Anthem

Clinical UM Guideline

Subject: Microprocessor Controlled Knee-Ankle-Foot Orthosis
Guideline #: CG-OR-PR-09
Status: New
Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description

This document addresses the use of a microprocessor controlled knee-ankle-foot orthosis (for example, the C-Brace®, Ottobock HealthCare LP, Austin, TX) that provides support for individuals with lower extremity weakness. This microprocessor controlled device is a stance and swing phase control orthosis (SSCO) intended to augment the function of individuals with peripheral or central neurologic conditions that result in weakness or paresis of the quadriceps and/or other knee extensor muscles.

Note: This device should not be confused with microprocessor controlled *prosthetic* devices, which are intended to replace or compensate for a missing limb or body part. For documents related to microprocessor controlled *prosthetic* devices see

- CG-OR-PR-05 Myoelectric Upper Extremity Prosthetic Devices
- CG-OR-PR-08 Microprocessor Controlled Lower Limb Prosthesis.

Note: Please see the following related document for additional information:

- CG-DME-22 Ankle-Foot & Knee-Ankle-Foot Orthoses

Clinical Indications

Medically Necessary:

I. Microprocessor controlled knee-ankle-foot orthoses are considered **medically necessary** when **all** of the following criteria set forth in (A) and (B) below have been met:
   A. Selection criteria:
      1. Individual is ambulatory and use of a knee-ankle-foot orthosis (KAFO) is appropriate; **and**
      2. Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology; **and**
      3. The provider has documented that there is a reasonable likelihood of better mobility or stability with the device instead of a KAFO; **and**
      4. There is documented need for ambulation in situations where the device will provide benefit (for example, regular need to ascend/descend stairs, traverse uneven surfaces or ambulate for long distances [generally 400 yards or greater cumulatively]);
         and
   B. Documentation and performance criteria:
      1. Complete multidisciplinary assessment of individual including an evaluation by a certified orthotist. The assessment must objectively document that all of the above selection criteria have been evaluated and met.

Not Medically Necessary:

The use of a microprocessor controlled knee-ankle-foot orthosis is considered **not medically necessary** when the criteria above have not been met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
L2006	Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure code listed above when criteria are not met.

Discussion/General Information

More than 1.8 million people in the United States use lower-extremity orthoses. For centuries, individuals with lower-extremity weakness, or specifically quadricep weakness, were prescribed an LKAFO. This device may cause abnormal gait patterns that can contribute to chronic pain, slower gait and decreased mobility (Deems-Dluhy, 2021). Since 1978, SCOs that allow users to flex their knee during the swing phase to prevent abnormal gait patterns have been another option to individuals who suffer from lower limb paresis or paralysis (Pröbsting, 2017). Devices such as LKAFOs and SCOs are limited in function whereas an MPO, such as the C-Brace, uses sensor technology to improve the balance, functional mobility and quality of life in individuals with lower-extremity impairments. The C-Brace combines electronic components with a specialized orthotic brace that provides support for individuals with conditions such as lesions of the femoral nerve, incomplete spinal cord injury, as well as orthopedic conditions that result in

uncontrolled knee flexion, failed knee joint replacement and knee joint derangement. The C-Brace's stance and swing phase of the gait cycle is controlled hydraulically with microprocessor sensor technology that receives information from the electronic sensors 100 times per second. This device stabilizes the knee in the sagittal plane and mimics the physiologic function of the quadriceps muscle which supports the user during the entire gait cycle. With the use of this microprocessor-controlled leg orthotic, an individual is able to obtain a closer physiological value of walking compared to the functionality of conventional paralysis orthoses that are limited to releasing and locking the knee joint.

The lack of functional ability of individuals with conditions that result in weakness or paresis of the quadriceps and/or other knee extensor muscles can have a significant impact on ADLs. The MMT Grading system is used by practitioners for the evaluation of strength of individual muscles or muscle groups. This grading system has a scale of 0 to 5 and the purpose of this grading system is to ensure accurate, consistent interpretation of MMT findings. The following classifications are used to determine strength and grade:

Level 0: No visible or palpable contraction
Level 1: Palpable muscle contraction but no joint movement, gravity eliminated
Level 1+: Less than or equal to half active range with gravity eliminated
Level 2-: Movement greater than half range but less than full range, gravity eliminated
Level 2: Full range of motion (ROM), gravity eliminated, cannot take resistance nor initiate against gravity
Level 2+: Completes less than or equal to half range actively against gravity and completes full ROM with gravity eliminated
Level 3-: Greater than half range but less than full range in antigravity position
Level 3: Full ROM, antigravity, cannot take resistance
Level 3+: Full ROM against gravity with slight resistance
Level 4-: Full ROM against gravity with mild resistance
Level 4: Full ROM against gravity with moderate resistance
Level 4+: Full ROM against gravity with slightly greater than moderate resistance
Level 5: Normal, maximal resistance

According to the U.S. Food and Drug Administration (FDA), the C-Brace is classified as a Class I device and exempt from the premarket notification 510(k) requirements as well as the Medical Device Good Manufacturing Practices (GMPs). A device may be exempt from 510(k) requirements if the FDA determines that a 510(k) is not required to provide reasonable assurance of safety and effectiveness for the device (FDA, 2019).

Traditionally, individuals who require the use of an orthosis due to a condition that results in weakness or paresis of the lower extremity have been prescribed and fitted with other types of orthoses such as an LKAFO or an SCO. The C-Brace, with its microprocessor-controlled hydraulic unit, makes the benefits of microprocessor controlled prosthetic knee joints to above-knee amputees now available to leg orthosis dependent individuals for the first time.

Individuals with lower limb weakness or paralysis may benefit from the use of a KAFO. There are different types of KAFOs and the mechanism of action of the KAFO that is prescribed depends on the individual's need and the remaining muscle function (Pröbsting, 2017). A stance controlled orthosis (SCO) is a form of KAFO which uses various technical switching mechanisms to allow locking the orthotic knee joint during stance for safe standing and walking as well as unlocking it at the end of the stance. Although this device allows an individual to flex their knee during the gait cycle, it is limited in function and safety due to its inconsistent control of the stance knee on stairs, ramps and uneven ground. (Deems-Dluhy, 2021). The C-Brace, with its sophisticated signal-processing algorithms, is the first microprocessor swing and stance controlled knee-ankle-foot orthosis (MPO) that supports walking with a wide variety of different gait velocities. This type of orthosis is appropriate for individuals who meet criteria for fitness, health and daily utilization expectations. According to the manufacturer of the device, there are prerequisites that must be met before an individual can be considered a candidate for the C-Brace and they include the following criteria: must be able to fully stabilize the trunk and to stand when knee flexion is blocked, the muscle strength of the hip extensors and flexors must permit the controlled swing-through of the affected leg and those individuals with insufficient hip flexors and extensors to swing through the affected leg, must have the ability to advance the limb by compensatory trunk movement, and the individual has a body weight of 275 pounds or less. Unlike the KAFO and SCO, the C-Brace offers controlled knee flexion during weight bearing and dynamic swing control which has led to improvements in perceived orthotic mobility and safety (Pröbsting, 2017).

Deems-Dluhy and colleagues (2021) evaluated the potential of an MPO to improve balance, functional mobility, and quality of life in individuals with lower-extremity impairments as compared to an SCO and conventional KAFO over a use-period of a month. The randomized controlled trial (RCT) included 18 participants who actively used a unilateral KAFO for neurologic or neuromuscular disease, orthopedic disease, or trauma. The study inclusion criteria consisted of participants: 18-80 years of age, regular and compliant use of a unilateral KAFO or SCO for impairment due to neurologic or neuromuscular disease, orthopedic disease, or trauma, ability to demonstrate a gait pattern to use the SCO and MPO trial tools, cognitive ability to understand and willingness to provide informed consent and follow the study protocol. Exclusion criteria included participants with ankle passive range of motion less than two degrees or knee flexion contracture or alignment resulting in the inability to actively use the study device, weight greater than 275 pounds, unstable neurologic or cardiovascular or pulmonary disease, or cancer, and participation in physical therapy specific to orthotic and gait training within 1 month of enrollment. Each potential participant was screened for inclusion and exclusion criteria and for the ability to use the study device trial tools safely prior to enrollment. Significant changes were observed in participants' self-selected gait speed ($p=0.023$), Berg Balance Scale (BBS) ($p=0.01$), functional gait assessment (FGA) ($p=0.002$), and stair assessment index (SAI) ($p<0.001$) between baseline and post-MPO assessment. Similar significant differences were seen when comparing post-MPO with post-SCO data. During the 6-minute walk test (6MWT), persons using the MPO walked significantly longer ($p=0.013$) than when using their baseline device. Participants reported higher quality of life scores in the Orthotic and Prosthetic User's Survey (OPUS) ($p=0.02$) and physical health domain of the World Health Organization Quality of Life (WHOQOL)-BREF ($p=0.037$) after using the MPO. Participants reported fewer falls when wearing the MPO versus an SCO or locked knee-ankle-foot orthosis (LKAFO). The study concluded that the MPO may contribute to improved quality of life and health status of individuals with lower extremity impairments by providing the ability to have better walking speed, endurance, and functional balance.

Pröbsting and others (2017) performed a study to evaluate the potential benefits of an MPO compared to SCO and LKAFO in activities of daily living (ADL). The study design was a survey of lower limb orthosis users before and after fitting of an MPO. There were 13 individuals enrolled in the study (9 males, 4 females, mean age 57.4 ± 14.4 years). Eight individuals were poliomyelitis survivors, 2 of which were affected bilaterally. Three of the participants suffered from an incomplete spinal cord injury, 1 participant had a peripheral lesion of the femoral nerve, and 1 participant had a leg paralysis after stroke. Manual muscle testing (MMT) demonstrated a variety of paretic or even paralytic patterns of hip and knee muscles. All participants were dependent on KAFOs. Only 1 participant needed orthoses for both legs. Five study participants were using LKAFOs and 8 used an SCO. Of the SCO participants, 2 had a NEURO MATIC (Fior & Gentz, Germany) and 1 used a Horton SCO (Horton's Orthotic & Prosthetic Lab, USA) that can both lock in all flexed positions of the knee joint. The SPL-2 (Basko Healthcare, NL), which can only lock in full extension or 15° flexion, was used by 1 participant. Three participants used the E-MAG Active (Otto Bock HealthCare GmbH, D) and 1 used the Free Walk (Otto Bock HealthCare GmbH, D) which can both lock in full extension only. An inclusion criterion was that individuals had to have used their previous orthosis for at least 6 months prior to enrollment in this study. As determined by the attending physicians of the

individuals, all previous orthoses had an optimal fit and the individuals had received appropriate gait training at the time of fitting. The average overall orthosis (LKAFO and/or SCO) use of the study sample was 24.3 ± 19.8 years. The study concluded that the MPO may facilitate an easier, more physiological, and safer execution of many ADLs compared to traditional leg orthosis technologies. As the MPO allows for knee flexion during weight bearing, it enables leg orthosis users to perform many important ADLs such as descending ramps and stairs in a nearly physiologic and naturally reciprocal manner. Moreover, its control of knee flexion and extension during swing supports walking with a wide variety of gait speeds. The results of this study suggest that users of LKAFOs and SCOs may benefit from MPO use in terms of perceived safer and easier execution of many ADLs.

Schmalz and colleagues (2016) conducted a study to compare the functionalities of conventional KAFOs and the C-Brace by using established biomechanical tests. The study enrolled 6 individuals who were fitted with a C-Brace for periods between 7 and 30 weeks and who had previously used other KAFOs. Four individuals had used unilateral SCO systems and 2 individuals, 1 unilateral and 1 bilateral, did not qualify for SCO fitting for safety reasons and had therefore used an LKAFO. Inclusion criteria for the participants in this study were ages between 18 and 70 years and dependency on the ability to walk on a KAFO, regardless of locked or posterior off-set KAFO or any type of SCO. Individuals were excluded from participation if they were using additional walking aids to ambulate on level ground. During the fitting process, the functional status of the muscles of the lower limb was determined for each participant with MMT using the Janda scale from 0 to 5. In contrast to the common pronounced weaknesses of the extensors of the knee joint, considerable individual variations of weakness of the other muscles of the affected lower limb were found resulting from different underlying clinical conditions. All participants examined were fitted with the C-Brace orthosis during the controlled market launch of the system. Immediately before being fitted, biomechanical tests were conducted with the participants using their previous orthoses in the gait laboratory. Level walking was tested first and for those participants who were able to descend ramps or stairs, respectively, step over step, this movement pattern was also analyzed. After having been fitted with the C-Brace orthosis, the participants used it in their everyday routine for at least 7 weeks. After this, all tests were repeated in the gait laboratory at a follow-up session using the C-Brace. Ground reaction forces acting during level walking were measured using two force plates (Kistler 9287A, Winterthur, Switzerland; scanning rate of 1080 Hz). The kinematics of movements were measured by recording the trajectories of passive markers using an optoelectronic camera system (six MCam series cameras, Vicon 460; ViconPeak, Oxford, UK; scanning rate of 120 Hz). To do this, 14 markers were used based on an established model (metatarsophalangeal joint V, lateral malleolus, knee centre defined by Nietert [pivot axis of the orthotic knee joint], trochanter, acromion, lateral humeral epicondyle, ulnar styloid process). The stairs used for the test consisted of five steps; the middle step was attached to a force plate. To measure descending a ramp, a 5-meter long ramp with an incline of 10° was used. In the middle of the ramp, a 40-centimeter long element was integrated with a direct connection to a force plate. On foot contact with this element, the ground reaction forces could thus be recorded for this movement as well. For each of the movement patterns examined, 8 to 10 gait cycles were measured. For level walking results, the group means of the time–distance parameters velocity and stride length did not show any significant differences between the previous KAFO and the C-Brace. The step length asymmetries (difference between the step length on the orthotic side and the sound side) measured for all 5 participants with a unilateral orthosis result from individually varying conditions. In 3 cases, a longer step was measured on the orthotic side with the previous device. With the C-Brace in these subjects, there was no difference in step length in 1 case and a longer step on the orthotic side in another case. Compared with healthy individuals, velocity and step length are considerably reduced with clearly greater step asymmetry. The orthotic function of allowing for knee flexion during weight bearing in stance is confirmed in 4 of 6 subjects (5 of 7 orthotic limbs) when using a C-Brace; a mean flexion angle of 11.0° (5.6°) is measured. In the swing phase, a mean maximum flexion angle of 74.0° (6.4°) was measured with the SCO system in contrast to 66.6° (8.5°) with the C-Brace. In regard to the use of a ramp, 2 participants were able to descend a ramp step over step using a handrail with their previous SCO or locked KAFO. However, individually varying considerable compensatory patterns were required to do this. The other 2 participants employed a step-to technique and made use of the handrail and a walking aid in this situation. With the C-Brace, all participants were able to descend a ramp using the natural step-over-step technique; only 1 person needed the handrail. Regarding results for use of the stairs, there were no individuals who were able to descend stairs in a natural step-over-step technique with the previous orthoses. However, when using the C-Brace, all individuals were able to descend stairs using the step-over-step technique with the use of the handrail. Overall, the tests showed that the C-Brace for situation-dependent knee flexion in the weight-bearing condition have been used by participants with a high level of confidence. It was demonstrated that due to the high safety potential, individuals will be able to use the C-Brace lower limb orthosis even if they are not able to use an SCO.

Based on the peer-reviewed literature, the C-Brace leg orthosis has shown that individuals may have better walking speeds, endurance and functional balance with the device. Due to technological advancements of leg orthoses, individuals with lower extremity impairment can have an easier execution of many ADLs and achieve an optimum quality of life.

Definitions

Knee Ankle Foot Orthosis (KAFO): A long-leg orthosis that spans the entire leg and is provided to compensate for muscle weakness, paralysis, or skeletal problems which cause lower limb instability.

Locked Knee Ankle Foot Orthosis (LKAFO): Knee-ankle-foot-orthosis with a locked orthotic knee joint.

Manual Muscle Test (MMT): A procedure for the evaluation of strength of individual muscle or muscles group, based upon the effective performance of a movement in relation to the forces of gravity or Manual Resistance through the available Range of motion (ROM).

Orthosis: An orthopedic appliance or apparatus used to support, align, prevent, or correct deformities, or to improve function of movable parts of the body. These types of devices are not prosthetic devices, which are intended to replace or compensate for a missing limb or other body part.

Stance Control Orthosis (SCOs): An orthosis which uses various technical switching mechanisms to allow locking the orthotic knee joint during stance for safe standing and walking as well as unlocking it at the end of the stance phase to allow for a free swing phase.

References

Peer Reviewed Publications:

1. Deems-Dluhy S, Hoppe-Ludwig S, Mummidisettty CK, et al. Microprocessor controlled knee ankle foot orthosis (KAFO) vs stance control vs locked KAFO. Arch Phys Med Rehabil. 2021; 102(2):233-234.
2. Pröbsting E, Kannenberg A, Zacharias B. Safety and walking ability of KAFO users with the C-Brace® Orthotronic Mobility System, a new microprocessor stance and swing control orthosis. Prosthet Orthot Int. 2017; 41(1):65-77.
3. Schmalz T, Pröbsting E, Auberger R, et al. A functional comparison of conventional knee-ankle-foot orthoses and a microprocessor-controlled leg orthosis system based on biomechanical parameters. 2016; 40(2):277-286.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Canadian Agency for Drugs and Technologies in Health (CADTH). Motorized walking devices for patients with compromised mobility: A review of clinical effectiveness, cost-effectiveness, and guidelines. Last Updated August 22, 2019. Available at: https://cadth.ca/sites/default/files/pdf/htis/2019/RC1165%20walking%20assistive%20devices%20Final.pdf. Accessed on August 7, 2023.
2. Centers for Disease Control and Prevention. National health survey. Number of persons using assistive technology devices. Page last reviewed: November 6, 2015. Available at: https://www.cdc.gov/nchs/nhis/ad292tb1.htm. Accessed on August 7, 2023.
3. Mendes LA, Lima IN, Souza T, et al. Motor neuroprosthesis for promoting recovery of function after stroke. Cochrane Database Syst Rev. 2020 Jan 14;1(1):CD012991.
4. U.S. Food and Drug Administration. Class I/II exemptions. Content current as of February 23, 2022. Available at: https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions. Accessed on August 7, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of OR-PR.00007 to new clinical utilization management guideline document with the same title.