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C-Brace. **Reimbursement Guide.**

August 2024.



Product Information.



The C-Brace.

Ottobock is the leading manufacturer of advanced, microprocessor controlled prosthetic knees (MPKs) for amputees, and has applied MPK technology to the microprocessor stance and swing feature of a custom-fabricated knee-ankle-foot-orthosis (KAFO); Trade Name: *C-Brace*.

The *C-Brace* stabilizes the knee in the sagittal plane mimicking the physiologic eccentric function of the quadriceps muscle and is indicated for patients with peripheral or central neurologic conditions that result in weakness or paresis of the quadriceps and/or other knee extensor muscles including, but not limited to, lesions of the femoral nerve, incomplete spinal cord injury, as well as orthopedic conditions that result in uncontrolled knee flexion including but not limited to, failed knee joint replacement, and knee joint derangement that cause pain in which the quadriceps fails to keep the knee extended during stance phase. In contrast to other KAFOs, the *C-Brace* allows the patient to walk safely and with nearly natural reciprocal gait on all kinds of terrains. In addition, its microprocessor swing control provides a stumble recovery feature and adaptability to varying walking speeds and cadence.

C-Brace Warranty.

The *C-Brace* Joint Unit comes with a three-year manufacturer warranty (extendable to six years) which includes:

- Repair costs*
- Condition-based maintenance service at 24 months or 2 million steps, whichever comes first.
- Patient is provided with a loaner unit during repair and service inspections
- Covers the charger and power supply

*Superficial damage and damage resulting from improper use, intent, negligence or force majeure are not covered.

Health Canada Compliance.

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a Class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

FDA Status for *C-Brace*.

Under FDA's regulations, the *C-Brace* is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness; therefore, safety and effectiveness research is not required for this device. *C-Brace* has met all applicable General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part 820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). Device Listing Number is E285393 and Product Code IQI.

Who Can Provide a C-Brace?

The *C-Brace* is prescribed by a physician and may only be provided by a qualified Orthotist that has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person training, online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

HCPCS Coding—U.S. only.

^{1, 2, 3} HCPCS Coding issued along with PDAC Verification (eff. January 1, 2020) and Fee Schedule (eff. October 1, 2022)

L2006 Knee ankle foot device, any material, single or double upright, swing and 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.

¹ HCPCS code L2006 was added to the Medicare Fee Schedule as of 10/01/2022. If you are working with a payer that does not have L2006 or an assigned fee schedule amount on their fee schedule, please contact Ottobock Reimbursement for assistance at reimbursement911@ottobock.com.

² CMS. 2020 Corrections to the Alpha-Numeric HCPCS File. Changed L2006 verbiage to “swing and stance phase microprocessor control” effective January 1, 2020.

³The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Suppliers contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides do not replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.



Justification.

Stumble Recovery.

The microprocessor swing control of the *C-Brace* provides a stumble recovery feature that activates high knee flexion resistance as soon as the orthotic shank starts the extension/forward movement after heel rise, allowing the patient to fully load the orthosis with his/her body weight to recover from a possible disruption of the swing phase (stumble).



Backward Walking.

With input from the IMU, the *C-Brace* provides additional safety and stability when the patient is forced to step backwards to clear potential threats or obstacles (e.g., opening door).

Intuitive Stance Function.

The Intuitive Stance function provided by the microprocessor based on IMU readings allows the patient to stand in a safe and relaxed manner with a flexed knee without the threat of knee collapse, and automatically switches back in the ambulation mode turning off the blocked knee flexion when the patient moves. This feature allows the patient to unload the sound leg and rest while securely standing on level or non-level surfaces.

Sitting/Standing.

The *C-Brace* assists the patient passively when sitting down and standing up from a chair by providing supporting resistance to flexion (bending) or extension. This adds an extra degree of safety and reduces stress to the upper extremities and the sound limb.

The microprocessor automatically detects from the sensor readings when the patient begins to sit down, adjusting the hydraulic resistance so the knee joint provides resistance against bending during the transition to sitting. This allows the patient to complete the sit-down motion in a controlled manner and at a controlled rate.

Likewise, the *C-Brace* automatically detects when the patient is starting to stand up from a seated position, adjusting the resistance against bending in a way that the patient can transfer his/her body weight to the *C-Brace* and reposition the sound foot for better leverage to complete the stand-up movement.

Real-Time Gait Analysis.

The *C-Brace* microprocessor receives information from the electronic sensors 100 times per second. Each time, gait is analyzed and the hydraulic controls are adjusted to prepare for the patient's next movement (in real-time). This allows the patient to walk with less concentration and easily change walking speeds. Additionally, the patient will walk with less compensation of the sound side (e.g. hip hike, circumduction, or vault), and use less energy to ambulate.

Stance Flexion Resistance.

C-Brace provides hydraulic resistance against knee flexion (bending), allowing controlled partial knee flexion in early stance phase during weight bearing, thus providing shock absorption and reduced impact. This allows the patient to securely walk down hills and ramps and to descend stairs step over step.



Stance Flexion Resistance Plus.

For patients with slow cadences, the *C-Brace* flexion resistance setting needs to be different when walking on level ground from that needed for descending ramps and stairs and stand to sit support. Stance Flexion Resistance Plus is a setting that allows the knee joint to provide increased knee flexion resistance during level ground walking, which helps maintain the center of gravity height.

Swing Flexion Resistance.

C-Brace adjusts swing flexion resistance to insure that the swing phase limb is exhibiting proper swing phase mechanics for walking speed/cadence adaptation. If the swing phase knee flexes too much (not damped), the limb lacks the timing for

the knee to be in the proper position at terminal swing. Without control of swing flexion the patient can be in a state of perpetual stumble at initial contact.

Stance Extension Resistance.

C-Brace provides microprocessor-controlled real-time hydraulic resistance during stance extension resulting in a more natural gait. This resistance reduces knee hyperextension thrust by controlling knee extension moment at terminal stance. This feature prevents the patient from over-rotating the pelvis posteriorly and overloading the lower back during ambulation on level ground.

Swing Extension Resistance.

C-Brace provides microprocessor-controlled real-time hydraulic resistance during terminal swing. This is essential to provide shock absorption against impact with faster walking speeds. Additionally, adjustment is provided for smooth deceleration at all cadences.



MyModes.

C-Brace is programmable for training during initial use, walking on all terrains and activity specific needs of the patient.

***C-Brace* Bibliography.**

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Contact information:

Ottobock Reimbursement North America

P 800 328 4058 F 800 230 3962

US: <https://shop.ottobock.us>

CA: <https://shop.ottobock.ca>

reimbursement911@ottobock.com