Microprocessor-Controlled Lower Limb Prostheses

<table>
<thead>
<tr>
<th>Type:</th>
<th>Medical Necessity and Investigational / Experimental</th>
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<tbody>
<tr>
<td>Policy Specific Section:</td>
<td>Durable Medical Equipment</td>
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<tr>
<th>Original Policy Date:</th>
<th>December 7, 2006</th>
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<tbody>
<tr>
<td>Effective Date:</td>
<td>September 27, 2013</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

A microprocessor-controlled lower limb prosthesis, also known as a computerized prosthesis, may include knee and ankle-foot prostheses, which 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. Microprocessor-controlled knees are most common and 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. The newer microprocessor-controlled ankle-foot prostheses have sensors in the feet which allow the foot to lift during the swing phase and adjust to changes in force, speed, and terrain during the step phase.

Policy

A microprocessor-controlled knee is considered **medically necessary** in amputees who meet **all** of the following criteria:

- Evaluation performed by a qualified physician (Physiatrist or Orthopedist familiar with prosthetic limb requirements) to determine the most appropriate prosthetic components and control mechanisms
- Functional activity level K3 or above (see Policy Guidelines)
- Demonstrated ability to utilize the swing and stance feature of the knee unit
- Potential to return to an active lifestyle
- Ability to tolerate weight of the prosthesis
- Ability to ambulate on variable cadence (K-3 guidelines) faster than their baseline speed
- Cognitive ability to master use and care requirements for a microprocessor-controlled prosthesis
- Physical ability, including cardiovascular and pulmonary reserve, for ambulation at variable speed and **one** of the following:
  - Demonstrated need for long distance ambulation at variable speeds (greater than 400 yards continuously) on a daily basis (use of the prosthesis in the home or for basic community ambulation is not sufficient to justify provision of the microprocessor-controlled limb over a standard prosthesis)
  - Demonstrated need for regular ambulation on uneven terrain or for regular stair use (use of the prosthesis for limited stair climbing in the home or employment environment is not sufficient to justify provision of the microprocessor-controlled prosthesis over a standard prosthesis)

A microprocessor-controlled knee is considered **not medically necessary** in individuals who do not meet these criteria.

The following lower limb prostheses are considered **investigational** for all indications:

- Microprocessor-controlled or powered foot
- Powered knee

Replacement or repair of a microprocessor-controlled knee is considered **medically necessary** when all of the following criteria are met:

- The current prosthesis is out of warranty
- The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis
Policy Guideline

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 (e.g., 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 two 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 degrees).
  - 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.

**Coding**

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

There is a specific HCPCS code for ankle foot system with a microprocessor control feature:
- **L5973**: Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

### Documentation Required for Clinical Review

<table>
<thead>
<tr>
<th>Task</th>
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<tbody>
<tr>
<td>History and physical including: date of amputation, physical and cognitive status, current functional K level and level patient is expected to attain and patients desire to ambulate</td>
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<tr>
<td>Prescription for the prosthesis from referring physician (Physiatrist or Orthopedist)</td>
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<td>Name of ordering prosthetist, fax and phone number</td>
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<tr>
<td>- Activities that will require long distance ambulation at variable rates, uneven terrain, or stairs?</td>
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<tr>
<td>- All prosthetist’s clinical/office notes including:</td>
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<tr>
<td>- Current make, model, components in use</td>
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<tr>
<td>- Describe daily activities and needs related to daily activities</td>
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<tr>
<td>- Has a prosthesis been previously worn?</td>
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<tr>
<td>- Has the patient successfully mastered the features of a swing and stance style hydraulic knee unit?</td>
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<td>- Is a prosthesis being currently used?</td>
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<tr>
<td>- What is the repair cost of the current prosthesis?</td>
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<tr>
<td>- What rehabilitation has patient received?</td>
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<tr>
<td>- Why is a swing and stance knee unit not appropriate?</td>
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Clearly list all HCPCS codes with descriptions of generic codes

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on
individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.