Medical Policy
Microprocessor Controlled Prostheses for the Lower Limb

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Policy Number: 133
BCBSA Reference Number: 1.04.05
NCD/LCD: Local Coverage Determination (LCD): Lower Limb Prostheses (L33787)

Related Policies
- Myoelectric Prosthetic Components for the Upper Limb, #227
- Neuromuscular Electrical Stimulation, #201

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

A microprocessor-controlled knee may be considered MEDICALLY NECESSARY in amputees who meet the following requirements:

- Demonstrated need for long distance ambulation at variable rates (use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications) OR demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application), AND
- Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed, AND
- Adequate cognitive ability to master use and care requirements for the technology.

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels, as well as the patient's physical and cognitive ability. A patient's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (eg, gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, daily and frequent need of 2 or more of these activities would be needed to show benefit.
For patients in whom the potential benefits of the microprocessor knees are uncertain, patients may first be fitted with a standard prosthesis to determine their level of function with the standard device.

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees.¹

**Patient Selection and Identification**

Contraindications for use of the microprocessor knee should include:

- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.
- Inability to tolerate the weight of the prosthesis.
- Medicare Level K 0—no ability or potential to ambulate or transfer.
- Medicare Level K 1—limited ability to transfer or ambulate on level ground at fixed cadence.
- Medicare Level K 2—limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.
- Inability to use swing and stance features of the knee unit.
- Poor balance or ataxia that limits ambulation.
- Significant hip flexion contracture (over 20°).
- Significant deformity of remaining limb that would impair ability to stride.
- Limited cardiovascular and/or pulmonary reserve or profound weakness.
- Limited cognitive ability to understand gait sequencing or care requirements.
- Long distance or competitive running.
- Falls outside of recommended weight or height guidelines of manufacturer.
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- Extremely rural conditions where maintenance ability is limited.

Indications for use of the microprocessor knee should include:

- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.
- Adequate strength and balance in stride to activate the knee unit.
- Should not exceed the weight or height restrictions of the device.
- Adequate cognitive ability to master technology and gait requirements of device.
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- Patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue.
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability—such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying.
- Medicare Level K 2—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 use 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.*
- Medicare Level K 3—unlimited community ambulator.
- Medicare Level K 4—active adult, athlete who has the need to function as a K 3 level in daily activities.
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable.
- Potential to unload and decrease stress on remaining limb.
- Potential to return to an active lifestyle.
Physical and Functional Fitting Criteria for New Amputees:
- New amputees may be considered if they meet certain 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.

A Microprocessor-controlled knee is considered **NOT MEDICALLY NECESSARY** in individuals who do not meet the above criteria.

A powered knee is considered **INVESTIGATIONAL**.

A microprocessor-controlled or powered foot is considered **INVESTIGATIONAL**.

**Medicare HMO Blue\textsuperscript{SM} and Medicare PPO Blue\textsuperscript{SM} Members**

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

**Local Coverage Determination (LCD): Lower Limb Prostheses (L33787)**


For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

**Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Yes</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Medicare HMO Blue\textsuperscript{SM}</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Medicare PPO Blue\textsuperscript{SM}</td>
<td>No</td>
</tr>
</tbody>
</table>

**CPT Codes / HCPCS Codes / ICD Codes**

*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.*

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:
### HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type</td>
</tr>
</tbody>
</table>

### ICD-9 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-9-CM procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>93.22</td>
<td>Ambulation and gait training</td>
</tr>
<tr>
<td>93.23</td>
<td>Fitting of orthotic device</td>
</tr>
<tr>
<td>93.24</td>
<td>Training in use of prosthetic or orthotic device</td>
</tr>
</tbody>
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### ICD-10-PCS Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>F07Z9CZ</td>
<td>Gait Training/Functional Ambulation Treatment using Mechanical Equipment</td>
</tr>
<tr>
<td>F07Z9DZ</td>
<td>Gait Training/Functional Ambulation Treatment using Electrotherapeutic Equipment</td>
</tr>
<tr>
<td>F07Z9EZ</td>
<td>Gait Training/Functional Ambulation Treatment using Orthosis</td>
</tr>
<tr>
<td>F07Z9FZ</td>
<td>Gait Training/Functional Ambulation Treatment using Assistive, Adaptive, Supportive or Protective Equipment</td>
</tr>
<tr>
<td>F07Z9GZ</td>
<td>Gait Training/Functional Ambulation Treatment using Aerobic Endurance and Conditioning Equipment</td>
</tr>
<tr>
<td>F07Z9UZ</td>
<td>Gait Training/Functional Ambulation Treatment using Prosthesis</td>
</tr>
<tr>
<td>F07Z9YZ</td>
<td>Gait Training/Functional Ambulation Treatment using Other Equipment</td>
</tr>
<tr>
<td>F07Z9ZZ</td>
<td>Gait Training/Functional Ambulation Treatment</td>
</tr>
<tr>
<td>F0DZ6EZ</td>
<td>Dynamic Orthosis Device Fitting using Orthosis</td>
</tr>
<tr>
<td>F0DZ6FZ</td>
<td>Dynamic Orthosis Device Fitting using Assistive, Adaptive, Supportive or Protective Equipment</td>
</tr>
<tr>
<td>F0DZ6UZ</td>
<td>Dynamic Orthosis Device Fitting using Prosthesis</td>
</tr>
<tr>
<td>F0DZ6ZZ</td>
<td>Dynamic Orthosis Device Fitting</td>
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<tr>
<td>F0DZ7EZ</td>
<td>Static Orthosis Device Fitting using Orthosis</td>
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<tr>
<td>F0DZ7FZ</td>
<td>Static Orthosis Device Fitting using Assistive, Adaptive, Supportive or Protective Equipment</td>
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<td>F0DZ7UZ</td>
<td>Static Orthosis Device Fitting using Prosthesis</td>
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<tr>
<td>F0DZ7ZZ</td>
<td>Static Orthosis Device Fitting</td>
</tr>
<tr>
<td>F0FZDEZ</td>
<td>Caregiver Training in Application, Proper Use and Care of Devices using Orthosis</td>
</tr>
<tr>
<td>F0FZDFZ</td>
<td>Caregiver Training in Application, Proper Use and Care of Devices using Assistive, Adaptive, Supportive or Protective Equipment</td>
</tr>
<tr>
<td>F0FZDUZ</td>
<td>Caregiver Training in Application, Proper Use and Care of Devices using Prosthesis</td>
</tr>
<tr>
<td>F0FZDZZ</td>
<td>Caregiver Training in Application, Proper Use and Care of Devices</td>
</tr>
<tr>
<td>F0FZFEZ</td>
<td>Caregiver Training in Application, Proper Use and Care of Orthoses using Orthosis</td>
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</table>
The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>L5969</td>
<td>Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)</td>
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<tr>
<td>L5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
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</tbody>
</table>

**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**

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, England), the Adaptive (Endolite, England), the Rheo Knee® (Össur, Iceland), the C-Leg®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN), and Seattle Power Knees (3 models include Single Axis, 4-bar and Fusion, from Seattle Systems). 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 IP) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) 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). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses utilize additional environmental input (eg, gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used, for example, in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Microprocessor-Controlled Ankle-Foot Prostheses
Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot’s movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially 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™ and Elan Foot are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates use of the Proprio Foot™ for low- to moderate-impact for transtibial amputees who are classified as level K3 (ie, community ambulatory, with the ability or potential for ambulation with variable cadence).

Powered Prostheses
In development are lower-limb prostheses that also replace muscle activity in order to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM® (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement (see Policy No. 227 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. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis. The Power Knee™ (Össur), 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 United States.

Summary
Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. Active joint control is intended to improve safety and function, particularly for patients who have the capability to maneuver on uneven terrain and with variable gait.

The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees versus hydraulic knee joints. For K3- and K4-level amputees, studies show an objective improvement in function on some outcome measures and a strong patient preference for microprocessor controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. It is concluded that a microprocessor-controlled knee may provide incremental benefit for these individuals. Those considered most likely to benefit from these prostheses have both the potential and need for frequent ambulation at variable cadence, on uneven terrain, or on stairs. The potential to achieve a high functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to be able to use the advanced technology.
Evidence is insufficient to permit conclusions regarding the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators. Evidence is also insufficient to permit conclusions regarding the effect of a next-generation microprocessor-controlled prosthesis on health outcomes. Therefore, these are considered investigational.

The limited evidence available to date does not support an improvement in functional outcomes with a microprocessor-controlled or powered ankle-foot prostheses compared with standard prostheses. Therefore, microprocessor-controlled or powered ankle-foot prostheses are considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>9/2016</td>
<td>Clarified coding information.</td>
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<tr>
<td>11/2015</td>
<td>Added coding language.</td>
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<tr>
<td>6/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>4/2014</td>
<td>Microprocessor foot or ankle system addition with power assist which includes any type motor (L5969) is not covered for Medicare Advantage based on Local Coverage Determination (L11464). Effective 1/1/2014. Clarified coding information</td>
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<tr>
<td>1/2014</td>
<td>Updated to add new HCPCS code L5969.</td>
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<tr>
<td>5/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>9/01/2010</td>
<td>Updated to require prior authorization for commercial products for this service.</td>
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<tr>
<td>5/18/2010</td>
<td>BCBSA National medical policy review.</td>
</tr>
<tr>
<td>11/1/2009</td>
<td>No changes to policy statements.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**