Knee Orthoses

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Introduction

Knee orthoses (braces) are addressed by this guideline.

Criteria

Pre-fabricated Knee Orthosis with Joints

A prefabricated knee orthosis with joints (HCPCS L1810, L1812, L1820, L1821) is medically necessary for an ambulatory or pre-ambulatory individual when **all** of the following apply:

- The individual can walk, but they encounter muscular weakness or structural abnormalities in the knee.
- Stabilizing the individual's knee is necessary for medical reasons.
- The individual's function will be improved by using the brace.

Pre-fabricated Knee Orthosis with a Locking Knee Joint or a Rigid Knee Orthosis

A prefabricated knee orthosis with a locking knee joint or a rigid knee orthosis (HCPCS L1831, L1836) is medically necessary when **both** of the following apply:

- The individual has a knee contracture, which means that the knee cannot bend or straighten as much as it should.
- The individual has at least 10 degrees of movement at the knee joint, which indicates it is possible to correct the non-fixed contracture.

Pre-fabricated Knee Orthosis Immobilizer without Joints or with Adjustable Knee Joints

A prefabricated knee orthosis without joints or with adjustable knee joints (HCPCS L1830, L1832, L1833, L1843, L1845, L1850, L1851, L1852) is medically necessary for an individual when **all** of the following applies:

- The individual can walk, but they encounter muscular weakness or structural abnormalities in the knee.
- There is documentation of **any** of the following:
  - The individual recently injured their knee.
  - The individual has arthritis in their knee, which makes it hard for them to walk.

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  - Stabilizing the individual's knee is necessary for medical reasons.
- The individual's function will be improved by using the brace.

Custom-fabricated Knee Orthosis

A custom-fabricated knee orthosis (HCPCS L1834, L1840, L1844, L1846, L1860) is medically necessary when criteria for a pre-fabricated knee orthosis has been met and there is documentation of **any** of the following:

- The individual is unable to be fitted with a pre-made brace.
- The condition requiring the brace is anticipated to be permanent or of long-standing duration beyond six months.
- The individual has a leg or knee deformity that necessitates a custom-made brace for a proper fit.
- A custom-made brace is necessary due to short or tall stature.

Additional Criteria

- Heavy-duty knee joints (HCPCS L2385, L2395) are medically necessary for individuals who weigh more than 300 pounds.
- Up to two removable soft interfaces (HCPCS K0672) are considered medically necessary per year.
- Concentric adjustable torsion style mechanisms used to assist knee joint extension (HCPCS L2999) are medically necessary for individuals who require knee extension assist in the absence of any co-existing joint contracture.
- Concentric adjustable torsion style mechanisms (HCPCS E1810) used for the treatment of contractures see *Dynamic Joint Extension and Flexion Orthoses.*
- Knee orthosis addition codes (see table below) describing components or features that can be physically incorporated in the specified prefabricated base orthosis are medically necessary when **all** of the following apply:
  - The addition is provided with the related base code orthosis.
  - The base orthosis is medically necessary
  - The addition is medically necessary.

Base Code	Addition Codes (Eligible for Separate Payment)
L1832	L2397, L2795, L2810
L1833	L2397, L2795, L2810
L1843	L2385, L2395, L2397
L1845	L2385, L2395, L2397, L2795

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Base Code	Addition Codes (Eligible for Separate Payment)
L1850	L2397
L1851	L2385, L2395, L2397
L1852	L2385, L2395, L2397, L2795

- Reimbursement for computer-aided design/computer-aided manufacturing (CAD/CAM) technology used to fabricate an orthosis is included in the allowance of the codes for custom fabricated orthoses.
- Evaluation of the individual, measurement and/or casting, and fitting/adjustments of the orthosis are included in the allowance for the orthosis.

Not Covered

- prophylactic knee braces
- prefabricated knee braces with an inflatable air bladder (HCPCS codes L1847, L1828)

Replacement Criteria

- Same or Similar Durable Medical Equipment
  - Duplication of the same or similar orthoses within the same case is not medically necessary.
- A Replacement orthosis is medically necessary when **all** of the following apply:
  - The individual has been seen recently by their provider and has a documented care plan that includes the use of the brace.
  - There is clinical documentation of **any** of the following:
    - The individual is no longer able to wear the brace because of growth or a change in physical condition.
    - The brace has been lost or stolen.
    - The brace is broken, unable to be repaired, and no longer under warranty.

Definitions

- Musculoskeletal knee braces can be divided into three categories:
  - **Rehabilitative knee braces** are designed to limit potentially harmful knee movements during the rehabilitation period following recent knee surgery or an acute knee injury. These knee braces include hinges that can be locked into place to limit range of motion.

  - **Functional knee braces** are designed to provide support during activities of daily living when a condition or injury causes instability at the knee.
  - **Unloader/offloader knee braces** are designed to provide support to individuals who have arthritis in the medial or lateral compartment of the knee. These knee braces apply a valgus or varus force and reduce load on the affected region of the knee.
- An **orthosis** (brace) is a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. An orthosis can be classified as either prefabricated (off-the-shelf), custom-fitted, or custom-fabricated.
- A **pre-fabricated orthosis** can be used for individuals requiring only minimal self-adjustment. A prefabricated orthosis can also be custom-fitted by a certified orthotist or individual with specialized training. Prefabricated orthoses are available in multiple sizes and can be adjusted to accommodate an individual's functional and anatomical needs.
- An **off-the-shelf (OTS) orthosis** is a prefabricated item that may or may not be supplied as a kit that requires some assembly. OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, and molding, assembling, or customizing to fit an individual. This fitting does not require expertise of a certified orthotist or an individual who has specialized training in the provision of orthoses to fit the item to the individual.
- A **custom-fitted orthosis** is prefabricated and may or may not be supplied as a kit that requires some assembly. Custom fitting can include trimming, bending, or molding of the prefabricated orthoses beyond minimal self-adjustment. This fitting at delivery requires the expertise of a certified orthotist or an individual who has specialized training in the provision of the orthosis to fit the item to the individual
- A **custom-fabricated orthotics** is made for a specific individual based on clinically-derived castings, tracings, molds, or images of the body part. Custom fabrication may be appropriate when specific fit issues are unable to be addressed by adjusting a prefabricated brace or orthosis (e.g., cutting, bending, adding extra straps). Custom-fabricated additions are appropriate only for custom-fabricated orthoses and should not be billed with prefabricated orthoses.
- A **molded-to-patient-model** is a particular type of custom-fabricated device in which either: an impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the individual, and this impression is then used to make a positive model of the body part from which the final product is crafted; or a digital image of the individual's body part is made using CAD/CAM systems software. This technology includes specialized probes/digitizers and scanners that create a computerized positive model, and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model.

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- A **positive model** is an exact replica of the actual body part for which the custom-fabricated orthosis is being constructed. Fabrication of an orthosis using molding, CAD/CAM, or similar technology without the creation of a positive model is considered to be a prefabricated orthosis.
- A **contracture** is the chronic loss of joint mobility caused by structural changes in tissue, including muscles, ligaments, fascia, and tendons. Contractures are distinguished from the temporary loss of range of motion of a joint following injury, surgery, or other immobilization.
- A **non-fixed contracture** is defined as a joint contracture with at least 10 degrees of passive movement on range of motion testing.
- A **knee flexion contracture** is a condition in which there is shortening of the muscles and/or tendons with the resulting inability to bring the knee to 0 degrees extension or greater (i.e., hyperextension) by passive range of motion. Zero degrees knee extension is when the femur and tibia are in alignment in a horizontal plane.
- A **knee extension contracture** is a condition in which there is shortening of the muscles and/or tendons with the resulting inability to bring the knee to 80 degrees flexion or greater by passive range of motion.

Evidence Discussion

Medical Background

The modern knee brace was invented in 1967 (Hiserman, 2020). Since that time, knee braces have evolved to include simple pull-on sleeve designs to fully customizable hinged designs. They are used for knee support following injuries, after surgery, and for support of arthritic or hypermobile knees.

The United States Food and Drug Administration (FDA) considers knee orthoses to be Class I devices and are considered low to moderate risk. As such, manufacturers are not required to complete pre-market notification or seek pre-market approval for these items (FDA, 2024).

Literature Review

Acute knee Injuries:

- Acute knee injuries are often associated with an inability to bear weight, swelling, or signs of instability. The literature suggests that knee injuries should be immobilized with a knee brace during the clinical evaluation period. A hinged brace may be used to stabilize the knee if there is evidence of multiligamentous injury (Karlin et al., 2020). Moreover, confirmed knee sprains may be non-operatively treated with a controlled-motion hinged brace for four to six weeks (Miller and Azar, 2021). In situations when there is concern for multiligamentous injury or

patellar dislocation, knee immobilizers may be used with the initiation of an appropriate rehabilitation program if indicated.

- Askenberger et al. (2018) conducted a randomized controlled trial including 74 children with acute traumatic lateral patellar dislocation. The study compared four weeks of therapy with a lateral stabilizing soft knee brace against immediate arthroscopic operative repair. The re-dislocation rate was significantly lower in the arthroscopic assisted repair group than in the knee brace group at final follow-up. The Knee injury and Osteoarthritis Outcome Score (KOOS) for children, sport/play, and quality of life sub-scales had lower scores in the arthroscopic repair group compared with the knee brace group. The authors concluded that operative repair significantly reduced the re-dislocation rate but did not improve knee function compared to the group using a knee brace and non-operative treatment.

Nonoperative anterior cruciate ligament (ACL) management:

- Ahn et al. (2010) conducted a study to examine the effects of conservative treatment of acute anterior cruciate ligament (ACL) injury. Forty eight participants with an acute ACL injury confirmed by MRI with mild instability (Lachman test grade ≤1) were treated non-operatively with bracing. The initial and follow-up Lachman test and pivot shift test were performed three weeks after the injury. At follow-up at 21.5 months, 41 individuals (87%) improved to grade 0 on the Lachman test. Thus, the authors suggested that nonoperative treatment of ACL tears in selected patients may be a successful therapeutic option.
- A review article by Paterno (2017) discussed the evidence regarding non-operative rehabilitation management after ACL injury. The author reported that the final phase of rehabilitation prior to returning to pivoting and cutting sports is the "Return to Sport Phase." In this phase, an individual who is ACL deficient may be treated non-operatively and still return to participation in after an intense rehabilitation program that includes a functional performance brace. The author noted that data suggests the functional brace may enhance stability by reducing anterior tibial translation and enhancing proprioception.

Arthritis:

- Peterson et al. (2016) conducted a systematic review including 24 articles to examine the biomechanical effect of unloader braces. Twenty articles demonstrated that valgus unloader braces significantly decrease the knee adduction moment. Seven of those studies reported a decrease of pain in individuals using braces. The authors concluded that in the majority of studies of individuals with knee osteoarthritis, a reduction in adduction force exerted at the joint was achieved when valgus bracing was used.
- Cudejko et al. (2018) conducted a systematic review including 11 studies to examine the effects of soft braces on pain and self-reported and performance-based physical function in individuals with knee osteoarthritis. The authors noted that the methodological quality of included randomized controlled trials was low. The authors concluded that the available evidence indicates soft braces

demonstrate moderate improvement in pain and small to moderate improvement in physical function in individuals with osteoarthritis compared with standard care. However, the authors noted that additional high quality studies are warranted.

- Gohal et al. (2018) conducted a systematic review including 31 studies to determine the effectiveness of valgus offloader braces in improving clinical outcomes for individuals with medial compartment knee osteoarthritis. The majority of studies reported that valgus offloader braces improved pain outcomes, but the studies did not demonstrate significantly improved functional outcomes and stiffness. In addition, offloader bracing was more effective at reducing pain when compared with neutral braces or neoprene sleeves. Thus, the investigators concluded that valgus offloader knee braces are an effective treatment for improving pain secondary to medial compartment knee osteoarthritis. However, the investigators noted that larger, prospective randomized trials with consistent assessment tools and consideration of compliance would be beneficial to assess the effects of valgus unloader bracing.
- A systematic review by Cudejko et al. (2018) identified 11 studies (including six randomized studies) to examine of the effects of soft knee bracing on pain and function in individuals with knee osteoarthritis. The authors found moderate improvement in pain and small to moderate improvement in physical function with the use of such bracing compared with standard care. Thus, the authors concluded that soft braces can help improve pain and function in both the short-term and long-term for knee osteoarthritis; however, additional high quality studies are needed.
- Thoumie et al. (2018) conducted a randomized controlled trial including 67 individuals with symptomatic medial knee osteoarthritis to evaluate the effects of bracing on pain, function, and safety. Participants randomly received six weeks of treatment with either an unloading knee brace and standard care, or standard care alone. The authors concluded that after six weeks of treatment, those individuals using an unloading knee brace had significantly less pain and improved functional mobility compared to the control group (standard care without a brace).
- In 2017, Cudejko and colleagues published the results of a nonrandomized trial including 44 individuals which examined the immediate effects of a soft knee brace on pain, activity limitations, self-reported knee instability, and self-reported knee confidence. The study also assessed the difference in effect between a non-tight and a tight soft brace in individuals with knee osteoarthritis. The outcome measures were pain and self-reported knee instability during treadmill walking (both level and varied surfaces) and activity limitations (10 meter walk test and the get up and go test). A soft brace significantly reduced pain during level walking, reduced the time to complete the 10 meter walk and the get up and go tests, and reduced self-reported knee instability and lack of confidence during level walking compared with not wearing a soft brace. There was no difference in effects between a non-tight and tight brace, except that the time to complete

the 10 meter walk test was significantly reduced when using a tight brace. The investigators concluded that compared to no brace, a soft knee brace significantly reduced pain, knee instability, lack of confidence, and time to complete a 10 meter walk test during both level and varied walking surfaces in individuals with knee osteoarthritis.

- Callaghan et al. (2015) conducted a randomized controlled study to determine if braces would decrease knee pain and patellofemoral bone marrow lesions (BMLs) in individuals with patellofemoral arthritis. One hundred twenty participants with patellofemoral arthritis were assigned to receive a patellofemoral brace or no brace for a six week period. The primary outcomes were a change in pain during a pre-selected painful activity, and BML volume change in the patellofemoral joint. The group that received bracing had a significant reduction in bone marrow lesion volume and decreased pain during aggravating activity compared to the control group. The authors concluded that a patellofemoral brace reduces pain and BML volume in the treated knee compartment. However, the authors noted that knee osteoarthritis is a long-term, chronic condition, and thus, additional studies with longer term outcomes are needed.
- Moen et al., (2010) performed a randomized study of 15 participants to evaluate the effectiveness of a pneumatic leg brace for the treatment of medial tibial stress syndrome. The participants were randomized to groups with and without a pneumatic knee brace, and both groups followed a rehabilitation program consisting of leg exercises and a graded running program. The authors found no significant difference in recovery time or functional outcomes between those using a pneumatic knee brace and those undergoing standard rehabilitation without the brace. Moreover, participants reported low comfort levels with the pneumatic knee brace, thus suggesting limited clinical benefit
- Rezaei et al., (2022) compared a conventional knee brace with a knee brace with a pneumatic cuff during walking in a patient with medial compartment knee osteoarthritis. The results of the study demonstrated that the knee range of motion (ROM) was reduced by 24% using the pneumatic knee brace without foot pressure. When conventional three points knee pressure were used, the degree of freedom on the knee sagittal plane dropped by 13%. The study concluded that pneumatic knee braces can significantly reduce knee range of motion (ROM), especially during the swing phase of gait. This reduction in ROM may lead to shorter step lengths and decreased foot clearance, potentially impacting mobility.

Post-stroke genu recurvatum:

- Genu recurvatum is a hyperextension deformity of the knee. In a prospective randomized crossover study, 34 post-stroke patients with hemiparesis and genu recurvatum were randomized to receive either a hinged soft knee orthosis or no knee orthosis for one month, and then switched to the other intervention (Portnoy et al., 2015). The results of the Berg Balance Scale, Six Minute Walk Test, 10-Meter Walk Test, and Timed Up and Go Test were significantly improved in the

intervention group. Notably, over 67% of subjects increased their gait velocity, which was considered a clinically meaningful difference on short-distance walks.

Professional organizations/societies:

- There has been conflicting evidence regarding the use of bracing after ACL injury. A 2022 American Academy of Orthopaedic Surgeons (AAOS) clinical practice guideline does not support the routine use of functional knee bracing following isolated ACL reconstruction. The authors noted that limited studies demonstrate no significant differences between braced and unbraced individuals returning to full activity following isolated primary ACL reconstruction. In addition, the authors reported a variance of bracing protocols and relatively small size of the study cohorts in the existing literature and thus recommend that additional research is warranted. Moreover, the AAOS guidelines report that prophylactic knee bracing is not a preferred option to prevent ACL injury. Although knee bracing may potentially be acceptable to athletes participating in higher risk sports; the authors noted that there is ample evidence that prophylactic knee bracing alters lower extremity biomechanics, and moreover, it is not likely feasible to employ prophylactic braces in every athlete for each competition and practice of high risk sport for ACL injury.
- A 2022 American Academy of Orthopaedic Surgeons (AAOS) clinical practice guideline provided a moderate recommendation that brace treatment could be used to improve pain, function, and quality of life in individuals with knee osteoarthritis (Brophy and Fillingham, 2022). The authors noted that braces can provide pain relief and improved function in individuals with unicompartmental knee osteoarthritis. In addition, there is a subjective feeling of normal tibiofemoral kinematics, which may transfer to an increased confidence and sense of security in the knee. However, the authors noted that future high quality studies are warranted to assess the efficacy of unloader braces versus knee sleeves in a population with a similar mechanical axis and a similar degree of osteoarthritis.
- A 2020 American College of Rheumatology/Arthritis Foundation clinical practice guideline strongly recommended tibiofemoral knee braces for individuals who have knee osteoarthritis and difficulty with ambulation, joint stability, or pain needing an assist device, and who are able to tolerate the associated inconvenience and burden associated with bracing (Kolasinski et al., 2020). In addition, the authors conditionally recommended patellofemoral braces for patellofemoral knee osteoarthritis, although the authors noted the variability in results across published trials and the difficulty some individuals will have in tolerating the inconvenience and burden of these braces.
- A 2020 Department of Veterans Affairs clinical practice guideline issued a weak recommendation for bracing of individuals with knee osteoarthritis to help decrease weight burden and provide stability (Krishnamurthy et al., 2021). The authors noted that the quality of evidence is low; however, the evidence does not specifically identify any harms associated with the use of bracing. Moreover, the authors recognized that bracing can lead to atrophy and functional loss if

appropriate exercise is not concurrently performed. Additional research is needed to determine how long, or under what circumstances, braces are needed to optimize outcomes.

- The 2022 National Institute for Health and Care Excellence (NICE) guidelines recommended that braces should be issued to individuals with knee osteoarthritis in the presence of the following: joint instability or abnormal biomechanical loading, when therapeutic exercise is ineffective or unsuitable without the addition of an aid or device, and when the addition of an aid or device is likely to improve movement and function.

Codes included

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

HCPCS	Description
L1810	Knee orthosis, 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, elastic with joints, prefabricated, off-the-shelf
L1820	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment
L1821	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off-the-shelf
L2999	Lower extremity orthoses, not otherwise specified
L1831	Knee orthosis, locking knee joint(s), positional orthosis, prefabricated, includes fitting and adjustment
L1836	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf

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HCPCS	Description
L1830	Knee orthosis, immobilizer, canvas longitudinal, prefabricated, off-the-shelf
L1832	Knee orthosis, 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, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf
L1843	Knee orthosis, 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	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, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1850	Knee orthosis, 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
L1834	Knee orthosis, without knee joint, rigid, custom fabricated

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HCPCS	Description
L1840	Knee orthosis, derotation, medial-lateral, anterior cruciate ligament, custom fabricated
L1844	Knee orthosis, 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
L1847	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1848	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf
L1860	Knee orthosis, 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
L2795	Addition to lower extremity orthosis, knee control, full kneecap
L2810	Addition to lower extremity orthosis, knee control, condylar pad
K0672	Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each

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