Policy Number	**DME103.002**
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Knee Braces

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Prefabricated Knee Braces
Prefabricated (off-the-shelf) knee braces **may be considered medically necessary** for individuals with knee instability due to injury or for individuals with painful osteoarthritis of the medial compartment of the knee.

Prefabricated (off-the-shelf) **unloader** knee braces **may be considered medically necessary** as a treatment for individuals with painful osteoarthritis involving the medial compartment of the knee.

NOTE 1: According to the HCPCS codes, off-the-shelf (OTS) models are described as prefabricated, requiring minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit to the individual. The individual is fitted to a limited selection of sizes, i.e., small, medium, large, etc. The brace may also be initially fitted by an orthotist, but this involves simple adjustments of these off-the-shelf braces.

Prefabricated (off-the-shelf) knee braces include, but are not limited to:

Manufacturer	**Brand Name**
Advanced Orthopedics (Philadelphia, PA)	ACL Knee Brace, Advanced Hinged Range of Motion, Airprene Hinged, Cobra Unloaded Knee, Deluxe Hinged, F.M. Hinged, Min-Knee Hinged Knee Brace, TM Wrap-Around Hinged Knee Brace, Wrap-Around Hinged Knee Brace
Bauerfeind USA, Inc. (Marietta, GA)	MOS Genu®, SecuTec® Genu, SofTec® series
Bledsoe Brace Systems (Grand Prairie, TX)	Aligner, Axiom series, Crossover series, Extender Plus, G3, Jet, Lever Lock, Merit, Merit OR, OA Impulse, Original Knee Brace, Primas, Revolution 3, Thruster, Z-12, Z-13, 20.50
Comfy Splints (Lenjoy Medical Engineering, Inc, Gardena, CA)	Comfy™ and Comfyprene™ series
DeRoyal® Industries (Powell, TN)	Deluxe Hinged, Flexgard™, Functional ACL, Hypercontrol®, M.3 or M.4® S Functional Knee Brace, OA Upright series, Slimline series, Transition series, Warrior® series
DonJoy/dj Orthopedics DJO, LLC (Vista, CA)	4TITUDE™, A22 Custom, ACL Everyday, Armor series, Competitor, Defiance series, Drytex™ Hinged Knee models, ELS, Female Fource, Fource Point™, OA FullForce, Hinged Lateral J, IROM Playmaker, Legend, OA Adjuster, OA Assist, OA Everyday, OA FullForce, OA Nano™, Playmaker models, TROM models (cool, Rehab, telescoping, with or without shells), TROM models, X-Act ROM
Mueller Sports Medicine, Inc. (Prairie du Sac, WI)	Hg80® Hinged Knee Brace, Hg80® Knee Stabilizer, Mueller® Green Adjustable Hinged Knee, MuellerHinge™ 2100, PRO LEVEL™ Hinged Knee Brace Deluxe
Ortho Innovations (Tempe, Arizona)	Mackie Hinge Knee Brace

Össur Americas (Foothill Ranch, CA)	Aspire®, C180 (various models), CTi® Series, Edge/Edge Lite, Extreme®, Flex® OTS, Flex Sport™, GII Unloader Express®, Innovator DLX®/DLX®+, Morph, OAsys® Carticare, MVP® Contour OTS, OAJ®, OASYS® OTS, Paradigm® OTS, PCL Opposition, Rebound® Cartilage series, Rehab, Sentry™, Trainer OA, Trainer OTS, Unloader® ADJ, Unloader Express®, Unloader One®Plus, Unloader® Select, Unloader Spirit®
Ottobock (Duderstadt, Germany)	Agilium Reactive, Patella Pro
Thuasne (Levallois-Perret, France)	Action Reliever, Active Reliever, Air Townsend, Air Townsend Lite, Bold, Dynamic Reliever, EXOGUARD, Genu Dynastab, Genu Ligaflex®, Genu Ligaflex® ROM, Genu PRO ACTIV®, Genuextrem, Ligastrap Genu, Motocross Series, Patella Reliever, Pediatric Air Townsend, Premier Reliever, Premier Reliever One, Premier Series, Rebel Ligament, Rebel Lite, Rebel Lock, Rebel Pro, Rebel Reliever, Reliever, Reliever Air, Reliever Air Lite, Reliever One, ROMX, Safe Limb, Silistab Genu, Sport Series, TS ROM 1200/1600, UniReliever
Townsend Design (Bakersfield, CA)	Active Reliever, Air Lite, Air Townsend, BOLD, Full Shell, Premier Series, Rebel Series, Reliever Series ROM Post Operative Knee Braces, SoftForce, Sport Series

Custom fabricated knee braces and custom fabricated unloader knee braces for individuals with knee instability due to injury or for individuals with painful osteoarthritis of the medial compartment of the knee **are considered not medically necessary** because of the availability of suitable off-the-shelf models.

EXCEPTION: Medical necessity of a custom fabricated knee brace for individuals with knee instability due to injury or for individuals with painful osteoarthritis of the medial compartment of the knee ***may be an individual consideration for those with abnormal limb contour, knee deformity, or large size, all of which would preclude the use of an off-the-shelf model.***

NOTE 2: Clinical documentation should note that an effort to adjust a prefabricated brace was attempted prior to selecting a custom fabricated knee brace. For example, use of a pediatric sized knee brace for individuals with small legs, the use of extra-long straps for individuals with large limbs or addition of extension segments for tall individuals. The request for a custom fabricated knee brace should include the individual's thigh measurement and the size of thigh the manufacturer's largest knee brace will fit.

NOTE 3: Custom fabricated describes a brace that is individually made according to precise measurements or mold/cast of an individual. Thus, only the individual should use that custom fabricated brace.

<u>Custom fabricated knee braces include, but are not limited to:</u>

Manufacturer	Brand Name
DeRoyal® Industries (Powell, TN)	Custom Knee Braces, OA Knee Brace
DonJoy/dj Orthopedics (Vista, CA)	OA Defiance®
Össur Americas (Foothill Ranch, CA)	CTi® OA models (Pro Sport, Standard, Vapor®), Custom OA Unloader® models (ADJ®, LP®, One®, Select®, XT®)
Townsend Design (Bakersfield, CA)	Polio & Trigger series, Premier & Reliever series (Custom-fabricated models for severe osteoarthritis)

Custom fabricated knee braces and custom fabricated unloader knee braces designed specifically for participation in elective sports **are considered not medically necessary**.

Prophylactic Knee Braces

Prophylactic knee braces **are considered not medically necessary.**

NOTE 4: Coverage of the Agilium Freestep Osteoarthritis device is addressed in Medical Policy DME103.001 Orthotics.

Policy Guidelines

None.

Description

Knee braces typically consist of three components: a superstructure (usually a rigid shell), a hinge, and a strap system. The superstructure extends proximally to and distally from a hinge centered around the knee's axis of motion. The strapping system secures the brace to the limb. In short, knee braces shift the bones into a different position, which results in releasing pressure on the joints and ligaments, improving circulation in the area, and relieving pain. They also reduce the chances of re-injury and boost the mobility of the knee joint. Knee braces can be subdivided into four categories that are based on their intended use:

- **Prophylactic braces** are those that attempt to prevent or reduce the severity of knee ligament injuries in a relatively normal (stable) knee. These braces are primarily designed to prevent injuries to the medial and lateral collateral ligaments and are often used in recreational or organized sports.
- **Rehabilitation braces** are designed to allow protected and controlled motion of injured knees that have been treated operatively or non-operatively. These braces allow for controlled joint motion and typically consist of hinges that can be locked into place to limit range of motion. Rehabilitation braces are commonly used for 6 to 12 weeks after injury. Rehabilitation braces are usually purchased prefabricated (off-the-shelf) and can be ordered

either as small, medium, or large or by a size-chart. Most rehabilitation knee braces can be adjusted within each size to allow for edema or atrophy and are not custom made.

- **Functional braces** are designed to assist or provide stability for unstable knees during activities of daily living (ADL) or vocational or avocational activities and may be either off-the-shelf or custom-made. Derotation braces are typically used after injuries to ligaments and have medial and lateral bars with varying hinge and strap designs. These derotation braces are designed to permit significant motion and speed; in many instances the braces are worn only during elective activities, such as sports. Braces made of graphite, titanium, or other lightweight materials are specifically designed for high performance sports. Functional knee braces have also been used in patients with osteoarthritis in order to decrease the weight on painful (e.g., arthritis pain) joints.
- **Unloader knee braces**, also referred to as off-loader knee braces, are specifically designed to reduce the pain and disability associated with osteoarthritis of the medial compartment of the knee. Individuals with osteoarthritis of the knee with varus or valgus deformity often develop increased pain in the affected compartment due to increased mechanical loading. Unloader knee braces are designed and constructed to reduce the asymmetric loading in such knees.

Rationale

This medical policy was created in May 1990 and has been updated regularly with searches of the PubMed database. The most recent literature review was performed through April 19, 2023.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these

purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

While evidence is limited, the use of knee braces for individuals with knee instability due to injury or for individuals with painful osteoarthritis of the medial compartment of the knee appears to be somewhat beneficial and has been well accepted clinically. However, there is little to no evidence supporting the advantage of the more expensive custom fabricated knee braces over off-the-shelf knee brace designs.

Prefabricated (Off-the-Shelf) vs Custom Fabricated Knee Braces

Draganich et al. (2006) compared the effectiveness of off-the-shelf and custom-made individual -adjustable, valgus-producing knee unloader braces in relieving pain, reducing stiffness, and improving function and in reducing varus angulation and the peak adduction moments of the knee during gait and stair-stepping in individuals with painful varus gonarthrosis of the knee. (1) Ten individuals wore each type of brace for 4-5 weeks (approximately 9 hours per day) in a randomized order. Pain scores were reduced from 197 mm (500 mm maximum) to 71 mm with the custom brace and 120 mm with the off-the-shelf brace. Stiffness was reduced from 91 mm (200 mm maximum) to 36 mm with the custom brace and 63 mm with the off-the-shelf brace. Function was improved from 664 mm (1,700 mm maximum) to 248 mm with the custom brace, whereas the off-the-shelf brace did not significantly affect function. Kinematic analysis showed a reduction in peak knee adduction moments during gait and stair-stepping and reduced varus angulation by 1.5 degrees, compared with baseline with the custom brace. The off-the-shelf brace did not reduce the varus angle. Investigators found that individuals with varus gonarthrosis of the knee may benefit significantly with respect to pain relief and reduced stiffness from use of either brace. While additional benefit in improved function and reduced stiffness, varus angulation, and medial compartment loading of the knee from use of the custom-made individual-adjustable brace was seen, additional study that captures longer periods of follow-up and/or larger populations is needed.

Soma et al. (2004) compared the performance of custom-made and off-the-shelf functional knee braces from 4 manufacturers. (2) The mechanical surrogate was interfaced with a servohydraulic materials testing system, which applied all anterior/posterior displacements to an ultimate anterior load of 400 N. Comparison of the individual custom versus premanufactured braces showed that the custom braces demonstrated a statistically significant difference for restraining anterior displacement (P=.0001 to P=.0005). Pooled data from all tests showed that the custom brace measurements as a group restrained anterior displacement better than the premanufactured brace group by a mean difference of 0.84 mm (P=.0001). However, the authors questioned whether such small, sub-millimeter findings between custom and off-the-shelf functional derotation braces represent any clinically significant differences.

Many sports medicine practitioners believe "custom-fit" functional braces are superior in performance to "off-the-shelf" braces for anterior cruciate ligament (ACL)-deficient knees. However, this is not well substantiated. In a 2001 study, Wojtys and Huston compared a Donjoy custom-fit ACL brace (CE 2000), Donjoy off-the-shelf brace (Goldpoint), and an athletic taping

technique to determine their role in our clinical practice. (3) Five individuals (3 men and 2 women) with isolated, unilateral, chronic ACL tears with an average age of 27 years (range: 19-35 years) were used to evaluate these three restraint systems. Anterior tibial laxity, quadriceps and hamstrings strength, endurance, standing long jump, brace migration with exercise, and pattern of muscle response to forced anterior tibial displacement were studied. Each individual was tested without a brace and then in each of the three test conditions (custom brace, off-the-shelf brace, and tape), with the order of testing randomized. The Donjoy custom-fit ACL functional brace did not reduce anterior laxity or improve standing long jump, muscle strength, endurance, or muscle response times significantly more than the off-the-shelf ACL brace. Both braces improved anterior stability over knee taping when the knee muscles were contracted under the low forces used in this study. After 1 hour of exercise, brace migration was significantly greater (P=.03) for the CE-2000 custom brace (18.6 mm) than for the Goldpoint off-the-shelf brace (4.5 mm). Authors concluded that there appears to be no advantage to the more expensive custom-fit knee brace over the off-the-shelf brace.

Prophylactic Knee Braces

Anterior cruciate ligament injuries most commonly occur after a perturbation. Prophylactic knee braces (PKBs) are off-the-shelf braces designed to prevent and reduce the severity of knee injuries during sports, yet their effectiveness has been debated. In a controlled laboratory study, Haddara et al. (2021) sought to identify differences in ACL agonist and antagonist muscle forces, during braced and unbraced conditions, while walking with the application of unexpected perturbations. (4) A total of 20 recreational athletes were perturbed during walking at a speed of 1.1 m/s, and motion analysis data were used to create individual-specific musculoskeletal models. Static optimization was performed to calculate the lower-limb muscle forces. Statistical parametric mapping was used to compare muscle forces between the braced and unbraced conditions during the stance phase of the perturbed cycle. The brace reduced muscle forces in the quadriceps (QUADS), gastrocnemius (GAS), and soleus (SOL) but not in the hamstrings. The peak QUADS muscle force was significantly lower with the brace versus without at 49% to 60% of the stance phase (28.9 ± 12.98 vs 14.8 ± 5.06 N/kg, respectively; $P < .001$) and again at 99% of the stance phase (1.7 ± 0.4 vs 3.6 ± 0.13 N/kg, respectively; $P = .049$). The SOL muscle force peak was significantly lower with the brace versus without at 25% of the stance phase (1.9 ± 1.7 vs 4.6 ± 3.4 N/kg, respectively; $P = .031$) and at 39% of the stance phase (1.9 ± 1.4 vs 5.3 ± 5.6 N/kg, respectively; $P = .007$). In the GAS, there were no significant differences between conditions throughout the whole stance phase except between 97% and 100%, where the braced condition portrayed a smaller peak force (0.23 ± 0.13 vs 1.4 ± 1.1 N/kg for unbraced condition; $P = .024$). Authors concluded that these findings suggested that PKBs that restrict knee hyperextension and knee valgus/varus motion can alter neuromuscular patterns, which result in a reduction of QUADS force. Understanding the way PKBs alter muscle function and knee mechanics can provide invaluable information that will help in making decisions about their use. Further studies should investigate different types of braces and perturbations to evaluate the effectiveness of PKBs.

The lower-limb muscles are believed to play an important role in stabilizing the knee joint. The purpose of a 2016 study from Ewing et al. was to investigate the changes in lower-limb muscle

function with prophylactic knee bracing in male and female athletes during landing. (5) Fifteen recreational athletes performed double-leg drop landing tasks from 0.30m and 0.60m with and without a prophylactic knee brace. Motion analysis data were used to create subject-specific musculoskeletal models in OpenSim. Static optimization was performed to calculate the lower-limb muscle forces. A linear mixed model determined that the hamstrings and vasti muscles produced significantly greater flexion and extension torques, respectively, and greater peak muscle forces with bracing. No differences in the timings of peak muscle forces were observed. These findings suggest that prophylactic knee bracing may help to provide stability to the knee joint by increasing the active stiffness of the hamstrings and vasti muscles later in the landing phase rather than by altering the timing of muscle forces. Further studies are necessary to quantify whether prophylactic knee bracing can reduce the load placed on the ACL during intense dynamic movements.

In a 2009 article, Rishiraj et al. discussed the potential role of prophylactic knee bracing in preventing knee ligament injury. (6) It is estimated that knee injuries account for up to 60% of all sport injuries, with the anterior cruciate ligament (ACL) accounting for almost half of these knee injuries. Many ACL (intrinsic and extrinsic) injury risk factors have been identified and investigated by numerous researchers. Although prevention programs have shown potential in decreasing knee ligament injuries, several researchers have suggested that no conclusive evidence has been presented in reducing the rate and/or severity of ACL injuries during sporting competition. Knee braces have been available for the last 30 years and have been used to assist individuals with ACL-deficient and ACL-reconstructed knees. However, research is limited on the use of knee braces (prophylactic and functional) to potentially prevent knee ligament injury in the non-injured population. One possible explanation for the limited research could be that the use of these devices has raised concerns of decreased or impaired athletic performance.

UpToDate

In 2022, UpToDate evaluated the literature on management of moderate to severe knee osteoarthritis (OA). As with mild knee OA, nonpharmacologic interventions, focusing on education, exercise, and weight management, are first-line therapies for patients with moderate to severe knee OA. Other nonpharmacologic measures that may be considered include knee braces and walking aids as well as psychological interventions.

Valgus (or unloader) knee bracing has been used to shift the load from the medial compartment with intent to relieve pain and improve function in individuals with medial tibiofemoral (TF) joint OA. For individuals who are amenable to this intervention and likely to comply with the treatment, use of a knee brace is commonly utilized as an adjunct to other core treatments. Individuals with medial TF joint OA who are more physically active and usually younger may experience greater improvements with unloader knee bracing.

“In a meta-analysis of six randomized trials, use of a brace compared with standard care (no orthosis use) was associated with a moderate improvement in both pain and function, while overall small improvements in pain were found when valgus bracing was compared with an

orthosis control group (neutral knee brace, neoprene knee sleeve, or insoles). There was great heterogeneity in the comparator and in the prescription of braces across the six studies included in the meta-analysis. In a randomized trial including 80 patients with medial knee OA comparing valgus bracing with a neutral brace, there was a small but statistically significant decrease in pain in the brace group. With regard to soft braces, there is limited evidence in support of their use. A meta-analysis including three low-quality randomized trials with variable follow-up of 6, 16, and 24 weeks found that there was a moderate improvement in pain and a small to moderate improvement in function with soft bracing compared with standard care.

In general, up to 25 percent of patients experience minor complications of bracing such as slipping and poor fit. In addition, relatively low compliance rates (45 to 58 percent in parallel-group studies) may also hamper optimal results in clinical practice.

Patellofemoral (PF) taping and bracing, on the other hand, aim at reducing joint stress in patients with symptoms arising from the PF joint and presence of patellar malalignment. There is evidence that patellar taping markedly improves pain in the short term, while PF bracing seems a more appealing option for long-term use such as in patients with PF OA. However, a crossover trial did not find differences in pain reduction when PF OA participants wore a specific type of off-the-shelf brace with or without the realigning strap applied. On the other hand, another study found small improvement in pain in the group that wore the brace for a mean of 7.4 hours daily for six weeks compared with a no-brace control group. In addition, the brace group had greater reduction in PF bone marrow lesion volume, suggesting a potential structure-modifying effect." (7)

In a Nov 2022 review on medial collateral ligament (MCL) injury of the knee, UpToDate indicated that injuries to the MCL occur frequently in athletes, particularly those involved in sports that require sudden changes in direction and speed and in individuals struck on the outside of the knee. Most heal well with conservative treatment, but some are associated with significant injuries. The use of a prophylactic knee brace to prevent injury or reinjury to the MCL is controversial, with little high-quality evidence to guide decision-making. Although functional knee bracing is used with some frequency in certain sports and positions, there is no clear evidence that such use decreases the incidence of knee injuries, specifically ligamentous injuries such as MCL tears.

An early review of studies on prophylactic bracing found mixed results. A prospective observational study of 987 college American football players with a total of 155,772 exposures reported a nonsignificant trend toward MCL injury prevention overall in those using a brace. However, the risk was increased among backfield players using braces. Subsequent studies have found no clear benefit with a review of the studies on bracing finding mixed results. Functional or hinged bracing may be helpful early during rehabilitation, particularly for unstable injuries. However, the knee should not be fully immobilized at any time. Benefit from prophylactic bracing remains unproven. Additionally, it was noted that braces may create a mechanical disadvantage in some instances. (8)

Summary of Evidence

While there is evidence in the published scientific literature to indicate that knee braces may be beneficial when individuals have knee instability due to injury or for those with painful osteoarthritis of the medial compartment of the knee, there is little to no evidence supporting the advantage of the more expensive custom fabricated knee braces over off-the-shelf knee brace designs. For individuals who cannot fit into off-the-shelf braces because of a deformity that interferes with fitting (i.e., disproportionate size of calf and thigh or minimal muscle mass upon which to suspend a knee brace), custom fabricated braces may be considered.

Prophylactic knee braces attempt to prevent or reduce the severity of knee ligament injuries, in a relatively normal (stable) knee and are designed to protect uninjured knees from valgus stresses that could damage the medial collateral ligaments. These injuries are among the most common athletic injuries. However, there is a lack of evidence to support that the use of prophylactic braces reduces the incidence or severity of injuries of ligaments of the knee, and they are not recommended for regular use.

Practice Guidelines and Position Statements

The American Academy of Orthopaedic Surgeons (AAOS)

The AAOS published an evidence-based clinical practice guideline (2022), on the management of anterior cruciate ligament injuries, including the following recommendations: (9)

- 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: 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 (OARSI)

The OARSI treatment guidelines on non-surgical management of knee, hip, and polyarticular osteoarthritis recommended against bracing of the knee due to inadequate efficacy and safety balance, stemming from very poor-quality evidence. (11)

The American Academy of Pediatrics (AAP)

The American Academy of Pediatrics (AAP) (2001) (12) published a technical report on the use of knee braces in young athletes and concluded, “There is insufficient evidence to recommend the use of prophylactic knee braces for the pediatric athlete, and available studies do not support the prescribing of most knee braces. However, the use of knee sleeves, functional braces, and postoperative braces have been accepted clinically on the basis of subjective performance. If used, knee braces should complement, rather than replace, rehabilitative therapy and required surgery.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	L1810, L1812, L1820, L1821, L1830, L1831, L1832, L1833, L1834, L1836, L1840, L1843, L1844, L1845, L1846, L1847, L1848, L1850, L1851, L1852, L1860

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

References

1. Draganich L, Reider B, Rimington T et al. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. J Bone Joint Surg Am 2006; 88(12):2645-2652. PMID 17142415
2. Soma CA, Cawley PW, Liu S, Vangsness CT Jr. Custom-fit versus premanufactured braces. Orthopedics. Mar 2004; 27(3):307-310. PMID 15058453
3. Wojtys EM, Huston LJ. "Custom-fit" versus "off-the-shelf" ACL functional braces. Am J Knee Surg. Summer 2001; 14(3):157-162. PMID 11491426
4. Haddara R, Harandi VJ, Lee PVS. Effect of prophylactic knee bracing on anterior cruciate ligament agonist and antagonist muscle forces during perturbed walking. Orthop J Sports Med. Feb 2021; 9(2):2325967120981641. PMID 33614810
5. Ewing KA, Fernandez JW, Begg RK, et al. Prophylactic knee bracing alters lower-limb muscle forces during a double-leg drop landing. J Biomech. Oct 2016; 49(14):3347-3354. PMID 27592299
6. Rishiraj N, Taunton JE, Lloyd-Smith R, et al. The potential role of prophylactic/functional knee bracing in preventing knee ligament injury. Sports Med. 2009; 39(11):937-960. PMID 19827861
7. Deveza LA, Bennell K. Management of moderate to severe knee osteoarthritis. In: UpToDate, Hunter, D (ed), December 20, 2022, Waltham, MA. Available at: <http://www.uptodate.com> (accessed May 5, 2023).
8. MacDonald, James. Medial (tibial) collateral ligament injury of the knee. In: UpToDate, Fricker, P (ed), November 29, 2022, Waltham, MA. Available at: <http://www.uptodate.com> (accessed May 5, 2023).
9. American Academy of Orthopaedic Surgeons Management of Anterior Cruciate Ligament Injuries. Evidence-Based Clinical Practice Guideline. Available at <http://www.aaos.org> (accessed April 6, 2023). Published August 22, 2022.
10. American Academy of Orthopaedic Surgeons (AAOS). The use of knee braces [position statement]. Rosemont, IL: AAOS; 1997 Oct. Revised 2003 Dec. Retired December 2008. Available at: <http://www.aaos.org> (accessed April 9, 2008).

11. The Osteoarthritis Research Society International (OARSI). OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. Nov 2019; 27(11):1578-1589. PMID 31278997
12. American Academy of Pediatrics Committee on Sports Medicine. Knees brace use in the young athlete. Pediatrics. Aug 2001; 108(2):503-507. PMID 11483826

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
05/15/2024	Reviewed. No changes.
07/01/2023	Document updated with literature review. Coverage unchanged. The following references were added: 9 and 11.
08/15/2022	Reviewed. No changes.
04/15/2022	Document updated with literature review. The following changes were made to Coverage: 1) Reorganized into three sections – Prefabricated Knee Braces, Custom Fabricated Knee Braces, and Prophylactic Knee Braces; 2) Revised knee brace example tables; 3) Revised NOTE 1; and 4) Added "Custom fabricated knee braces and custom fabricated unloader knee braces designed specifically for participation in elective sports are considered not medically necessary." Added the following references: 3-6, and 8-12; some removed and others updated. 18.
07/15/2018	Reviewed. No changes.
10/01/2017	Document updated with literature review. The following note was added as clarification for individual consideration of a custom fabricated knee brace as medically necessary: "Clinical documentation should note that an effort to adjust a prefabricated brace was attempted prior to selecting a custom fabricated knee brace. For example, use of a pediatric sized knee brace for individuals with small legs, the use of extra-long straps for individuals with large limbs or addition of extension segments for tall individuals. The request for a custom fabricated knee brace should include the individual's thigh

	measurement and the size of thigh the manufacturer's largest knee brace will fit."
03/15/2016	Reviewed. No changes.
07/01/2015	Document updated with literature review. Coverage unchanged.
10/01/2014	Reviewed. No changes. CPT/HCPCS code(s) updated
10/15/2013	Document updated with literature review. Coverage unchanged.
10/01/2008	Revised/updated entire document.
04/01/2003	CPT/HCPCS code(s) updated
08/01/2002	Revised/updated entire document
01/01/2000	Revised/updated entire document
05/01/1996	Medical policy number changed
05/01/1990	New medical document