C-Leg Microprocessor-Controlled Prosthetic Knee
Reimbursement Reference Guide (Revised 11/01/2016)

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

C-Leg Coding
The Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Rather than issuing new HCPCS Level II national codes to describe the various microprocessor knees that came to market, the Alpha-Numeric HCPCS Panel instead issued add-on codes to upgrade the mechanical (non-microprocessor) knee codes.

The following codes are PDAC Verified for C-Leg

- **L5828** Hydraulic Swing and Stance Phase Knee
- **L5845** Stance flexion feature
- **L5848** Hydraulic stance extension feature
- **L5856** Microprocessor control feature, swing and stance phase, includes sensors

Additional codes for C-Leg’s new functionality
Verify coverage with your payer
- **L5850** Knee extension assist
- **L5925** Manual lock
- **L5999** Inertial Motion Unit Control Feature for intuitive standing and walking backwards.

Additional codes that might be on a C-Leg claim

- **L5920** Alignable System (for a complete new prosthesis or when the prosthesis needs to be realigned)
- **L5950/L5960** Ultralight Material (when added to a socket)

FDA Status
Under FDA’s regulations, the C-Leg Microprocessor-Controlled Prosthetic Knee is a Class II device, exempt from the premarket notification [510(k)] requirements. C-Leg prosthetic knee has met all the 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). The C-Leg prosthetic knee is listed under external assembled lower limb prosthesis; Listing Number is E206060.

Warranty
Three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those associated with damages resulting from improper use. No fixed service inspections are required.

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 are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

2 It is not recommended to bill L5999 to Medicare for Microprocessor Knees.
C-Leg Features and Benefits

Hydraulic Swing and Stance Phase Knee

- Hydraulic swing control allows for adequate resistance to be applied during heel rise, allowing 65 ± 3 degrees of knee flexion. This ensures appropriate toe clearance, reduces the chance of catching the toe in midswing, and offers the patient security for the next heel strike (does not leave the patient feeling as if “waiting for the knee to come through”).
- Hydraulic swing control also applies during extension of the knee preventing terminal impact by decelerating the limb while restraining the need for further hip flexion. This resistance mimics the eccentric contraction of the anatomical hamstrings and gluteus maximus. Full extension is then reached in preparation for heel strike.
- Hydraulic swing control allows patients to vary cadence. The hydraulic fluid flows through narrow channels, providing a frictional resistance, which increases with the speed of compression; a faster gait speed allows quicker knee extension.
- With hydraulic stance phase control, resistance occurs automatically when there is a tendency for the knee to buckle. This allows the patient to walk on uneven terrain and results in a more natural step-over-step pattern when descending inclines and stairs. This resistance also contributes to the stance flexion and “stumble recovery.”

Microprocessor Swing and Stance Control

- The C-Leg’s main microprocessor gathers sensoric information at a rate of 100 times per second. It processes this information following programmed instructions to adjust the valve positions via servo motors in real time. The valve positions define the hydraulic fluid resistance of the two independent valves (extension and flexion valves) and therefore the resistances of the knee against flexion and extension separately and variably.
- During whole gait cycle the programmed instructions define whether the resistance is high for securing stance phase support or low for allowing initiation of swing (Microprocessor Stance control). Using the programmed instructions the knee can far more reliably determine if the knee should be in a low resistance for initiating swing than any mechanical mechanism. This eliminates erroneous stance releases that often cause falls in purely mechanical designs.
- During swing phase the programmed instructions control the maximal swing angle by adjusting the flexion valve in real time (Microprocessor Swing Control). The patient will be able to walk more naturally and vary cadence with the knee adapting more accurately and more quickly than without a microprocessor.

Stance Flexion

- When the prosthesis initially contacts the ground, this feature allows the patient to load the knee in a flexed position. Benefits include shock absorption, reducing the modulation of the center of gravity throughout the gait cycle, energy efficiency (less energy spent on “pulling back” on hamstrings to lock a fully extended knee), and an overall more natural gait pattern. Hip and lower back stress will also be minimized.
- 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) when sitting into a chair, kneeling, and when descending stairs and slopes.
- This resistance will also be there for the patient should the toe catch during midswing, serving as a “stumble recovery” feature. As soon as the knee stops flexing and maximum heel rise is achieved, this feature is immediately activated; thus, if at any point the toe catches a supporting resistance is available. This allows patients enough time to bring their contralateral side through to catch themselves, thus preventing a fall and keeping it at a controlled “stumble.” The newest algorithm in the updated version of C-Leg® allows this resistance to be angle dependent, meaning it will provide additional resistance compared to normal stance phase resistance. From that point on, the further the knee bends (or the further the patient is into the fall) the higher the resistance that will be provided.
C-Leg Features and Benefits

Hydraulic Stance Extension

- After the knee is flexed during stance phase (stance flexion), it needs to extend again to advance the body forward through mid-stance. This feature provides increased resistance to this extension. Without this increased resistance the patient will feel a pronounced “snap back” or “jerk” at the knee, and will also present with an unnatural looking gait pattern. Energy is conserved by having this feature, as the patient will not have to attempt to use hamstrings to control this motion.

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.

Locking Function

- The manual lock allows the user to lock the knee in full extension, e.g. for safer standing or more comfortable standing due to equal weight distribution on the prosthetic and sound sides. The manual lock is activated and deactivated by the patient by three different methods: motion pattern, remote, or via a cellular telephone App.

Activity Report

- The practitioner is able to print out reports including:
  1. Average number of steps/day
  2. Average walking speed
  3. Number of steps on slopes, ramps and stairs
  4. Time totals for walking, sitting, standing

Inertial Motion Unit Control Function for Intuitive Standing and Walking Backwards

- The Inertial Motion Unit in the C-Leg allows intuitive standing and backward walking.

- This patented technology provides stability when taking steps backwards. (Traditional microprocessor knees do not accommodate backward walking, because the knee is programmed to go into swing when the toe is loaded, causing the knee to collapse when stepping backward).

- Allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). With traditional prosthetic knees people with limb loss must use hip extension to stabilize the knee or cognitively ensure that their center of mass stays ahead of their knee axis to prevent unexpected flexing of the prosthetic knee.

Protective Covers

- C-Leg 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.

2. Hahn A, Lang M. Effects of mobility grade, age, and etiology on functional benefit and safety of subjects evaluated in more than 1200 C-Leg trial fittings in Germany. *J Prosthet Orthot* 2015; 27(3): 86-95.


C-Leg and C-Leg Compact
Clinical Studies


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