C-Leg Reimbursement Guide.

January 2026

Product Information.

[1]Coding (U.S. only)

The following codes are PDAC Verified for *C-Leg 4*

L5828	Hydraulic Swing and Stance Phase Knee
L5845	Stance flexion feature
L5848	Hydraulic stance extension feature
L5850	Knee extension assist
L5856	Microprocessor control feature, swing and stance phase, includes sensors
L5925	Above knee manual lock

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

Under FDA's regulations, the *C-Leg* Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. *C-Leg* prosthetic knee has met all applicable general control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The *C-Leg* prosthetic knee is listed under external limb prosthetic component; Listing Number is E253231.

Warranty

The *C-Leg 4* has a three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those associated with damages resulting from improper use. Fixed service inspections are not required during the warranty period.

Who Can Provide a *C-Leg*?

The *C-Leg 4* is prescribed by a physician and may only be provided by a qualified Prosthetist who 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 and 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.

[1] The 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 Supplier's 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.

Introduced in 1997, the C-Leg was the first prosthetic knee joint to control and adapt to an individual's complete gait pattern during stance and swing phase using a microprocessor. Today's C-Leg 4 actively controls all aspects of the swing and stance phase with the microprocessor-controlled hydraulics and adapts to variation in walking speeds. The result is a system that recognizes which phase of gait and situation the patient is in—and adapts in real time. The new functionality of C-Leg 4 includes patented technology which provides intuitive standing function and backward walking recognition and adjustments.

Stumble Recovery Plus

Swing phase flexion and extension resistance:
The Stumble Recovery Plus feature on the C-Leg 4 takes stability to a new level by actively controlling and adjusting swing flexion and extension resistance in real time. If there is any disruption of swing flexion or swing extension the stance resistance is automatically increased. This ensures that the proper amount of resistance is in place to enable recovery in the event of a stumble.

Varied Cadence

Microprocessor controlled hydraulic swing:
The C-Leg 4's main microprocessor gathers information from the various data sources and processes this information to adjust the knee joint´s functionality in real time. This allows the patient to walk more naturally and vary cadence with the knee, adapting more accurately and more quickly than without a microprocessor. Hydraulic swing resistance also provides smooth deceleration when changing walking speed, thus reducing the need for compensation.

Small or Quick Steps

A new ruleset of the C-Leg 4 allows for easier stance release when taking small or quick steps. This is beneficial, for example, when cooking in a kitchen or in a crowded elevator.

Knee Extension Assist:

The knee extension assist is used in promoting knee extension at the beginning of swing phase extension. This function allows the user to walk more efficiently at variable cadence since the spring extension assist mechanically limits the knee flexion at the end range and begins to bring the knee into extension for a more symmetrical gait at faster walking speeds. It also ensures the knee comes to full extension for the beginning of stance phase for a more secure loading condition during level walking but in particular when descending stairs where full extension facilitates the positioning of the foot on the edge of a stair.

Support for Sitting

Stance flexion: This feature also provides supported sitting down and allows the clinician to adjust the stance flexion beyond the programmed level of support if additional stability for sitting is needed.

Stairs, Slopes, Ramps, Challenging Terrain

Stance flexion: The C-Leg 4 provides hydraulic resistance against knee flexion (bending) mimicking the eccentric action of the quadriceps muscle. This allows the patient to securely walk up and down slopes and ramps, negotiate uneven/challenging terrain, and to descend stairs step-over-step. This resistance can be increased throughout the range and provides customized added support when decending stairs and ramps.

Back-up, Step Away

Inertial Motion Unit (IMU): The patented IMU on the *C-Leg 4* provides stability when taking steps backwards/backing-up. Contrast this to traditional microprocessor knees which do not accommodate backward walking, causing the knee to collapse when stepping backward.

Smooth and Natural Gait

Hydraulic stance extension damping:

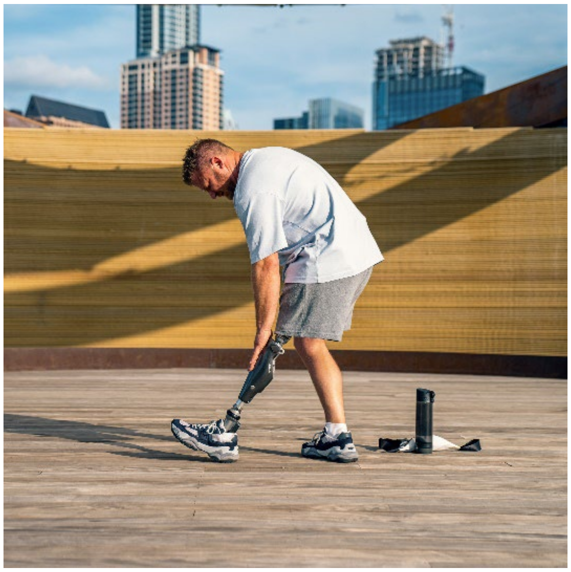
The C-Leg 4 provides microprocessor-controlled progressive resistance in real time during stance extension resulting in a more natural gait. Without this increased resistance the patient would feel a pronounced "snap back" or "jerk" at the knee and would also present with an unnatural looking gait pattern.

Intuitive or Deliberate Standing

The C-Leg 4 allows for selection of intuitive or deliberate stance which offers customized support during static activities of daily living. With intuitive stance the patient is able to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). Deliberate stance allows for standing on a flexed knee, but it takes longer to activate and deactivate. Deliberate stance is often preferred by bilateral amputees.

Manual Lock

The manual lock allows the patient to manually lock the knee at full extension. The user can manually lock and unlock the knee joint by tapping the patella area of the knee three times with their hand while in a standing position which activates the manual locking switch. This function can be used in situations where an enhanced feeling of safety from the manual lock is required while walking or standing.



Patients with Dysvascular Amputation

One of the clinical trials that studied the benefits of a microprocessor controlled prosthetic knee (*C-Leg*) in above-knee amputees (1) enrolled a significant share of patients with a dysvascular amputation who comprised 78% of patients in a subgroup further analyzed in a systematic review of microprocessor knee studies (2). This subgroup of mostly dysvascular above-knee amputees experienced a significant 80% reduction in falls from 2.1 ± 1.5 to 0.4 ± 0.7 ($p=.05$) within a 60-day period when using the *C-Leg* as compared to their previous non-microprocessor-controlled knees. Furthermore, patients were able to significantly increase their fast-walking speed on level ground by 14.4% ($p=.01$) and on uneven terrain by 19.9% ($p=.008$), representing a significant improvement in the overall walking capabilities of the patients by using the *C-Leg*. Quality of stair descent as assessed by the Montreal Rehabilitation Performance Profile also improved significantly by 62.8% ($p=.04$) (2).

These results of clinical studies demonstrate that dysvascular above-knee amputees may benefit to the same extent from using a *C-Leg* as patients with a traumatic or malignancy-related amputation.

Activity Reports

The practitioner can print out reports including average number of steps per day, average walking speed, ranges of different walking speeds/cadences, number of steps on slopes, ramps and stairs and time totals for walking, sitting, and standing.

Protective Covers

C-Leg 4's Protective Covers are used to provide greater defense for protecting the knee unit. These covers are custom designed for this knee unit only and are able to withstand sudden jolts that may penetrate the knee unit.

1. Kahle JT, Highsmith MJ, Hubbard SL: Comparison of Non-microprocessor Knee Mechanism versus *C-Leg* on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference; J Rehabil Res Dev 2008; 45 (1):1-14.
2. Kannenberg A, Zacharias B, Pröbsting E: Benefits of microprocessor prosthetic knees to limited community ambulators: A systematic review. J Rehabil Res Dev 2014; 51 (10): 1469-1495.

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Evidence Essentials.
C-Leg microprocessor knee.

	Mobility need or deficit of the patient	Evidence for benefits of the C-Leg vs. NMPK
Safety	Patient has a history of fall-related injury Patient stumbles and/or falls repeatedly Patient avoids activities due to fear of falling Patient sustained fall-related injuries	- **Significant 65% reduction of patients who experience injurious falls** (Campbell et al., 2020) - **Significant reduction in falls of up to 80%** (Hafner et al., 2007 and 2009; Highsmith et al., 2010; Kahle et al., 2008; Kannenberg et al., 2014, Kaufman et al., 2018; Davie-Smith et al., 2021) - **Significant reduction in stumbles of up to 57%** (Hafner et al., 2009; Highsmith et al., 2010; Kahle et al., 2008; Kannenberg et al., 2014) - **Significant improvements in balance and indicators for the risk of falling, such as Timed-up-and-go-test, forced gait perturbations in the gait lab, ABC scale, etc.** (Blumentritt et al., 2009; Burnfield et al., 2012; Hafner et al., 2007 and 2009; Kannenberg et al., 2014; Kaufman et al., 2007; Lansade et al., 2018; Davie-Smith et al., 2021)
Mobility	Patient has difficulty negotiating slopes/hills	- **Significant improvement in quality of slope/hill descent towards natural, reciprocal (step-over-step) gait pattern** (Hafner et al.; 2007 and 2009; Highsmith et al., 2013; Kannenberg et al., 2014) - **Significant increase in downhill walking speed of up to 40%** (Burnfield et al., 2012; Hafner et al., 2007 and 2009; Highsmith et al, 2013; Kannenberg et al., 2014)

	Mobility need or deficit of the patient	Evidence for benefits of the C-Leg vs. NMPK
Mobility	Patient has difficulty negotiating uneven terrain and obstacles	- **Significant increase in walking speed on uneven terrain and obstacle courses of up to 21%** (Kahle et al., 2008; Seymour et al., 2007)
Mobility	Patient has difficulty descending stairs with reciprocal (step-over-step) gait	- **Significant improvement in quality of stair descent towards natural, reciprocal (step-over-step) gait pattern** (Hafner et al., 2007 and 2009; Kahle et al., 2008; Kannenberg et al., 2014; Schmalz et al., 2007)
Mobility	Patient has difficulty with dual tasking while walking with the prosthesis	- **Significant reduction in cognitive demand while walking with the prosthesis** (Hafner et al., 2007 and 2009; Seymour et al., 2007; Williams et al., 2006) - **Significant reduction in cortical brain activity and perfusion during dual-tasking** (Möller et al., 2019; Ramstrand et al, 2020) - **Significantly improved capacity and performance in executing a concurrent task while walking with the prosthesis** (Hafner et al., 2007 and 2009; Morgan et al., 2015; Seymour et al., 2007; Williams et al., 2006)
Mobility	Patient is limited in his/her mobility	- **About 50% of K2 patients are able to improve their overall mobility level to K3** (Hafner et al. 2009; Kahle et al., 2008; Kannenberg et al., 2014)
Musculo-skeletal pain	Patient suffers from joint and back pain due to gait asymmetry and excessive loading	- **Significant improvement in gait symmetry and, thus, loading of the locomotor system** (Kaufman et al, 2007 and 2012; Segal 2006) - **Significant stance knee flexion that results in shock absorption to unload proximal joints and the spine** (Kaufman et al., 2007; Segal et al., 2006)

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