

BSC1.05	Knee Braces (Custom)		
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Section:	1.0 Durable Medical Equipment	Page:	Page 1 of 17

Policy Statement

- I. **Custom-fabricated functional or derotation knee braces** may be considered **medically necessary**, when **all** of the following are met (this list may not be all-inclusive):
 - A. Documentation of **any** of the following:
 1. Knee instability due to injury (including history of surgery for the injury)
 2. Non-fixed flexion or extension knee contracture
 3. Knee deformity requiring stabilization
 4. Knee instability by physical exam
 5. Neurological weakness requiring stabilization of the knee
 - B. **Off-the-shelf** knee brace would not provide a satisfactory fit
 - C. Documentation of **any** of the following:
 1. **Abnormal limb contour** (i.e., disproportionate **size/shape** [See Policy Guidelines])
 2. Knee deformity (i.e., valgus [knock-kneed], varus [bow legged] deformity) minimal muscle mass upon which to suspend the orthosis

- II. **Custom-fabricated unloading/offloading knee braces (single or double upright)** may be considered **medically necessary** when **all** of the following are met:
 - A. Documentation of **any** of the following:
 1. Knee instability due to injury (including history of surgery for the injury)
 2. Painful unicompartamental osteoarthritis (OA) of the knee, which interferes with normal activities of daily living
 3. Non-fixed flexion or extension knee contracture
 4. Knee deformity requiring stabilization
 5. Knee instability by physical exam
 6. Neurological weakness requiring stabilization of the knee
 - B. **Off-the-shelf** knee brace would not provide a satisfactory fit
 - C. Documentation of **any** of the following:
 1. **Abnormal limb contour** (i.e., disproportionate **size/shape** [See Policy Guidelines])
 2. Knee deformity (i.e., valgus [knock-kneed], varus [bow legged] deformity) minimal muscle mass upon which to suspend the orthosis

- III. **Knee brace add-ons** may be considered **medically necessary** for **any** of the following:
 - A. Daily activity level (i.e., employment) requires a brace designed for high-impact/high-stress activities
 - B. Extensions for an unusually tall individual
 - C. individual with a non-fixed flexion contracture of the knee
 - D. Pediatric model for an individual with short stature
 - E. Weight is greater than 250 pounds

- IV. Prophylactic braces (either prefabricated or custom) are considered **not medically necessary** for any indication. They are used frequently for sports and recreation to try to prevent injury before and after surgery. This use has not been proven to improve net health outcome in literature.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

All other knee brace add-ons may be considered with a prescription signed by the referring provider that specifies each add-on code, along with the appropriate diagnosis and clinical documentation to support its use.

Knee braces are divided into the following four categories based on their intended use. Rehabilitation and prophylactic purposes use functional or unloader braces:

- **Functional** knee braces are designed to assist or provide stability for unstable knees during activities of daily living (ADL) or vocational or avocational activities:
 - Off-the-shelf or prefabricated
 - Custom fabricated (custom made) or molded to the individual
- **Rehabilitation** knee braces are designed to allow protected motion of injured knees that have been treated operatively or non-operatively, are usually purchased off the shelf and used for 6 to 12 weeks after injury:
 - Off-the-shelf or prefabricated
- **Unloader** knee braces are specifically designed to reduce the pain and disability associated with severe unicompartmental osteoarthritis of the knee by bracing the knee in the valgus position in order to unload the compressive forces on the involved compartment:
 - Off-the-shelf or prefabricated
 - Custom fabricated (custom made) or molded to the individual
- **Prophylactic** knee braces attempt to prevent or reduce the severity of knee ligament injuries, and are primarily used in recreational or organized sports:
 - Off-the-shelf or prefabricated
 - Custom fabricated (custom made) or molded to the individual

Off-The-Shelf Knee Brace Sizing Chart¹

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"-15.5" (33-39 cm)	12"-13" (30.5-33 cm)	10"-12" (25.5-30.5 cm)
S (X=2)	15.5"-18.5" (39-47 cm)	13"-14" (33-35.5 cm)	12"-14" (30-35.5 cm)
M (X=3)	18.5"-21" (47-53.25 cm)	14"-15" (35.5-38 cm)	14"-16" (35.5-40.5 cm)
L (X=4)	21"-23.5" (53.25-59.5 cm)	15"-17" (38-43 cm)	16"-18" (40.5-47 cm)
XL (X=5)	23.5"-26.5" (59.5-67.25 cm)	17"-19" (43-48.25 cm)	18"-20" (47-50.75 cm)
XXL (X=6)	26.5"-29.5" (67.25-75 cm)	19"-21" (48.25-53.25 cm)	20"-22" (50.75-56 cm)
XXXL (X=7)	29.5"-32" (75-81.25 cm)	21"-23" (56-61 cm)	22"-24" (53.25-58.5 cm)

Coding

Prefabricated Knee Brace

- **L1810**: Knee orthosis (KO), elastic with joints, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
- **L1812**: Knee orthosis (KO), elastic with joints, prefabricated, off-the-shelf

- **L1820:** Knee orthosis (KO), elastic with joints, prefabricated, off-the-shelf
- **L1830 (knee immobilizer):** Knee orthosis (KO), immobilizer, canvas longitudinal, prefabricated, off-the-shelf
- **L1831:** Knee orthosis (KO), locking knee joint(s), positional orthosis, prefabricated, includes fitting and adjustment
- **L1832 (post-operative brace):** Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
- **L1833:** Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf
- **L1836 (knee immobilizer):** Knee orthosis (KO), rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
- **L1843 (functional brace/unloader brace):** 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, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
- **L1845 (functional brace/unloader brace):** Knee orthosis (KO), 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, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
- **L1847 (functional brace):** Knee orthosis (KO), 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
- **L1848:** Knee orthosis (KO), double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf
- **L1850:** Knee orthosis (KO), Swedish type, prefabricated, off-the-shelf
- **L1851:** 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, prefabricated, off-the-shelf
- **L1852:** Knee orthosis (KO), 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, prefabricated, off-the-shelf

Custom-fabricated Knee Brace

- **L1834 (functional brace/knee immobilizer):** Knee orthosis (KO), without knee joint, rigid, custom fabricated
- **L1840 (functional brace/unloader brace/knee immobilizer):** Knee orthosis (KO), derotation, medial-lateral, anterior cruciate ligament, custom fabricated
- **L1844 (functional brace/unloader brace):** 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 (functional brace/unloader brace):** Knee orthosis (KO), 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 (functional brace):** Knee orthosis (KO), modification of supracondylar prosthetic socket, custom fabricated (SK)

Additions to Knee Brace

Covered when medically necessary for an individual who meets criteria for a custom-fabricated knee brace and either daily activity level requires a brace designed for high-impact/high stress activities, the individual weighs greater than 250 pounds or the individual has a non-fixed flexion contracture of the knee:

- **L2755:** Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only
- **L2800:** Addition to lower extremity orthosis, knee control, knee cap, medial or lateral pull, for use with custom fabricated orthosis only

Additions to Knee Brace

- **K0672*:** Addition to lower extremity orthotic, removable soft interface, all components, replacement only, each
- **L2397:** Addition to lower extremity orthosis, suspension sleeve
- **L2820*:** Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
- **L2830*:** Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
- **L2840:** Addition to lower extremity orthosis, tibial length sock, fracture or equal, each
- **L2850:** Addition to lower extremity orthosis, femoral length sock, fracture or equal, each
- **L2385:** Addition to lower extremity, straight knee joint, heavy-duty, each joint
- **L2395:** Addition to lower extremity, offset knee joint, heavy-duty, each joint

***Note:** Not covered/not medically necessary when billed in addition to the initial dispensing of the device.

Repair /Replacement

- **L4205:** Repair of orthotic device, labor component, per 15 minutes
- **L4210:** Repair of orthotic device, repair or replace minor parts

Description

Knee braces typically consist of three components: a superstructure (rigid or semi-rigid), a hinge, and a strap system. The super structure extends proximally and distally to a hinge centered on the knee axis of motion. The strapping system secures the brace to the limb.

Related Policies

- Knee Arthroplasty for Adults

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Knee braces typically consist of 3 components: a superstructure (usually a rigid shell), a hinge, and 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.

Knee braces are divided into the following four categories based on their intended use:

- **Functional** knee braces are designed to assist or provide stability for unstable knees during activities of daily living (ADL) or vocational or avocational activities:
 - Off-the-shelf or prefabricated
 - Custom fabricated (custom made) or molded to the patient
- **Rehabilitation** knee braces are designed to allow protected motion of injured knees that have been treated operatively or non-operatively, are usually purchased off the shelf and used for 6 to 12 weeks after injury:
 - Off-the-shelf or prefabricated
- **Unloader** knee braces are specifically designed to reduce the pain and disability associated with severe unicompartmental osteoarthritis of the knee by bracing the knee in the valgus position in order to unload the compressive forces on the involved compartment:
 - Off-the-shelf or prefabricated
 - Custom fabricated (custom made) or molded to the patient
- **Prophylactic** knee braces attempt to prevent or reduce the severity of knee ligament injuries, and are primarily used in recreational or organized sports:
 - Off-the-shelf or prefabricated
 - Custom fabricated (custom made) or molded to the patient

Literature Review

Functional Knee Braces

Functional knee braces come in a variety of forms and are designed to assist or provide stability for unstable knees during activities of daily living (ADL) or vocational or avocational activities. They can be either off-the-shelf, prefabricated, custom fabricated (custom made) or molded to the patient.

Methods of preventing and treating knee injuries have changed with the rapid development and refinement of knee braces. Functional knee braces are intended to stabilize knees during rotational and anteroposterior forces. They offer a useful adjunct to the treatment and rehabilitation of ligamentous knee injuries.²

Birmingham et al reported a randomized controlled trial (RCT) that compared the use of an off-the-shelf functional knee brace or Neoprene sleeve beginning 6 weeks after anterior cruciate ligament (ACL) reconstruction. Of 150 patients randomly assigned to a brace or sleeve after surgery, 127 (85%) completed 24-month follow-up. Compliance was similar for the 2 groups, and 3 patients from each group had graft failures and revision surgeries. Confidence in the knee was rated higher for the brace (70 vs 55, respectively out of 100), as was the rating of help in returning to sport (66 vs 53, respectively). No other outcome measures differed between the groups, including the ACL-quality-of-life questionnaire, highest activity level, satisfaction with the brace/sleeve, side-to-side laxity, or functional tests. As this report described evaluators as blinded to the patient's group allocation, it does not appear that the patients were wearing the brace or sleeve at the time of functional testing.³

Functional knee-braces are widely used to protect injured or reconstructed anterior cruciate ligaments, despite the fact that few scientific data support their efficacy. Beynon et al studied seven functional braces, representative of both the typical custom-fit and off-the-shelf designs. The braces were tested on subjects who had a normal anterior cruciate ligament and were scheduled for arthroscopic meniscectomy or exploration of the knee under local anesthesia. After the operative

procedure, a Hall-effect strain-transducer was applied to the anterior cruciate ligament. Under low anterior shear loads, two braces provided some protective strain-shielding effect compared with no brace, but this strain-shielding effect did not occur at the higher anterior shear loads expected during the high-stress activities common to athletic events. The DonJoy, Townsend, C.Ti., and Lenox Hill braces demonstrated a strain-shielding effect on the anterior cruciate ligament with an internal torque of five newton-meters applied to the tibia. None of the braces had any effect on strain on the anterior cruciate ligament during active range of motion of the knee from 10 to 120 degrees or during isometric contraction of the quadriceps. Wearing of a brace did not produce an increase in the value for strain on the anterior cruciate ligament. For the activities that were evaluated in this study, none of the braces produced adverse effects on the anterior cruciate ligament, and there were no significant differences in the strain on the anterior cruciate ligament between the use of a custom-fit or an off-the-shelf brace design. There were no apparent advantages of the more expensive custom-made braces compared with the off-the-shelf designs.⁴

There is evidence in the published scientific literature to indicate that functional braces are beneficial when the patient has demonstrated knee instability and is not a candidate for ACL reconstruction. Swirtun et al evaluated the effect of functional knee bracing on non-operated acute ACL-deficient patients, ninety-five patients (18 to 50 years old) with an acute ACL tear were included in the study. The subjects were randomized to either brace group, treated with functional bracing from the first testing session (less than 5 weeks postinjury) to 12 weeks postinjury or a control group, treated without bracing. The patients were followed for 6 months. Twenty-one subjects were excluded due to the following exclusion criteria: partial rupture or articular cartilage injury shown on Magnetic Resonance Imaging (MRI) or with arthroscopy, or other injuries that negatively affected rehabilitation, or dropped out due to surgery (n = 22), or personal reasons (n = 10). Forty-two patients remained in the study, 22 in the brace group and 20 in the control group. When using the brace, the subjects in the brace group experienced less (P = 0.047) sense of instability, evaluated with visual analogue scale, than the control group. However, bracing had no effect on any of the variables in Knee Osteoarthritis Outcome Score or Cincinnati knee score and no effect on quadriceps or hamstring muscle peak torque. Subjectively, the brace group experienced a positive effect of the brace on rehabilitation. The nonoperated acute ACL-deficient patients experienced a positive effect of the brace regarding sense of instability and rehabilitation. However, these findings were not supported by objective outcomes.⁵

Vianos et al completed a study at the University Hospitals of Cleveland including one hundred and forty-four boys who had Duchenne muscular dystrophy and who were managed at a single center between 1953 and 1994 and were followed for a mean of 8.9 years. The long duration of follow-up provided an opportunity to examine the effects of physical therapy and orthopaedic treatment on contractures of the lower extremities and on the duration of the ability to walk. Contractures of the lower extremities were controlled best when patients were managed with a combination of daily passive stretching exercises, prescribed periods of standing and walking, tenotomy of the Achilles tendon, posterior tibial-tendon transfer, and application of knee-ankle-foot orthoses. Approximately two years after bracing, the severity of the contracture of the heel cords was similar in the patients who had had an operation and those who had not. By the fourth year after bracing, however, the patients who had had an operation had less severe contractures than those who had had bracing alone. Five to seven years after the operation and bracing, control of contractures was still good, especially for the patients who had had posterior tibial-tendon transfer. Contracture of the knee was well controlled five to seven years after bracing in all patients who had had bracing, with or without an operation. The program enabled the patients who had been managed with bracing to walk until a mean age of 13.6 years. After loss of the ability to walk with bracing, the ability to stand continued for an additional two years with use of orthoses. The findings of the present study demonstrate the value of traditional methods of operative treatment and bracing for controlling contractures of the lower extremities in patients who have Duchenne muscular dystrophy and for prolonging their ability to walk.⁶

Custom-Fitted Prefabricated Functional Knee Braces

Functional knee braces are fabricated from a variety of materials, including carbon composites, aluminum, and Kevlar. Despite their relatively high cost, knee braces composed of carbon composites (also known as carbon fiber or graphite) are favored by competitive athletes because of their lightness. There are, however, no medical advantages of carbon fiber braces over braces composed of materials that are heavier, but equally as strong, such as steel or aluminum. A variety of suspension systems and knee joint designs are used in functional knee braces. There is, however, no evidence of medical benefits from one knee joint design over another. Therefore, custom-made braces are only considered medically necessary for persons who cannot fit into off-the-shelf braces because of a deformity that interferes with fitting (disproportionate size of calf and thigh or minimal muscle mass upon which to suspend a knee brace). Even persons who are very tall, short, or markedly obese, can be fitted with an off-the-shelf functional brace that have been modified with attachments, such as extensions and extra-long straps or size.

There were no controlled trials that compared the performance of custom-made and custom-fitted functional knee braces for use after reconstructive knee surgery. Decoster and Vailas reported on the results of their survey of knee bracing in patients with deficient or reconstructed ACLs. A total of 287 of the contacted 1,194 orthopedists responded. The survey revealed a wide range of practices and the authors concluded that there was no scientific basis for bracing decisions. For example, 13% of respondents stated that they never recommend braces for those undergoing ACL reconstruction, and 50% of respondents reported that they recommend bracing less frequently than five years ago.⁷ Soma and colleagues compared the performance of custom-made and off-the-shelf functional knee braces from four manufacturers.⁸ As a group, the custom-made knees braces restrained anterior displacement better than the off-the-shelf models by a mean difference of 0.84 mm. The clinical significance of this difference is questionable.

No data in the published peer-reviewed literature show that custom-made functional knee braces offer any benefit over off-the-shelf braces in terms of activities of daily living. In addition, many of the custom-made functional knee braces are designed specifically for participation in elective sports and thus would be considered not medically necessary.^{4,9}

Rehabilitation Knee Braces

Rehabilitation knee braces are designed to allow protected motion of injured knees that have been treated operatively or non-operatively, are usually purchased off-the-shelf or prefabricated and used for 6 to 12 weeks after injury. Rehabilitation knee braces are used to limit the movement of the knee in both medial and lateral directions- these braces often have an adjustable range of motion stop potential for limiting flexion and extension following ACL reconstruction. They are larger in size than other braces, due to their function.

Rehabilitative knee braces are intended to control the knee flexion-extension angle during the initial healing period after cruciate ligament or meniscal fracture management or reconstructive surgery. Rehabilitative braces are typically used short term for the early postoperative period to protect the fracture site or surgical repair while range-of-motion, weight bearing, and muscle activity are initiated. This type of brace generally consists of foam liners, rigid bars with hinges, and nonelastic straps that hold the brace in place, and they are frequently purchased off-the-shelf. They are designed to allow controlled joint motion and are commonly used for 6 to 12 week's post-acute injury or surgery. They allow adjustment for swelling and are easy to remove for examinations and, therefore, may be preferred over splinting or casting postoperatively. They are preferred over full knee immobilization because they allow motion and loading and have been shown to decrease muscle atrophy, maintain cartilage health, and decrease the chance of knee stiffness. The American Academy of Orthopedic Surgeons (AAOS) believes that after anterior cruciate ligaments (ACL) reconstruction, there may be a role for rehabilitation braces used in the early post-surgical phase, but functional braces used later during recovery appear to provide no added protection to the knee following a well-performed reconstruction.¹⁰

Prefabricated Rehabilitation Knee Braces

Wright and Fetzer conducted a systematic review of bracing for rehabilitation following ACL reconstruction.¹¹ Review of 12 randomized controlled trials “found no evidence supporting the routine use of functional or rehabilitative bracing in a patient with a reconstructed ACL. In particular no study demonstrated a clinically important finding of improved range of motion, decreased pain, improved graft stability or decreased complications and reinjuries.” The body of evidence currently present in the orthopaedic literature does not support post-operative functional bracing for ACL reconstruction. For improvement of long-term clinical outcomes, there is no role for empiric bracing in the treatment algorithm.¹²

Unloading and Offloading Knee Braces

Unloader knee braces are specifically designed to reduce the pain and disability associated with severe osteoarthritis of the medial compartment of the knee by bracing the knee in the valgus position in order to unload the compressive forces on the medial compartment. They can be either off-the-shelf, prefabricated, custom fabricated (custom made) or molded to the patient.

With regard to unloader knee braces, three publications were identified. Kirkley and colleagues reported on a controlled trial that randomized 119 patients with medial compartment osteo-arthritis to receive standard medical management, medical management plus a poly-chloroprene (Neoprene) sleeve, or medical management plus an unloader knee brace.¹³ Compared to the control group, the unloader knee brace was associated with a significant improvement in quality of life and function. In comparing the unloader knee brace with the neoprene sleeve, there was a significant difference in functional outcomes favoring the unloader knee, but no significant difference in terms of quality of life measures. Other uncontrolled studies in patients with unicompartamental arthritis suggest that unloader knee braces are associated with an improvement in gait.¹⁴ Finally, Pollo and colleagues evaluated 11 patients with osteoarthritic knees in an uncontrolled study and found that valgus bracing reduced medial compartment load and pain and improved knee function.¹⁵ A Cochrane review of braces and orthoses for treating osteoarthritis of the knee concluded that there was limited evidence in favor of an unloader knee brace.¹⁶

A randomized multi-center trial of 117 patients compared off-the-shelf unloading braces and conservative therapy with conservative therapy alone for unicompartamental (valgus or varus) osteoarthritis of the knee.¹⁷ The addition of a brace resulted in a slight increase in reported walking distances at three, six, and 12 months (effect size of 0.4), with trends for improvement in subjective pain (-0.63 on a 10-point visual analogue scale) and knee function (three points on a 100-point Hospital for Special Surgery score). Quality of life did not differ between the two groups. The authors noted that adherence to the brace was low, with 16 of 60 patients (27%) discontinuing by three months and another nine (15%) stopping treatment by 12 months. Patient-reported reasons for discontinuing use of the unloading brace were lack of benefit and adverse effects (i.e., skin irritation, bad fit).

Another study from 2006 compared the effectiveness of off-the-shelf and custom-made patient-adjustable, valgus-producing knee unloader braces in relieving pain, reducing stiffness, and improving function and in reducing varus angulation and the peak adduction moments about the knee during gait and stair-stepping in patients with painful varus gonarthrosis of the knee. Ten adult patients wore each type of brace for four to five weeks (≈ 9 h/d) in a randomized order. Both braces significantly reduced pain and stiffness ($p < 0.05$), with the custom brace reducing stiffness significantly more than the off-the-shelf brace ($p = 0.030$). The custom brace significantly improved function ($p = 0.010$) and reduced the peak knee adduction moments during gait ($p = 0.033$) and stair-stepping ($p = 0.002$) compared with baseline values and compared with the off-the-shelf brace ($p = 0.029$ and $p = 0.027$, respectively). Kinematic analysis showed a reduction in peak knee adduction moments during gait and stair-stepping and reduced varus angulation by 1.5° , compared with baseline ($p = 0.001$) and by 1.3 degrees compared with the off-the-shelf brace ($p = 0.009$). The off-the-

shelf brace did not reduce the varus angle. The authors only investigated the short-term effects of custom and off-the-shelf patient-adjustable valgus-producing knee "unloader" braces and found that patients with varus gonarthrosis of the knee may benefit significantly with respect to pain relief and reduced stiffness from use of either brace. However, such patients may experience additional significant benefit in improved function and reduced stiffness, varus angulation, and medial compartment loading of the knee from use of the custom-made patient-adjustable brace.¹⁸

Ostrander et al conducted a study to determine the efficacy of a medial unloader brace in reducing the pain and symptoms associated with varus knee OA. Braces designed to unload the more diseased compartment of the knee have been used to provide symptomatic relief from osteoarthritis (OA). Research on the efficacy of these braces is needed. Thirty-one patients with knee OA were randomized to receive an unloader brace ($n = 16$) or not to receive a brace (control group, $n = 15$). Knee Injury and Osteoarthritis Outcomes Score (KOOS) and visual analog scale (VAS) scores were used to evaluate outcomes. KOOS results showed that the brace group had significantly less pain ($P < .001$), fewer arthritis symptoms ($P = .007$), and better ability to engage in activities of daily living ($P = .008$). There was no difference in function in sport and recreation ($P = .402$) or in knee-related quality of life ($P = .718$). VAS results showed that the brace group had significantly less pain throughout the day ($P = .021$) and had improved activity levels ($P = .035$). There was no difference in ability to sleep ($P = .117$) or in use of nonsteroidal anti-inflammatory drugs ($P = .138$). Our study results showed that use of an unloader brace for medial compartment knee OA led to significant improvements in pain, arthritis symptoms, and ability to engage in activities.¹⁹

Custom-Fabricated Unloading and Offloading Knee Braces

Research on unloader knee braces for osteoarthritis has focused on the custom-made knee braces. There is minimal data available for off-the-shelf unloader knee braces. Several case series suggest that unloader knee braces appear to be associated with a reduction in pain in patients with painful osteoarthritis of the medial compartment.^{20,21}

Patellofemoral Knee Braces

Warden et al reported a meta-analysis of 16 randomized or quasi-randomized studies assessing patellar taping or bracing effects on chronic knee pain. Thirteen trials investigated taping or bracing for anterior knee pain and three investigated taping for osteoarthritis. The authors concluded there was limited evidence to demonstrate the efficacy of patellar bracing.

They reported high heterogeneity between study outcomes and significant publication bias in the studies.²²

Patellofemoral knee braces have been used to treat anterior knee disorders and offer moderate subjective improvement without significant disadvantages. Additional well-designed studies are needed to demonstrate objectively the benefits of all knee braces. Knee braces should be used in conjunction with a rehabilitation program that incorporates strength training, flexibility, activity modification and technique refinement.²

Prophylactic Knee Braces

Prophylactic knee braces attempt to prevent or reduce the severity of knee ligament injuries, and are primarily used in recreational or organized sports. They can be either off-the-shelf, prefabricated, custom fabricated (custom made) or molded to the patient. Prophylactic knee braces are designed to protect uninjured knees from valgus stresses that could damage the medial collateral ligaments. However, no conclusive evidence supports their effectiveness, and they are not recommended for regular use.²

Supplemental Information

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) published an evidence-based clinical practice guideline in 2014 on the management of anterior cruciate ligament injuries, including the following recommendations²⁵:

- 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. Additional research could investigate the effect of prophylactic bracing in other populations (i.e. adolescent female soccer players) in which ACL injury rates are high.
- 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 Osteoarthritis Research Society International

The Osteoarthritis Research Society International (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."²⁴ This guideline is based in part on the Brower study previously referenced 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.¹⁷

References

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Clinical records indicating pain and/or functional disability that interferes with ADLs if applicable
 - Reason a custom brace is needed (rather than an off-the-shelf type of brace)
 - Documentation of current instability if applicable
 - Documentation of limited range of motion if applicable
 - Knee circumference measurements if applicable
 - Treatment plan (i.e., surgical intervention) if applicable
 - Physical therapy reports if applicable
 - Prior conservative treatments, duration, and response
 - Pertinent past procedural and surgical history
- Radiology report(s) (i.e., X-Rays, MRI, CT)
- A copy of the manufacture's invoice if the provider's office is supplying the brace
- Prescription, signed and dated by provider that includes the diagnosis and rationale for each HCPCS code requested
- Documentation to support Knee Brace Add-on codes if applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	K0672	Addition to lower extremity orthotic, removable soft interface, all components, replacement only, each
	L1810	Knee orthosis (KO), elastic with joints, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1812	Knee orthosis (KO), elastic with joints, prefabricated, off-the-shelf
	L1820	Knee orthosis (KO), elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment
	L1830	Knee orthosis (KO), immobilizer, canvas longitudinal, prefabricated, off-the-shelf
	L1831	Knee orthosis (KO), locking knee joint(s), positional orthosis, prefabricated, includes fitting and adjustment
	L1832	Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1833	Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the-shelf
	L1834	Knee orthosis (KO), without knee joint, rigid, custom fabricated
	L1836	Knee orthosis (KO), rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
	L1840	Knee orthosis (KO), derotation, medial-lateral, anterior cruciate ligament, custom fabricated
	L1843	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, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	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
	L1845	Knee orthosis (KO), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and

Type	Code	Description
		rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1846	Knee orthosis (KO), 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
	L1847	Knee orthosis (KO), 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
	L1848	Knee orthosis (KO), double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf
	L1850	Knee orthosis (KO), Swedish type, prefabricated, off-the-shelf
	L1851	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, prefabricated, off-the-shelf
	L1852	Knee orthosis (KO), 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, prefabricated, off-the-shelf
	L1860	Knee orthosis (KO), modification of supracondylar prosthetic socket, custom fabricated (SK)
	L2385	Addition to lower extremity, straight knee joint, heavy-duty, each joint
	L2395	Addition to lower extremity, offset knee joint, heavy-duty, each joint
	L2397	Addition to lower extremity orthosis, suspension sleeve
	L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only
	L2800	Addition to lower extremity orthosis, knee control, knee cap, medial or lateral pull, for use with custom fabricated orthosis only
	L2820	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
	L2830	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
	L2840	Addition to lower extremity orthosis, tibial length sock, fracture or equal, each
	L2850	Addition to lower extremity orthosis, femoral length sock, fracture or equal, each
	L4205	Repair of orthotic device, labor component, per 15 minutes
	L4210	Repair of orthotic device, repair or replace minor parts

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
01/11/2008	New Policy Adoption
03/10/2008	Coding Update CPT Codes modified and deleted

Effective Date	Action
06/24/2009	Policy Review and update
01/15/2010	Coding Update
02/22/2010	Policy Revision with clarification of documentation required
06/09/2010	Coding Update
07/03/2014	Coding Update
01/30/2015	Coding update
07/31/2015	Coding update
01/01/2017	Policy revision without position change
10/01/2017	Policy revision without position change
09/01/2018	Policy revision without position change
08/01/2019	Policy revision without position change
05/01/2020	Annual review. Policy statement, guidelines and literature updated.
07/01/2020	Administrative update. Policy statement updated.
05/01/2021	Annual review. No change to policy statement.
06/01/2022	Annual review. No change to policy statement.
05/01/2023	Annual review. Policy statement and guidelines updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT

<p style="text-align: center;">BEFORE Red font: Verbiage removed</p>	<p style="text-align: center;">AFTER Blue font: Verbiage Changes/Additions</p>
<p>Knee Braces (Custom) BSC1.05</p> <p>Policy Statement: Custom-fabricated functional or derotation knee braces may be considered medically necessary, when all of the following are met (this list may not be all-inclusive):</p> <ul style="list-style-type: none"> I. Documentation of any of the following: <ul style="list-style-type: none"> A. Knee instability due to injury (including history of surgery for the injury) B. Non-fixed flexion or extension knee contracture C. Knee deformity requiring stabilization D. Knee instability by physical exam E. Neurological weakness requiring stabilization of the knee II. <u>Off-the-shelf</u> knee brace would not provide a satisfactory fit III. Documentation of any of the following: <ul style="list-style-type: none"> A. <u>Abnormal limb contour</u> (i.e., disproportionate <u>size/shape</u> [See Policy Guidelines]) B. Knee deformity (i.e., valgus [knock-kneed], varus [bow legged] deformity) minimal muscle mass upon which to suspend the orthosis <p>Custom-fabricated unloading/offloading knee braces (single or double upright) may be considered medically necessary when all of the following are met:</p> <ul style="list-style-type: none"> I. Documentation of any of the following: <ul style="list-style-type: none"> A. Knee instability due to injury (including history of surgery for the injury) B. Painful unicompartmental osteoarthritis (OA) of the knee, which interferes with normal activities of daily living C. Non-fixed flexion or extension knee contracture D. Knee deformity requiring stabilization E. Knee instability by physical exam F. Neurological weakness requiring stabilization of the knee II. <u>Off-the-shelf</u> knee brace would not provide a satisfactory fit 	<p>Knee Braces (Custom) BSC1.05</p> <p>Policy Statement:</p> <ul style="list-style-type: none"> I. Custom-fabricated functional or derotation knee braces may be considered medically necessary, when all of the following are met (this list may not be all-inclusive): <ul style="list-style-type: none"> A. Documentation of any of the following: <ul style="list-style-type: none"> 1. Knee instability due to injury (including history of surgery for the injury) 2. Non-fixed flexion or extension knee contracture 3. Knee deformity requiring stabilization 4. Knee instability by physical exam 5. Neurological weakness requiring stabilization of the knee B. <u>Off-the-shelf</u> knee brace would not provide a satisfactory fit C. Documentation of any of the following: <ul style="list-style-type: none"> 1. <u>Abnormal limb contour</u> (i.e., disproportionate <u>size/shape</u> [See Policy Guidelines]) 2. Knee deformity (i.e., valgus [knock-kneed], varus [bow legged] deformity) minimal muscle mass upon which to suspend the orthosis II. Custom-fabricated unloading/offloading knee braces (single or double upright) may be considered medically necessary when all of the following are met: <ul style="list-style-type: none"> A. Documentation of any of the following: <ul style="list-style-type: none"> 1. Knee instability due to injury (including history of surgery for the injury) 2. Painful unicompartmental osteoarthritis (OA) of the knee, which interferes with normal activities of daily living 3. Non-fixed flexion or extension knee contracture 4. Knee deformity requiring stabilization 5. Knee instability by physical exam 6. Neurological weakness requiring stabilization of the knee B. <u>Off-the-shelf</u> knee brace would not provide a satisfactory fit

POLICY STATEMENT

BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
<p>III. Documentation of any of the following:</p> <ul style="list-style-type: none"> A. <u>Abnormal limb contour</u> (i.e., disproportionate <u>size/shape</u> [See Policy Guidelines]) B. Knee deformity (i.e., valgus [knock-kneed], varus [bow legged] deformity) minimal muscle mass upon which to suspend the orthosis <p><u>Knee brace add-ons</u> may be considered medically necessary for any of the following:</p> <ul style="list-style-type: none"> I. Daily activity level (i.e., employment) requires a brace designed for high-impact/high-stress activities II. Extensions for an unusually tall person III. Patient with a non-fixed flexion contracture of the knee IV. Pediatric model for a person with short stature V. Weight is greater than 250 pounds <p>Prophylactic braces (either prefabricated or custom) are considered not medically necessary for any indication. They are used frequently for sports and recreation to try to prevent injury before and after surgery. This has not been proven in literature.</p>	<p>C. Documentation of any of the following:</p> <ul style="list-style-type: none"> 1. <u>Abnormal limb contour</u> (i.e., disproportionate <u>size/shape</u> [See Policy Guidelines]) 2. Knee deformity (i.e., valgus [knock-kneed], varus [bow legged] deformity) minimal muscle mass upon which to suspend the orthosis <p>III. <u>Knee brace add-ons</u> may be considered medically necessary for any of the following:</p> <ul style="list-style-type: none"> A. Daily activity level (i.e., employment) requires a brace designed for high-impact/high-stress activities B. Extensions for an unusually tall individual C. individual with a non-fixed flexion contracture of the knee D. Pediatric model for an individual with short stature E. Weight is greater than 250 pounds <p>IV. Prophylactic braces (either prefabricated or custom) are considered not medically necessary for any indication. They are used frequently for sports and recreation to try to prevent injury before and after surgery. This use has not been proven to improve net health outcome in literature.</p>