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C-Brace®

Physician quick reference and documentation guide



What is the C-Brace?

Ottobock has fundamentally changed orthotics with the C-Brace. The world's first mechatronic stance and swing phase control orthosis (SSCO®) system, which controls both the stance and swing phase hydraulically with microprocessor sensor technology, remains unique.

The functionality of conventional paralysis orthoses is limited to releasing and locking the knee joint. However, the C-Brace, with its microprocessor-controlled hydraulic unit, supports the user during the entire gait cycle and adapts to everyday situations in real-time. Flexion under load, navigating slopes, walking on uneven terrain, or going down stairs step-over-step - all this defines a new level of mobility.

How is the C-Brace different from other leg orthoses?

In the past, orthotic fittings for patients with neurological indications of the lower limbs consisted solely of leg braces with locked or manual locking knee joints. With the C-Brace, users do not have to settle with a locked KAFO, and can live their life with the freedom and independence they deserve.

C-Brace is the only microprocessor-controlled hydraulic SSCO on the market that provides dynamic control of the entire gait cycle in real-time. Movement is smoother, safer, more controlled, and more stable, even on uneven terrain.



How will the C-Brace help patients?

C-Brace encourages natural body posture, reducing excessive strain on the sound-side limb. Advanced stumble-control features facilitate a greater sense of stability and security. In addition, C-Brace may provide a number of functional benefits:

- Knee control when walking down hills and ramps, descending stairs (step-over-step), and while sitting down into a chair
- Comfortable secure standing on level ground or slopes
- Ability to safely navigate uneven terrain
- Improved safety with time to recover if a stumble occurs
- Reduced contralateral limb pain and overuse injuries



Indications

C-Brace may be considered for patients with all neurologic conditions resulting in paresis or paralysis of the knee extensors or orthopedic conditions in which the quadriceps fail to keep the knee extended during stance phase who do not present any of the contraindications.

Contraindications

- Hip flexor strength of less than grade 3, unless patient has the ability to advance the limb by compensatory trunk movement (unilateral)
- Hip flexor contractures that cannot be compensated by lumbar lordosis
- Knee flexor contractures greater than 10°
- Quadriceps spasticity that stops loaded knee flexion and prevents reciprocal slope and stair descent
- Hamstring tone during terminal swing resulting in more than normal knee stance flexion
- Fixed knee valgus/varus greater than 10 degrees beyond anatomic neutral

- Cognitive inability or lack of care provider to charge battery on daily basis
- Cognitive inability to participate in structured gait training in Physical Therapy
- · Lack of access to physical therapy
- Bilateral users with less than Grade 3 hip flexors and hip abductors, and positive Trendelenburg present during ambulation
- Leg length discrepancy in excess of 6 inches
- Orthoprosthesis
- Body weight over 275 lbs.

How can patients get access to this technology?

A trial evaluation must be conducted to find out if the patient is a candidate for the C-Brace. Orthosis evaluations are conducted by trained and certified orthotists, often in coordination with a physical therapist or physiatrist.

1. Refer patient to an orthotist

If patient does not already have an orthotist, Ottobock can recommend one.

2. Start the documentation process

The C-Brace requires a physician prescription and insurance pre-authorization.

3. Contact Ottobock

If you have any questions, contact us at 512 806 2897 to speak with a member of the Professional and Clinical Services team.

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C-Brace[®] Justification

Physician Documentation Guide

Documentation may come from the prescribing physician or other pertinent sources (e.g. primary care, specialists, hospital, rehabilitation, home health, etc.). Information should be documented (if possible) in the contemporaneous medical record, as many payors do not accept Letters of Medical Necessity/Templates.

History of the Injury, Illness, or Condition

- Diagnosis related to medical necessity for the orthosis
- · Affected side
- Symptoms
- Clinical course
- Therapeutic interventions and results
- Prognosis

Functional Limitations (ordering physician)

- Describe activities prior to illness or injury and those activities that patient wants to get back to including:
 - Description of current activities of daily living and how impacted by deficit(s)
- Diagnoses causing these symptoms
- Other comorbidities either relating to ambulatory problems or impacting the use of new orthosis (e.g. cardiovascular reserve, condition of contralateral limb, fatigue)
- Ambulatory assistance (cane, walker, wheelchair, caregiver) currently used in addition to the orthosis
- State whether any of these limitations will affect your patient's ability to use the C-Brace

Physical Examination

- Recent physical examination that is relevant to functional deficits
 - Focus should be on the body systems responsible for the patient's ambulatory difficulties or impact on the patient's functional ability
 - Include comprehensive manual muscle tests (if disease is progressive, these should be taken early in the day to avoid false reading due to fatigue)
- Include spasticity test results demonstrating no spasticity. Knee extensor spasticity is allowed as long as it does not interfere with weighted knee flexion (as required for reciprocal slope and stair descent)

Orthosis Use (ordering physician)

- Problems with current orthosis/component(s), including limitations or inability to perform daily activities
- Past experience with orthoses/braces and other failed treatments
- Estimate how long it will take and if physical therapy will be required

Motivation and Participation (ordering physician)

- Document that patient is motivated to use the C-Brace
- Document that patient is able to cognitively and physically function at a level necessary to operate a microprocessorcontrolled orthosis and is willing and able to participate in training for use of the device

Document Criteria for a Custom Fabricated KAFO

- · Patient is ambulatory
- Patient has weakness/deformity of the foot and ankle, and requires stabilization for a medical reason
- Patient requires additional stabilization of the knee
- Patient has the potential to benefit functionally
- The condition necessitating the C-Brace is expected to be permanent or of longstanding duration (more than 6 months)

Prescription (ordering physician)

 Provide a clear and specific prescription/order for a custom fabricated microprocessor-controlled swing and stance knee-ankle-foot-orthosis with rationale for your decision