previous version; they have been corrected.

Date	Comments
11/10/14	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).
03/11/15	Update Related Policies. Add 1.01.529.
03/24/15	Update Related Policies. Change title to 7.01.549.
05/27/15	Annual Review. Added an off the shelf knee brace sizing chart to the Policy Guidelines section.
04/01/16	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.
04/14/16	Coding Update. Removed prefabricated codes from policy.
05/15/16	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.
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.
10/01/18	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 added. Removed HCPCS code L1847. Added HCPCS codes L1945 and L2755.
05/01/19	Annual Review, approved April 2, 2019. References 13-16, 26-28, 35-38, 44, 48-50, 54-55 added. Minor edits for clarity; otherwise, policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. References updated. Policy statements unchanged.
11/01/21	Annual Review, approved October 21, 2021. Policy reviewed. Reference added. Policy statement unchanged.
10/01/22	Annual Review, approved September 13, 2022. Policy reviewed. Policy title changed to "Custom-made Knee Orthoses (Braces), Ankle-Foot-Orthoses, and Knee-Ankle-Foot-Orthoses" from "Knee Orthoses (Braces), Ankle-Foot-Orthoses, and Knee-Ankle-Foot-

Date	Comments
	Orthoses". Specific prefabricated orthoses criteria removed from the policy. References added. Clarifying edits made for when criteria is not met for custom functional knee braces. Changed from "patient" to "individual" for standardization.
02/01/23	Annual Review, approved January 23, 2023. Policy reviewed. No references added. Policy statements unchanged.
05/01/24	Annual Review, approved April 22, 2024. Policy reviewed. Policy statements unchanged.

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.

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