Clinical Practice Guideline: **Knee Orthoses**

Date of Implementation: **March 16, 2017**

Product: **Specialty**

Other related CPGs:
•CPG 143: Strapping
•CPG 145: Casting and Splinting
•CPG 152: Orthotic Training and Evaluation
•CPG 186: Inserts and Other Shoe Modifications for Individuals without Diabetes
•CPG 205: Ankle Foot Orthoses

GUIDELINES

Prophylactic Knee Braces

American Specialty Health, Inc. (ASH) considers prophylactic knee braces experimental and investigational. The American Academy of Orthopedic Surgeons has concluded that prophylactic bracing has not been proven to be effective and, in some cases, may actually contribute to knee injury.

Functional Knee Braces

I. Basic Braces

American Specialty Health, Inc. (ASH) considers knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) medically necessary for ambulatory patients who have weakness or deformity of the knee and require stabilization.

If an L1810, L1812 or L1820 is provided but the criteria above are not met, the orthosis will be denied as not reasonable and necessary.

HCPCS Descriptions

HCPCS codes covered if above criteria are met:	
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

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

II. Non-fixed Contracture Braces

ASH considers prefabricated rigid knee orthoses without joints and knee orthoses with joints that lock a knee into a particular position to be medically necessary for persons with non-fixed flexion contractures of the knee (patients with flexion or extension contractures of the knee with movement on passive range of motion (ROM) testing of at least 10 degrees) 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 ROM. (0 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 ROM. A contracture is distinguished from the temporary loss of ROM of a joint following injury, surgery, casting, or other immobilization.

These knee orthoses are considered experimental and investigational for other indications. If an L1831, L1832, L1833, or L1836 orthosis is provided but the criterion above is not met, the orthosis will be denied as not reasonable and necessary.

There is no proven clinical benefit to the inflatable air bladder incorporated into the design of code L1847 or L1848; therefore, claims for code L1847 or L1848 will be denied as not reasonable and necessary. A prefabricated knee orthosis with locking joints and inflatable air support chambers is considered experimental and investigational because there is no proven clinical benefit to the inflatable air bladder incorporated into the design of this knee orthosis.

HCPCS Descriptions

Prefabricated rigid knee orthoses without joints and knee orthoses with joints that lock a knee into a particular position:	
HCPCS codes covered if above criteria are met:	
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
L1836	Knee orthosis (KO), rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
Prefabricated knee orthosis with locking joints and inflatable air support chambers:	
HCPCS codes not covered for indications listed in the CPG:	
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

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

III. Varus or Valgus Braces

ASH considers knee orthoses with varus or valgus adjustment medically necessary for ambulatory persons with the following indications:

- Aseptic necrosis of the tibia/fibula; or
- Failed total knee arthroplasty; or
- Knee ligamentous disruption; or
- Meniscal cartilage derangement; or
- Moderate to severe unicompartmental osteoarthritis; or
- Tibial plateau fracture.

For persons with these indications, valgus or varus bracing alleviates pressure on the medial or lateral compartment of the knee. These knee orthoses are considered experimental and investigational for other indications because their effectiveness has not been established.

HCPCS Descriptions

Knee orthoses with varus or valgus adjustment:	
HCPCS codes covered if above criteria are met:	
L1830	Knee orthosis (KO), immobilizer, canvas longitudinal, prefabricated, off-the-shelf
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
L1845	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
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

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

IV. Injury or Post-Surgery Braces

ASH considers the following prefabricated knee braces medically necessary when criteria below are met:

- Knee immobilizer
- Knee orthosis with adjustable flexion and extension joints

- Knee orthosis with adjustable flexion and extension joint, and medial-lateral and rotational control

Medical necessity criteria:

- Member has recent (within 6 weeks prior to brace application) surgical intervention or injury to the ligaments of the knee requiring ROM limitations. Note: When used for this indication, the knee brace is considered a rehabilitation brace (also known as a post-operative or post-injury brace) and is considered an integral part of the orthopedic protocol. Examples include Bledsoe Postop Brace, DonJoy IROM Brace; or
- Member is ambulatory and has instability due to ligament insufficiency/deficiency or reconstruction. Note: When used for this indication, the knee brace is considered a functional (derotational) knee brace and is considered DME. Examples include Lenox Hill Brace, Boston Knee Brace, DonJoy CI Brace. L1832.

HCPCS Descriptions

Knee immobilizer:	
HCPCS codes covered if selection criteria are met:	
L1830	Knee orthosis (KO), immobilizer, canvas longitudinal, prefabricated, off-the-shelf
Knee orthosis with adjustable flexion and extension joints:	
HCPCS codes covered if selection criteria are met:	
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
Knee orthosis adjustable flexion and extension joint, and medial-lateral and rotational control:	
HCPCS codes covered if selection criteria are met:	
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

L1845	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

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

These prefabricated knee orthoses are considered experimental and investigational for all other indications because their effectiveness has not been established.

V. Swedish-type Brace

ASH considers knee orthosis, Swedish type, prefabricated (L1850) as medically necessary for a patient who is ambulatory and has knee instability due to genu recurvatum - hyperextended knee.

HCPCS Descriptions

Knee orthoses with double uprights and thigh and calf pads (Swedish-type knee orthosis):	
HCPCS codes covered if criteria are met:	
L1850	Knee orthosis (KO), Swedish type, prefabricated, off-the-shelf

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

The following table lists addition codes which describe components or features that can be and frequently are physically incorporated in the specified prefabricated base orthosis. Addition codes may be separately payable if:

- They are provided with the related base code orthosis; and
- The base orthosis is reasonable and necessary; and
- The addition is reasonable and necessary.

Addition codes will be denied as not reasonable and necessary if the base orthosis is not reasonable and necessary or the addition is not reasonable and necessary.

Base Code	Addition Codes - Eligible for Separate Payment
L1810	None
L1812	None
L1820	None

Base Code	Addition Codes - Eligible for Separate Payment
L1830	None
L1831	None
L1832	L2397, L2795, L2810
L1833	L2397, L2795, L2810
L1836	None
L1843	L2385, L2395, L2397
L1845	L2385, L2395, L2397, L2795
L1847	None
L1848	None
L1850	L2397
L1851	L2385, L2395, L2397
L1852	L2385, L2395, L2397, L2795

VI. Custom-Made Braces

Knee braces may be custom-fitted prefabricated or custom-made. Custom-made functional braces (also known as "custom-fabricated" or "molded" knee orthoses) are considered medically necessary if the member meets criteria for a prefabricated knee brace below but is unable to be fitted with a custom-fitted prefabricated knee brace. Examples of situations in which a person may meet criteria for a custom-made knee brace include, but are not limited to:

- Deformity of the knee or leg that interferes with fitting;
- Disproportionate size of thigh and calf;
- Minimal muscle mass upon which to hold an orthosis.

HCPCS Descriptions

Custom - made functional braces (custom-fabricated or molded knee orthoses):	
HCPCS codes covered if above criteria are met:	
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 (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	Knee orthosis (KO), modification of supracondylar prosthetic socket, custom fabricated (SK)
L2126	Knee-ankle-foot-orthosis (KAFO), fracture orthosis, femoral fracture cast orthosis; thermoplastic type casting material, custom fabricated
L2128	Knee-ankle-foot-orthosis (KAFO), fracture orthosis, femoral fracture cast orthosis, custom fabricated
L2800	Addition to lower extremity orthosis; knee control, kneecap, medial or lateral pull, for use with custom fabricated orthosis only

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

Other considerations:

- Exceptionally tall or short stature or obesity does not, by itself, establish the medical necessity for custom-made functional knee braces. Exceptionally tall persons can usually be fitted with a prefabricated brace with extensions, short persons can usually be fitted with a pediatric prefabricated brace, and obese persons can usually be fitted with a prefabricated knee brace with extra-large straps.
- Custom-fabricated orthoses are not considered medically necessary for treatment of knee contractures. Custom-fabricated orthoses are considered experimental and investigational when criteria are not met.
- Knee braces composed of high-strength, lightweight material are considered medically necessary for persons who meet criteria for a knee orthosis and whose weight is greater than 300 lbs. Knee braces composed of high-strength, lightweight materials are considered experimental and investigational for other indications.

HCPCS Descriptions

Knee braces composed of high-strength, lightweight material:	
HCPCS codes covered if above criteria are met:	
L2755	Addition to lower extremity orthosis; high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only

VII. Osteoarthritis Braces (Unloader Braces)

American Specialty Health, Inc. (ASH) considers prefabricated unloader braces medically necessary DME as an alternative to surgery for members with severe symptomatic osteoarthritis of the knee who have pain that has failed to respond to medical therapy and knee bracing with a neoprene sleeve, who have progressive limitation in activities of daily living, and who do not have *any* of the following:

- Arthritis other than osteoarthritis; or a recent knee operation (within the previous 6 weeks); *or*
- Diseases that would preclude use of a brace (e.g., skin disease, peripheral vascular disease, or varicose veins); *or*
- Inability to apply the brace because of physical limitations such as arthritis of the hands or inability to bend over; *or*
- Paresis or other disease that would preclude ambulation; *or*
- Severe cardiovascular deficit; *or*
- Symptomatic disease of the hip, ankle or foot.

A custom-fabricated unloader brace is considered medically necessary for members who meet criteria for a prefabricated unloader brace and meet medical necessity criteria for a custom-made brace noted in the section on functional and rehabilitation knee braces above. Unloader braces are considered experimental and investigational when criteria are not met.

Examples: Generation II Unloader, Orthotech Performer and Vixie Enterprise MKSIII

HCPCS Descriptions

Osteoarthritis Braces (Unloader Braces):	
Prefabricated unloader brace:	
HCPCS codes covered if selection criteria are met:	
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
For custom-fabricated unloader brace:	
HCPCS codes covered if selection criteria are met:	
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

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

Rehabilitation Braces

ASH considers other post-operative and post-injury braces medically necessary when applied within 6 weeks of surgery or injury. Their use is safe, and the current standard of care as supported by the American Academy of Orthopedic Surgeons (AAOS). These braces are considered experimental and investigational for other indications because their effectiveness for indications other than the one listed above has not been established.

Note: Rehabilitation braces are considered an integral part of the surgical or fracture care protocol.

HCPCS Descriptions

Rehabilitation Braces:	
HCPCS codes related to the CPG:	
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material
E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1812	Dynamic knew, extension/flexion device with active resistance control
L1600 - L2999	Orthotic devices - lower limb - knee only

For associated ICD-10 codes and descriptions, see Centers for Medicare and Medicaid. Local Coverage Article: Knee Orthoses – Policy Article (A52465)

The following table lists addition codes which describe components or features that can be and frequently are physically incorporated in the specified custom fabricated base orthosis. Addition codes may be separately payable if:

- They are provided with the related base code orthosis; and
- The base orthosis is reasonable and necessary; and
- The addition is reasonable and necessary.

Addition codes will be denied as not reasonable and necessary if the base orthosis is not reasonable and necessary or the addition is not reasonable and necessary.

Base Code	Addition Codes - Eligible for Separate Payment
L1834	L2795
L1840	L2385, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2755, L2785, L2795
L1844	L2385, L2390, L2395, L2397, L2405, L2492, L2755, L2785
L1846	L2385, L2390, L2395, L2397, L2405, L2415, L2492, L2755, L2785, L2795, L2800
L1860	None

The following table lists addition codes which describe components or features that can be physically incorporated in the specified custom fabricated base orthosis but are considered not reasonable and necessary. These addition codes, if they are billed with the related base code, will be denied as not reasonable and necessary.

Base Code	Addition Codes - Not Reasonable and Necessary
L1834	L2397, L2800
L1840	L2275, L2800
L1844	None
L1846	None
L1860	L2397

Replacement Braces

Replacement of a previously covered knee brace is limited to the following conditions:

- Reasonable and useful lifetime (RUL) has been exceeded (see chart below); or
- When still within the RUL:
  - Irreparable damage;
  - Excessive wear;
  - A change in the member's condition; or
  - When necessitated due to growth.

The following chart reflects the reasonable useful lifetime of prefabricated knee orthoses:

Base Code	Useful Lifetime
K0901	3 years
K0902	3 years
L1810	1 year
L1812	1 year
L1820	1 year
L1830	1 year
L1831	2 years

Base Code	Useful Lifetime
L1832	2 years
L1833	2 years
L1836	3 years
L1843	3 years
L1845	3 years
L1850	2 years

The reasonable useful lifetime of custom-fabricated orthoses is 3 years.

L2999 (lower extremity orthoses, not otherwise specified) should not be used as it lacks the necessary specificity.

DESCRIPTION/BACKGROUND

Orthotics are usually rigid or semi-rigid devices that provide stability or restrict motion, prevent deformity, protect against injury, assist with function, or support weak or injured body parts. When speaking of foot orthotics specifically, they function to protect fixed or long-term malalignment or biomechanical faults, cushion exposed bones or protect skin at risk of breakdown due to disease or other conditions that result from disease. Functional devices realign or assist the neuromuscular system by providing dynamic or static support. Static orthoses are rigid and are used to support severe weakness or paralysis of a body part or parts [e.g., ankle-foot orthosis (AFO) for a patient with hemiplegia]. Dynamic orthoses are used to facilitate movement to allow function. Orthoses are typically named by anatomic region, such as foot, ankle, ankle-foot, and knee-foot-ankle orthoses. Foot orthoses refer to devices that are placed in shoes. Ankle orthoses are supportive in nature and may be used to provide immobilization. AFOs have a shoe insert component as well as an ankle component. The knee—ankle-foot orthoses (KAFO) add a knee component to the AFO. AFOs and KAFOs are for neurologic patients that have weakness or paralysis of lower extremity musculature. This policy does not address any of these conditions. See *Ankle Foot Orthoses (CPG 205 – S)* clinical practice guideline for more information.

Other terms that may be used relative to orthoses are splints and braces. A splint is defined as an appliance for preventing movement of joints. A brace is defined as a rigid or semi-rigid device, orthosis or appliance that supports or holds a joint in a corrected position and/or restricts motion in certain directions. It can be used to allow function while restricting movement in directions that could potentially re-injure aspects of the joint.

Some orthoses are prefabricated but can be trimmed or molded to accommodate the patient. Other orthoses are custom-fabricated and are made specifically for the individual and their special biomechanical issues. Development of these custom products requires considerable labor. Typically, an unmodified, prefabricated orthosis is used initially and if results are poor, a prefabricated, modified or custom type is selected.

Knee Orthoses

Knee braces are designed to resist abnormal motions, augment the mechanical stability of the knee, and assist in the recovery and rehabilitation of an injured knee (France & Paulos, 1994). Knee braces may also be indicated to prevent future injury in an unstable knee. The braces are rigid or semi-rigid to provide support for the injured knee or restrict or eliminate motion from the injured knee. A variety of materials are used in knee braces, along with the implementation of hinges and straps. Knee braces may be custom-fitted or custom-made. A custom-fitted prefabricated brace is one in which only measurements and a sizing chart are needed for fitting. A custom-made (custom-fabricated or made-to-order) knee brace is one that requires an initial impression of the knee for fitting. Knee orthoses that are custom fitted require the assistance of an orthotist in adjusting the brace to the correct size, but do not require an initial impression of the knee for fitting. Custom-made functional knee braces have not been shown to be medically superior to custom-fitted prefabricated functional knee braces. Therefore, use of custom-made functional knee braces is reserved for those patients who are hard to fit because of a deformity of the knee or leg that interferes with fitting. Exceptionally tall persons can be fitted into a custom-fitted prefabricated brace with extensions, short persons can be fitted with a pediatric custom-fitted prefabricated brace, and obese persons can be fitted into a custom-fitted prefabricated knee brace with extra-large straps.

A classification scheme devised by the American Academy of Orthopedic Surgeons (AAOS) divides knee braces into three categories:

- Prophylactic knee braces are designed to prevent or reduce the severity of an injury. This type of brace is often used to protect the medial collateral ligament (MCL) from valgus stresses, and the anterior cruciate ligament (ACL) from rotational stresses in a relatively normal knee. Prophylactic knee braces and other protective gear (such as helmets, elbow pads, gloves, eye goggles, etc.) are considered safety items and are therefore not covered under terms of this policy. The common occurrence of medial collateral sprains in football and other sports led to the fabrication of prophylactic hinge braces designed to prevent or attenuate this injury. These braces have lateral or sometimes medial and lateral hinges designed to absorb valgus impact to the knee. Prophylactic knee braces are available custom-fitted prefabricated (not custom-made) and without a prescription.
- Functional knee braces are designed to improve stability for an unstable or postoperative knee in activities of daily living and sports and are often referred to as de-rotational braces. Their main function is to reduce risk of injury by preventing excessive loading, while maintaining normal ROM. Functional knee braces are designed to provide support to the knees made unstable by injury or to provide additional protection following surgery to correct such instabilities. They are usually recommended in the postoperative period and after completion of rehabilitation when full activity is resumed, or for the patient with a diagnosis of anterior cruciate ligament insufficiency in whom a non-operative approach is used.

- Rehabilitative knee braces are designed to allow protected motion of an injured knee treated operatively or non-operatively early after the injury. As an example, they control flexion-extension during the initial healing period after ligament or meniscal surgery, or reconstruction surgery. They are designed to allow controlled motion, and the ROM can be adjusted as the healing process progresses. Rehabilitative braces are used as alternatives to knee immobilizers used immediately after surgery or injury to both control knee motion and protect the knee during rehabilitation. Rehabilitative knee orthoses offer the patient early limited mobility to improve recovery time and decrease the effects of disuse on the graft or reconstructed ligament. Rehabilitative knee orthoses are custom-fitted prefabricated, and can be ordered either as small, medium, or large, or by a size chart. Most of them can be adjusted within each size to allow for edema or atrophy, and thus can be conveniently stocked in a hospital or clinic for quick fittings. In collateral ligament injuries that do not involve a complete tear (second degree injuries), the torn fibers are internally splinted from excessive stress by the intact ligament fibers, and the use of the knee immobilizer or rehabilitative brace is only for comfort. Unloading/Offloading knee braces are used in the treatment of moderate to severe osteoarthritis of the knee, to decrease pain and disability. Another type of brace is the patellofemoral knee brace, or knee sleeve. These braces are used for patellar subluxation, dislocation, or patellar hypermobility. Knee sleeves are also used to treat postoperative knee swelling, and patellofemoral pain syndrome.

EVIDENCE REVIEW

Prophylactic

Knee Braces: The effectiveness of prophylactic knee braces for collateral ligament injury to the knee is controversial. Prophylactic knee braces have not been shown to be effective. Indeed, some studies have shown that the risk of knee injury may be increased with use of prophylactic knee braces. Pietrosimone et al. (2008) looked at the relative risk reduction with the use of prophylactic knee braces in the prevention of knee injuries in collegiate football players. They were able to identify seven studies that met their criteria. The number of participants and frequency of knee injuries were used to calculate the relative risk reduction or increase. They found a relative risk reduction in 3 studies, but a relative increased risk of injury in 4 studies. Their findings were inconsistent due to the flaws in methodology of many of the studies. Due to the nature of the study, it is not possible to blind the participant or the athletic trainer from the intervention. Most of the studies did not assign the players randomly, and players with previous injuries were assigned the prophylactic brace. The braces used also varied, sometimes using different models within the same study. The authors concluded that they could not recommend or discourage the use of prophylactic knee braces. They also acknowledged the possibility that the knee braces may increase the risk of injury. Rishiraj et al. (2009) reviewed the literature and also

concluded that the research on the prophylactic brace is limited. This is due to the lack of non-injured athletes using the brace for fear of decreased performance.

Kemker III et al. (2021) authored an article on hip and knee bracing in a systematic review. Although prophylactic knee braces are commonly used in contact sports, such as football, prophylactic braces have not consistently reduced MCL injuries and lack evidence for routine use in uninjured knees. Despite the thought that these braces may be beneficial in protecting against varus-valgus knee stresses in contact sports, athletes who play with frequent rotational moments on the knee may be safer without wearing the brace. The purpose of these braces is to limit excessive, post-reconstruction tibial rotation from pivoting during sporting activities. Some studies have shown that the braces may decrease the risk of noncontact knee injuries in sporting activities. In addition, prophylactic knee braces may stabilize the knee joint in the landing phase of athletes' dynamic movements by increasing the stiffness of the hamstrings. However, other studies have shown no difference in the number of knee injuries in athletes who wore the prophylactic brace compared with those who did not. Because of the conflicting evidence on efficacy, the routine use of prophylactic knee braces is not recommended.

Blecha et al. (2022) summarized the literature on prophylactic knee bracing for sports. Prophylactic knee braces (PKBs) have been designed to protect the knee and decrease risk of recurrence of these injuries. Despite their success, PKBs have not been proven to be consistently effective and cost of the device must be evaluated to optimize its use in sports, particularly American football. Biomechanical studies have suggested that increased hip and knee flexion angles may reduce frontal plane loading with bracing which can protect the knee joint. This is essential with knee loading and rotational moments because they are associated with jumping, landing, and pivoting movements. The clinical efficacy of wearing PKBs can have an impact on athletic performance with respect to speed, power, motion, and agility, and these limitations are evident in athletes who are unaccustomed to wearing a PKB. Despite these concerns, use of PKBs increases in patients who have sustained an MCL injury or recovering from an ACL reconstruction surgery. As the evidence continues to evolve in sports medicine, there is limited definitive data to determine their beneficial or detrimental effects on overall injury risk of athletes, therefore leading those recommendations and decisions for their usage in the hands of the athletic trainers and team physicians' experience to determine the specific brace design, brand, fit, and situations for use.

Functional Knee Braces

Functional knee braces are considered medically necessary if they are needed for activities of daily living, such as standing, walking, and climbing stairs, and thus are worn throughout the day. Functional knee braces are most commonly used in persons with prior ligamentous knee injuries. The ligaments of the knee include the anterior cruciate ligament (ACL), the posterior cruciate ligament (PCL), the lateral collateral ligament (LCL), and the medial

collateral ligament (MCL). Functional knee braces are considered not medically necessary when used primarily for sports, because participation in sports is considered an elective activity. Some of these braces are ready-made in sizes to provide for immediate fit (so-called custom-fitted prefabricated braces). Others require custom construction based on some form of cast molding or measurement of the person's leg (so called custom-made or custom-fabricated braces). Functional braces usually involve some form of hyperextension stop, as well as straps or fitted shells to control rotation. There is no clear-cut advantage of shell braces over strap 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 considered medically necessary only for persons who cannot be fit into off the shelf braces because deformity. Even persons who are very tall or markedly obese, however, can be fitted with custom-fitted prefabricated functional braces that have been modified with attachments, such as extensions and extra-long straps. No study has demonstrated medically significant advantages of custom-made functional knee braces over custom-fitted prefabricated functional knee braces in patients with knee ligament injuries. Because the benefits of functional knee braces are due to their ability to affect heightened proprioception and to the sense of security they impart, the precise fitting of the brace, as through custom-fabrication or custom-molding, is not essential to its effectiveness. More than 50 functional braces are on the market, with no clear-cut advantage for any brand. In proving that one brace is superior to another, the manufacturer must demonstrate brace efficacy in studies designed to approximate the in vivo situation. Current studies do not provide adequate evidence to conclude that custom-made functional knee braces result in medical benefits beyond those provided by custom-fitted prefabricated braces. The manufacturer claiming superiority of their brace must be asked to verify claims and to provide documentation of efficacy.

Functional knee braces are most commonly used in persons with prior ligamentous knee injuries. The ligaments of the knee include the anterior cruciate ligament (ACL), the posterior cruciate ligament (PCL), the lateral collateral ligament (LCL), and the medial collateral ligament (MCL). Up to 70 % of acute ACL injuries occur during sports. Episodes occur during sports requiring quick turns, sudden stopping, jumping, or lateral movements (such as football, volleyball, basketball, and racquetball). For patients treated conservatively, optional bracing has been used after rehabilitation to assist patients in returning to low-demand activity. However, neuromuscular rehabilitation and activity modification are far more important. The use of the functional brace for the ACL-deficient knee remains controversial. Laboratory studies have shown that functional braces do not

prevent abnormal tibial displacement, even at physiologic loads. However, persons with prior cruciate ligament injuries subjectively feel more secure in these devices. Loss of the anterior cruciate ligament has been associated with a loss of ability to detect knee joint motion due to disruption of normal neural input. Some have hypothesized that knee braces can substitute for this lost kinesthetic awareness, and that subjective improvements while wearing the brace are due to heightened proprioception (position sense), although the evidence supporting this hypothesis is inconclusive. Others feel that psychological support may be the greatest benefit of functional braces. Despite the subject's subjective improvement, giving away episodes can occur in spite of wearing the functional brace.

McDevitt et al. (2004) conducted a prospective, randomized, multicenter clinical trial to determine whether postoperative functional knee bracing is effective. They assigned one hundred volunteers from the 3 US service academies with ACL injuries into the braced or non-braced groups. Surgical procedures and postoperative physical therapy were identical. There were no statistically significant differences between groups in the different outcome measures at a minimum 2-year follow-up. Two braced subjects had re-injuries and three non-braced subjects had re-injuries. Rishiraj et al. (2012) studied single leg peak vertical ground reaction forces (PVGRF) in 23 healthy male students while wearing a functional knee brace during a drop jump, as compared to not wearing the knee brace. There was a significant decrease in the PVGRF in the braced group. The authors concluded that the brace could keep GRF low enough from reaching the ACL and causing a tear. Bodendorfer et al. (2013) reviewed the literature on anterior cruciate ligament bracing in providing stability and preventing injury or graft re-rupture. Despite widespread use of prophylactic and functional knee braces, the evidence supporting their efficacy in reducing and/or preventing injury remains limited. Knee braces have been shown to be more effective in preventing medial collateral ligament injuries than anterior cruciate ligament injuries in both cadaveric and clinical studies. The use of functional braces after anterior cruciate ligament reconstruction has been supported and refuted in both postoperative and long-term studies.

The medial collateral ligament is the most commonly injured knee ligament in sports. Persons with a first-degree MCL sprain need only wear a knee immobilizer for a few days, and no functional brace is necessary. A first-degree sprain is, by definition, an injury to the ligament in which there is no increased laxity of that ligament. If there is laxity present, then there is either a second- or third-degree sprain. A second-degree sprain is differentiated clinically from a third-degree sprain by the feel of the "end-point" on examination and the amount of laxity. A second-degree sprain has a "firm" end point on stressing, as the ligament fibers that were not torn in the injury become taut. A third-degree sprain has a "soft" end point, as translation is gradually stopped when other ligaments and tendon fibers (secondary restraints) become taut. For the patient with a second-degree MCL sprain (partial tear), it is appropriate to prescribe a custom-fitted prefabricated functional knee brace after the rehabilitative knee brace is removed, and have the patient use this brace

for up to 8 weeks after injury. Isolated third-degree MCL injuries (complete tear) may be treated with a hinged rehabilitative brace, rather than a knee immobilizer, for the first 6 weeks after injury. (An isolated MCL sprain is one where the ACL and PCL (posterior cruciate ligament) have been proven intact by MRI and instrumented laxity testing.) The posterior cruciate ligament is infrequently injured. Functional bracing has little role in PCL injuries because there is no clinical benefit or biomechanical evidence for the use of a functional brace in the PCL-injured knee. The lateral collateral ligament is the least frequently injured of all the knee ligaments in sports because the knee is usually protected from a blow to the medial side by the person's other leg. Treatment for first- and second-degree sprains follows the same program and a very similar time frame that was used for MCL injuries. A custom-fitted prefabricated functional brace is appropriate for the patient that desires early return to activity.

Rehabilitative Knee Braces

There are few objective studies offering objective data about the stabilizing effects of various types, and no guidelines for choosing any particular rehabilitative knee brace over another. Choice of rehabilitation brace is usually based on availability, ancillary features, and ease of use. Rehabilitative knee braces do not require precise fitting (and, hence, are never custom-made) because their size must be repeatedly readjusted throughout the course of rehabilitation to accommodate changes in swelling that occur following injury or surgery to the knee.

There is little published data supporting the use of rehabilitative braces, but they are accepted clinically, and avoid the risks associated with casting.

Rannou et al. (2010) reviewed the literature on unloading knee braces and recommended their use for decreasing pain and improving function. The AAOS also concludes that some unloading knee braces may provide significant reduction in pain for patients if they are fitted correctly. Steadman et al. (2014) reviewed the current state of unloading braces on knee mechanics, clinical impact and long-term disease progression. Authors concluded that despite the significant research that has been done to show improvement in OA symptoms with unloading brace use, current literature shows an existing debate on the effectiveness of these braces to change biomechanics of the knee and thus affect disease progression. However, clinical findings show overall improvements in pain, function, instability and quality of life. Duivenvoorden et al. (2015) updated an earlier Cochrane review on braces and orthoses for treating osteoarthritis of the knee. Authors concluded that evidence was inconclusive for the benefits of bracing for pain, stiffness, function and quality of life in the treatment of patients with medial compartment knee OA. Low-quality evidence shows lack of an effect on improvement in pain, stiffness and function between patients treated with a valgus knee brace. Moyer et al. (2015) completed a meta-analysis of randomized trials on the effects of valgus knee bracing on pain and function, and compliance and complications, in patients with medial knee osteoarthritis (OA). Six studies met criteria

and were included in the meta-analysis. Overall, there was a statistically significant difference favoring the valgus brace group for improvement in pain. When compared to a control group that did not use an orthosis, the effect size was moderate for pain and function. When compared to a control group that used a control orthosis, only a small, statistically significant effect for pain remained Compliance ranged from 45% to 100%. Up to 25% of patients reported minor complications with brace use. Meta-analysis of randomized trials suggests valgus bracing for medial knee OA results in small-to-moderate improvements in pain.

Robert-Lachaine et al. (2020) evaluated usage, comfort, pain, and knee adduction moment (KAM) of three knee braces each worn 3 months by patients. Twenty-four patients with knee osteoarthritis (KOA) were assigned in a randomized crossover trial a valgus three-point bending system brace (V3P-brace), an unloader brace with valgus and external rotation functions (VER-brace) and a stabilizing brace used after ligament injuries (ACL-brace). Functional questionnaires and gait assessment were carried out before and after each brace wear period of 3 months. Brace usage was similar, but the V3P-brace was slightly less worn. Discomfort was significantly lowered with the VER-brace. All knee braces relieved pain and symptoms from 10% to 40%. KAM angular impulse was reduced with the three braces, but the VER-brace obtained the lowest relative reduction of 9%. The interaction between time and wear indicated that part of the KAM reduction with brace wear was maintained post treatment. All three knee braces have great benefits for pain and function among the medial KOA population. The VER-brace offers additional advantages on daily use, comfort and KAM, which could improve compliance to brace treatment. Fan et al. (2020) evaluated the clinical outcomes of valgus knee bracing in patients with KOA in a meta-analysis of clinical randomized controlled trials (RCTs) on pain and functional changes in patients with KOA after using valgus knee braces. A total of 10 articles were included in this study, including 739 patients. These results indicated that the valgus knee bracing has no statistical significance in pain and functional activity improvement of patients with KOA. The subgroup analysis showed that the follow-up time was the source of the heterogeneity of the VAS pain score. Authors concluded that the current evidence suggests that valgus knee bracing may not improve pain release and function activates in KOA patients in the long-term period, but only being beneficial to the short-term rehabilitation.

A Cochrane Review by D'hondt et al. (2002) on orthotic devices for treating patellofemoral pain found the evidence too limited to draw any definite conclusions. One trial did show that a Protonics orthosis was significantly more effective at decreasing pain at six weeks when compared to no treatment. Dixit et al. (2007) reported that there was little evidence to support the use of knee braces in patellofemoral pain, and better outcomes were produced with physical therapy. Smith et al. (2015) assessed the effects (benefits and harms) of knee orthoses (knee braces, sleeves, straps or bandages) for treating PFPS. We included five trials (one of which was quasi-randomized) that reported results for 368

people who had PFPS. Participants were recruited from health clinics in three trials and were military recruits undergoing training in the other two trials. Although no trials recruited participants who were categorized as elite or professional athletes, military training does comprise intensive exercise regimens. All five trials were at high risk of bias, including performance bias reflecting the logistical problems in these trials of blinding of participants and care providers. Overall, this review has found a lack of evidence to inform on the use of knee orthoses for treating PFPS. There is, however, very low-quality evidence from clinically heterogeneous trials using different types of knee orthoses (knee brace, sleeve and strap) that using a knee orthosis did not reduce knee pain or improve knee function in the short term (under three months) in adults who were also undergoing an exercise program for treating PFPS. This points to the need for good-quality clinically relevant research to inform on the use of commonly available knee orthoses for treating PFPS.

Collins et al. (2018) authored a consensus statement, from the 5th International Patellofemoral Research Retreat held in Australia in July 2017 that focuses on exercise therapy and physical interventions (e.g., orthoses, taping and manual therapy) for patellofemoral pain. Evidence-based statements were developed from included papers and presented to a panel of 41 patellofemoral pain experts for consensus discussion and voting. Recommendations from the expert panel support the use of exercise therapy (especially the combination of hip-focused and knee-focused exercises), combined interventions and foot orthoses to improve pain and/or function in people with patellofemoral pain. The use of patellofemoral, knee or lumbar mobilizations in isolation, or electrophysical agents, is not recommended. There is uncertainty regarding the use of patellar taping/bracing, acupuncture/dry needling, manual soft tissue techniques, blood flow restriction training and gait retraining in patients with patellofemoral pain. Sisk and Fredicson (2020) note that recent studies of bracing and taping have found them to be helpful for patients in the short-term management of pain and improving function. However, less is known about their exact mechanism, but studies are encouraging that they have a subtle role in changing patellofemoral biomechanics. The treatment of patellofemoral pain and patellar tendinopathy consists of a multi-faceted approach of physiotherapy and physical modalities. There is evidence for short-term use of taping and bracing for these conditions. Authors conclude that physicians should feel comfortable integrating taping and bracing into their anterior knee pain treatment.

Wallis et al. (2021) conducted a systematic review to evaluate clinical practice guidelines (CPGs) for the physical therapist management of patellofemoral pain. Four CPGs were included. One guideline evaluated as higher quality provided the most clinically applicable set of recommendations for examination, interventions, and evaluation processes to assess the effectiveness of interventions. Guideline-recommended interventions were consistent for exercise therapy, foot orthoses, patellar taping, patient education, and combined interventions and did not recommend the use of electrotherapeutic modalities. Two

guidelines evaluated as higher quality did not recommend using manual therapy (in isolation), dry needling, and patellar bracing. Authors concluded that recommendations from higher-quality CPGs may conflict with routine physical therapist management of patellofemoral pain. This review provides guidance for clinicians to deliver high-value physical therapist management of patellofemoral pain.

Kemker III et al. (2021) authored an article on hip and knee bracing in a systematic review. Authors report for support for functional knee bracing for ACL, MCL and PCL injuries or post-reconstruction and unloader bracing for knee OA. They state that efficacy for bracing for patellofemoral pain is not confirmed. Alfatafta et al. (2021) aimed to systematically review the effect of using this brace on pain and activity levels in the last 20 years in patients with medial compartment knee osteoarthritis. Seven randomized controlled studies and 17 cohort studies (in total 579 participants) were included in the systematic review. Most of these studies found using a knee valgus brace effective in reducing pain and improving activity level over different time intervals. The majority of the included studies (14 studies) evaluated the impact of the brace for a considerably short-term (less than 6 months). Thus, limited evidence is available on the long-term use of the knee valgus brace and its associated complications. Authors concluded that the knee valgus brace is an effective conservative intervention to improve the quality of life and reduce pain during daily activities for some patients. However, the long term of using this brace is still not very convenient, and the patients who benefit most from using the brace should be identified with high methodological quality studies. Gueugnon et al. (2021) aimed to compare the effectiveness, safety, and cost-utility of a custom-made knee brace versus usual care over 1 year in medial knee osteoarthritis (OA). 120 patients with medial knee OA (VAS pain at rest >40/100), classified as Kellgren-Lawrence grade II-IV, were randomized into two groups: ODRA (a distraction-rotation, custom-made knee brace) plus usual care (ODRA group) and usual care alone (UCA group). The primary effectiveness outcome was the change in VAS pain between M0 and M12. Secondary outcomes included changes over 1 year in KOOS (function) and OAKHQOL (quality of life) scores. Drug consumption, compliance, safety of the knee brace, and cost-utility over 1 year were also assessed. The ODRA group was associated with a higher improvement in: VAS pain, all KOOS subscales; other symptoms; function in activities of daily living; function in sports and leisure; quality of life, OAKHQOL subscales pain and physical activities, and with a significant decrease in analgesics consumption at M12 compared with the UCA group. Despite localized side-effects, observance was good at M12 (median: 5.3 h/day). The ODRA group had a more than 85% chance of being cost-effective for a willingness-to-pay threshold of €45 000 per QALY. Authors concluded that the ERGONOMIE RCT demonstrated significant clinical benefits of an unloader custom-made knee brace in terms of improvements in pain, function, and some aspects of quality of life over 1 year in medial knee OA, as well as its potential cost-utility from a societal perspective.

Documentation Requirements to Substantiate Medical Necessity

"Medically necessary" or "medical necessity" shall mean health care services that a healthcare practitioner/provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing, or treating an illness, injury, disease or its symptoms, and that are (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient or healthcare provider, and 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 that patient's illness, injury, or disease.

The patient's medical records should document the practitioner's clinical rationale for using the specific orthoses, as well as the patient's response.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and expert training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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