

**Title**

**Microprocessor Controlled Prostheses for the Lower Limb<sup>1</sup>**

**Description**

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will be quite different than a younger, active person. In general, key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees also vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace that is adjusted to the individual amputee from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are generally prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (Blatchford, U.K.), the Adaptive (Endolite, England), the Rheo (Ossur, Iceland) and the C-Leg (Otto Bock Orthopedic Industry, Minneapolis, MN). These devices are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. In addition, these devices (with the exception of the Intelligent Prosthesis) use microprocessor control in both the swing and stance phases of gait. By improving stance control, they may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain, and reduction in energy expenditure and concentration required for ambulation. The C-Leg was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA, K991590).

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Ossur) and the iPED (developed by Martin Bionics LLC and licensed to College Park Industries). Sensors in the feet determine the direction and speed of the foot's movement, allowing the foot to lift during the swing phase and adjust to changes in force, speed and terrain during the step phase. The intent of the technology is to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. The Proprio Foot® is the only microprocessor-controlled foot prosthesis that is commercially available at this time, and is a class I device that is exempt from 510(k)

marketing clearance. The manufacturer must register the prosthesis with the restorative devices branch of the FDA and keep a record of any complaints, but does not have to undergo a full review. Information on the Ossur website indicates use of the Proprio Foot® for low to moderate impact for transtibial amputees who are classified as level K3 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence).

In development are lower-limb prostheses that also replace muscle activity in order to bend and straighten the prosthetic joint. For example, the Power Foot (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that use muscle activity from the remaining limb for the control of ankle movement (see policy 1.04.04 for a description of myoelectric technology). This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis. The Power Knee (Ossur), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot in order to anticipate and respond with the appropriate movement required for the next step. The Power Knee is currently in the initial launch phase in the U.S.

#### **When services are covered for commercial products and Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx**

We cover microprocessor-controlled knees in amputees who meet the following criteria under A and B below:

##### A) Patient selection criteria:

- 1) Patient has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology and to allow for faster than normal walking speed; and
- 2) Patient has demonstrated the ability to ambulate faster than their baseline rate using a standard prosthetic application with a swing and stance control knee; and
- 3) Patient has a documented need for daily long distance ambulation (i.e., greater than 400 yards) at variable rates. (In other words, use within the home or for basic community ambulation is not sufficient to justify the computerized limb over standard limb applications); and
- 4) Patient has a demonstrated need for regular ambulation on uneven terrain or regular use on stairs. Use of limb for limited stair climbing in the home or place of employment is not sufficient to justify the computerized limb over standard limb applications; and
- 5) Patient has adequate strength and balance in stride to activate the knee unit; and
- 6) Patient does not exceed the weight or height restrictions of the device; and
- 7) The patient can achieve one of the following activity levels:
  - a) limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to utilize the prosthesis. *The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator; or*
  - b) unlimited community ambulator; or
  - c) active adult, athlete, who has the need to function as an unlimited community ambulator in daily activities; and
- 8) Patient has the potential to return to an active lifestyle; and
- 9) Patient has none of the following contraindications:
  - a) Any condition which prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.
  - b) Inability to tolerate the weight of the prosthesis.
  - c) No ability or potential to ambulate or transfer.
  - d) Limited ability to transfer or ambulate on level ground at fixed cadence.
  - e) Limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improved stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.

- f) Inability to utilize swing and stance features of the knee unit.
- g) Poor balance or ataxia that limits ambulation.
- h) Significant hip flexion contracture (over 20 degrees).
- i) Significant deformity of remaining limb that would impair ability to stride.
- j) Limited cardiovascular and/or pulmonary reserve or profound weakness.
- k) Limited cognitive ability to understand gait sequencing or care requirements.
- l) Long distance or competitive running.
- m) Falls outside of recommended weight or height guidelines of manufacturer.
- n) Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- o) Extremely rural conditions where maintenance ability is limited.

**B) Documentation and performance criteria:**

- 1) Complete multidisciplinary assessment of patient including an evaluation by a trained prosthetic clinician. The assessment must objectively document that all of the above patient selection criteria have been evaluated and met.

**When services are not covered for commercial products or for Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx**

We do not cover microprocessor-controlled knees in individuals who do not meet the above criteria.

We do not cover a powered knee as it does not meet our Medical Technology Assessment Guidelines #[350](#).

We do not cover a microprocessor-controlled or powered foot as it does not meet our Medical Technology Assessment Guidelines #[350](#).

**Other information**

Patients with hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral lower extremity amputees, are candidates if they meet functional criteria as listed.

Physical and Functional Fitting Criteria for New Amputees:

- New amputees may be considered if they meet the criteria as outlined above.
- Premorbid and current functional assessment important determinant.
- Requires stable wound and ability to fit socket.
- Immediate postoperative fit is possible.
- Must have potential to return to active lifestyle.

**Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

**For services already billed**

Blue Cross Blue Shield of Massachusetts  
 Provider Appeals  
 PO Box 986065  
 Boston, MA 02298

**Prior to performance of service**

Blue Cross Blue Shield of Massachusetts  
 Case Creation/Medical Policy  
 One Enterprise Drive  
 Quincy, MA 02171  
 Tel: 1-800-327-6716  
 Fax: 1-888-641-5330

**Authorization Information**

**For Managed Care members:**

- Authorization is not required for this service; see *Managed Care Guidelines* for additional requirements.

**For Indemnity and PPO members:**

- Authorization is not required for this service; see *Indemnity and PPO Guidelines* for additional requirements.

**Managed Care Guidelines**

All authorization requirements are determined by the individual’s subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

**Indemnity and PPO Guidelines**

All authorization requirements are determined by the individual’s subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual’s subscriber certificate.
- Referrals to a specialist are not required.

**Coding information**

*Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

**HCPCS codes:**

There are specific HCPCS codes that describe the microprocessor-controlled knee prosthesis:

- **L5856:** Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
- **L5857:** Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
- **L5858:** Addition to lower extremity prosthesis, endoskeletal knee skin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type

**Policy update history**

New policy, effective 11/01/09.

**References**

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#### **Footnotes**

<sup>1</sup> Based on BCBSA policy # 1.01.25, Microprocessor Controlled Prosthesis for the Lower Limb.