



C-Brace[®] Reimbursement Starter Packet

Table of Contents

- ➔ Four Steps to Preauthorization
- ➔ Orthotist Documentation Guide
- ➔ Activity Chart Guide
- ➔ Lower Limb Orthotic Activity Chart
- ➔ How to Rule Out Less Costly Devices
- ➔ Physician Documentation Guide

C-Brace® Reimbursement Starter Packet February 2022



Four Steps to Preauthorization and Coverage

1. Complete activities listed in the C-Brace Orthotist's Guide to Justification
2. Send patient to ordering physician with the following:
 - a. C-Brace Physician Quick Reference and Documentation Guide
 - b. Prepared to discuss Activities from Activity Chart
3. Request chart notes from MD and make sure that all elements in the Physician Documentation Guide are addressed
4. Prepare Preauthorization Request

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Orthotist Documentation Guide

Verify Insurance

- ➔ Confirm where you can find the medical coverage policies that the patient's plan uses.
- ➔ Download the Orthotic medical coverage policy and identify the coverage criteria.
- ➔ Some payers require C-Brace candidates to meet their Lower Limb Microprocessor prosthetic policy, so we recommend reviewing that as well.
- ➔ Also, review the exclusions in the patient's plan summary (or benefit summary). Search for words such as deluxe, electronic, bionic, and microprocessor.
- ➔ If the coverage policy or plan summary has an exclusion for electronic devices or considers them investigational, you will need to ask for an exception in the preauthorization request.

Thorough Evaluation

- ➔ Complete Evaluation Form – Part B
 - ➔ Document timed walk tests, self-reported outcome measures, manual muscle test results; family, living, and job situation depicting the daily ambulation and activity needs of the patient.
 - ➔ If your patient has a progressive neurological condition, you will want to gather manual muscle test results taken in the past 3-5 years – and use that information to confirm slow progression of the disease and convince the payer that patient will be able to use the device for long term. Any new tests should be taken early in the day to avoid false reading due to fatigue.
 - ➔ Include feedback from the patient during trial use of C-Brace (e.g. daily usage of C- Brace versus usage of the previous device).
 - ➔ Document why other devices (e.g. locked KAFO, stance control orthosis, etc.) are not suitable–(see Ruling out Less Costly Devices).
 - ➔ Create (with the patient) an Activity Chart to compare C-Brace to patient's current device. Put this chart in your medical record and use the information in your cover letter. Patient should also discuss the activities with the ordering physician (see Activity Chart and Activity Chart Guide).
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Orthotist Documentation Guide

Pre-authorization Request Letter:

- ➔ With most insurance payers, a letter/template will not stand on its own. There must be other medical documentation (physician, rehabilitation, home health, etc.) including your own documentation to corroborate the information in your letter.
- ➔ State a clear objective.
 - Example: “Keep the patient ambulatory and independent, and prevent him/her from becoming wheelchair-dependent for as long as possible.”
- ➔ Leverage your professional knowledge to build a chain of arguments specific to your patient that is difficult to deny.
 - Include arguments based on patient’s prior and current activities as well as goals for future activities.
 - Discuss why the other devices will not allow patient to achieve his/her goals.
- ➔ Every hour invested in the initial justification will save multiple hours should you have to deal with a denial/appeal.

If you decide to include videos:

- ➔ Shoot videos without a device and/or using the current device and reshoot the video with patient using the C-Brace in the exact same situations for direct comparison of the effects of the new device.
- ➔ Focus on the features and benefits of C-Brace that your patient can do better with C-Brace.
- ➔ Shoot videos early in the day when patient is not fatigued.

If you need help:

- ➔ Contact the Ottobock Reimbursement Team
 - Call 800-328-4058 and ask for reimbursement, or
 - Email your request to Reimbursement911@Ottobock.com

C-Brace Activity Chart Guide

Comparing C-Brace to Patient's Current Device

The purpose of this guide is to strengthen your C-Brace Activity Chart. First we will go over the features and benefits and identify how the C-Brace can help your patient. Then there are some examples of how to complete the Activity Chart using this information.

Falls and Stumbles

Stumble Recovery

If medical records state that there are documented falls, your records will be stronger if you include detail about the number of falls and respective injuries and costs incurred as a result. The insurance payer likely paid for those injuries, but may not take the time to look back when deciding whether to cover C-Brace or not.

After compiling a history of falls and injuries state the following: “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).”

Difficulty Walking Backward

Describe activities where that require stepping/walking backwards, such as when opening a door and the difficulties encountered. Follow with “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).”

Need to Stand Securely on Level Ground or on Slopes

Intuitive Stance

Describe activities that when on a level surface or on an incline your patient might have to stop and rest or stand in a locked position. Follow that with “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.”

C-Brace Activity Chart Guide

Comparing C-Brace to Patient's Current Device

Difficulty Transitioning to a Sitting/Standing Position or Relaxing in a Confined Space

Describe the lack of control observed when your patient transitions to a sitting/standing position. Follow with “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.

Unable to Change Walking Speed Compensatory Movements Energy Expenditure Issues

Real-Time Gait Analysis

When discussing activities that require changes in walking speed (e.g. walking in crowds or crossing a busy street), follow with “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.”

C-Brace Activity Chart Guide

Comparing C-Brace to Patient's Current Device

Long Distance Walking Requirement

For microprocessor-controlled prosthetic knees, most payers require patients have a need to ambulate more than 400 yards per day and many have this same requirement for microprocessor-controlled orthotic components. Establish this need based on what the patient desires to do on a typical day (not current). This should be realistic activities that patient will be able to do using C-Brace, and based on patient's activity level prior to the injury/illness. Measure the distances out using Google Maps.

Unable to navigate Stairs, Slopes, Ramps or Challenging Terrain Requires Support for Sitting Down

Stance Flexion Resistance

Describe activities that include slopes, ramps or stairs and then state that "C-Brace provides hydraulic resistance against knee flexion (bending) mimicking the eccentric action of the quadriceps muscle. This controlled knee flexion occurs in early stance phase during weight bearing, and also provides shock absorption and reduced impact, thus allowing the patient to securely walk up and down slopes and ramps, negotiate uneven/ challenging terrain, and to descend stairs step over step."

"This feature also allows patients to "ride" the knee (the knee supports patients' weight on flexed knee without buckling and lowers them into desired position) such as when sitting into a chair."

Patient with Slow Walking Speed

Stance Flexion Resistance Plus

Describe activities that your patient has had difficulty performing due to a slow walking speed, such as transitioning from level ground walking to descending a ramp/stairs, or transitioning to an activity requiring increased knee flexion resistance for level ground walking. Follow with "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 or for 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.

C-Brace Activity Chart Guide

Comparing C-Brace to Patient's Current Device

Knee is not in Correct Position at Terminal Swing

Swing Flexion (Angle) Resistance

Describe situations where the swing phase knee flexes too much (not damped) and the limb lacks the timing for the knee to be in the proper position at terminal swing. Follow this with: "C-Brace adjusts hydraulic resistance of swing knee flexion during swing phase to insure that the swing phase limb is exhibiting proper swing phase mechanics. Without control of the swing flexion angle, the patient can be in a state of perpetual stumble at initial contact."

Knee Hyperextension Thrust

Low Back Pain

Stance Extension Resistance

Document the patient's hyperextension thrust during stance extension and the resulting low back pain and any medical treatment, associated expenses, etc. Follow with "The 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 the 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."

Patient with Fast Walking Speed

Difficulty with Deceleration

Swing Extension Resistance

Describe activities that require fast walking speed. Also describe any difficulties with deceleration. Follow with "The C-Brace provides microprocessor-controlled real-time extension hydraulic resistance during terminal swing. This resistance is essential to provide shock absorption against impact with faster walking speeds. Additionally, adjustment is provided for smooth deceleration at all cadences."

C-Brace Activity Chart Guide

Comparing C-Brace to Patient's Current Device

Daily Activity Chart Example:

Daily Activities	Distance Traveled	Without a mobility aide or orthosis?	With current orthosis and/or mobility aid.	How will patient be able to do it better with the C-Brace?
<p>Prior to the injury, patient was employed as a _____. He would like to return to work, requiring he use public transportation, which entails:</p> <ul style="list-style-type: none"> Walking 700 yd./day Bus access - stairs Busy street with timed crossing light Sidewalk slope 10 degrees Sidewalk cracks - uneven 	<p>Goal: 700 yds. /day (5 days/wk)</p> <p>Approx. 2 miles per week</p>	<p>Without a mobility aid, his knee collapses when he puts weight on it.</p>	<p>He currently uses a locked KAFO and Lofstrand crutches, which is very tedious. He can only walk 100 yards without resting.</p> <p>He would not be able to get on the bus, due to the locked knee. He cannot get across a busy street before the light changes and is at risk of falling on slopes and uneven terrain.</p> <p>While using his locked KAFO, he has fallen 8 times in the past year, broke his wrist, injured his back, and incurred \$9500 of related medical expenses.</p> <p>Recently he started using crutches with the KAFO, and still stumbles frequently and feels unsafe. While using his crutches, he cannot carry objects nor do other activities using his hands. They also cause stress and pain in his wrists and shoulders, which in turn requires pain medication. Already, he has had PT for wrist and shoulder pain.</p>	<p>He trialed the C-Brace for several hours and was able to ambulate on a slope and uneven terrain, walk down stairs step-over-step. He used one crutch during the trial, but should be able to discontinue use within a month.</p> <p>C-Brace provides hydraulic resistance against knee flexion (bending) mimicking the eccentric action of the quadriceps muscle. This controlled knee flexion occurs in early stance phase during weight bearing, and also provides shock absorption and reduced impact, which will allow him to securely walk up and down slopes and, negotiate uneven challenging terrain and should increase his overall confidence.</p> <p>Hydraulic resistance against knee flexion (bending) will also allow him to safely navigate bus stairs.</p> <p>The C-Brace analyzes and adjusts the hydraulics in real-time, which will help him to walk faster when crossing the street, and microprocessor-controlled progressive extension resistance during terminal swing will provide shock absorption against impact with faster walking speeds.</p>
<p>Prior to the injury, patient went to the gym 3X per week and walked 2 miles on the treadmill. Realistically, he would like to get back up to 1 mile</p>	<p>Goal: 1 mile @ 3X/wk</p>		<p>He attempted to walk on the treadmill with his locked KAFO. He had to walk at a very slow rate completely supporting himself with the bars. He was afraid of falling and this hurt his shoulders.</p>	<p>The C-Brace will give him the necessary stability to walk on the treadmill using the bars similar to an able-bodied person, without fear of falling.</p>
<p>Prior to the injury, patient went hiking in the mountains on steep and uneven terrain at least 12 times per year. Generally, these would be 5-10 mile hikes. He would like to start slowly doing this again.</p>	<p>Goal: 1-2 miles per month</p>		<p>He has not attempted any hiking with his locked KAFO.</p>	<p>The C-Brace's stumble recovery feature hydraulic resistance against knee flexion will allow him to safely navigate uneven terrain and slopes. The microprocessor-controlled progressive extension resistance during terminal swing will provide smooth deceleration when coming down off the mountain. No other orthosis has these features.</p>

Daily Activity Chart

Potential Daily Activities
 List activities that patient has done in the past and would like to get back to using a new device (e.g. home, work, therapeutic, exercise, & leisure). Focus on activities that meet criteria stated in the insurance payer's coverage policy (if available) and activities that the new orthosis will allow that the current orthosis does not.

Daily Activities	Distance Traveled (use Google Maps)	Describe how patient does the activity without a mobility aide or orthosis. (Focus on difficulties, such as falls, stumbles, ramps, curbs, stairs, uneven terrain, not making it across street before light changes, inability to change speed when needed, etc.)	Describe how patient does the activity with current orthosis and/or mobility aid. (Focus on difficulties, such as falls, stumbles, ramps, curbs, stairs, uneven terrain, not making it across street before light changes, inability to change speed when needed, etc.)	How will patient be able to do it better with the new orthosis? (What feature does the new orthosis offer that will help your patient achieve the activity? Hint: Ottobock might have a brochure or reimbursement guide that includes features and benefits.)
Activities Prior to the injury or illness				
Current Activities that patient is struggling with that he/she could better with the new orthosis.				
Potential Future Activities using the new orthosis (If these vary from prior activities, an explanation will be required)				

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Ruling out Less Costly Devices

Locked Knee-Ankle-Foot-Orthosis (LKAFO)

Locked knee-ankle-foot-orthoses (LKAFO) are often prescribed for patients with paralysis or paresis. The problem is that they only work well on level terrain and the user has to swing the braced limb in a circular motion (“circumduction”) and hike the hip in order to clear the foot. Walking in this fashion consumes a great amount of energy and wears on the hip joint. LKAFOs are mostly used for ambulating in the home and do not provide the potential for safe, physiological gait in the community, at work, during exercise, or for other daily activities. That is because LKAFOs cannot be used in a reciprocal manner on uneven terrain, ramps or stairs due to the knee being locked. It is also difficult to transfer from standing to a sitting position or back to standing. Bilateral patients using LKAFO generally require crutches for balance, which are not suitable for longterm use and are known to cause injuries (e.g. carpal tunnel syndrome, compressive neuropathy) causing severe pain to hands, arms and shoulders.

Stance Control Orthosis (SCO)

Similar to LKAFOs, stance control orthoses do not provide safe walking on ramps or stairs and bilateral patients generally require crutches for balance, which are not suitable for longterm use and are known to cause injuries (e.g. carpal tunnel syndrome, compressive neuropathy) causing severe pain to hands, arms and shoulders.

C-Brace Microprocessor Stance and Swing Phase Controlled Hydraulic KAFO

The C-Brace’s technology is based on the C-Leg microprocessor controlled prosthetic knee. It is the only orthosis currently on the market that has microprocessor-controlled stance and swing phase. The C-Brace is a passive orthosis and not powered by actuators (motors). The C-Brace monitors the gait cycle in real time and automatically adjusts resistance to prepare for the next movement to provide the potential for a safe and physiologic gait. This allows patients to walk with more ease and less concentration. Additionally, users experience less sound side compensation and stress as well as potential complications. Unlike locked KAFOs and SCOs, the C-Brace allows for safe navigation of uneven terrain, descension of stairs and ramps, and the potential to recover from a stumble.

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Physician Documentation Guide

* Information should be documented (if possible) in the contemporaneous medical record, as many payers do not accept Letters of Medical Necessity and templates.

History of the Injury, Illness, or Condition

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

Functional Limitations

Describe activities prior to illness or injury and those activities that patient want 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 and the device being ordered.

- 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

- 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

- 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 microprocessor- controlled 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

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

*This documentation guide is based on reasonable judgement and is not recommended to replace the physician’s judgement. These recommendations may be subject to revision based on additional information/regulation.

C-Brace Reimbursement Starter Packet

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