



MEDICAL COVERAGE GUIDELINES
SECTION: DURABLE MEDICAL EQUIPMENT (DME)

ORIGINAL EFFECTIVE DATE: 04/04/12
LAST REVIEW DATE: 04/15/14
LAST CRITERIA REVISION DATE: 04/03/13
ARCHIVE DATE:

MICROPROCESSOR CONTROLLED LOWER LIMB PROSTHESES

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Microprocessor-Controlled Prosthetic Knee:

Microprocessor controlled prosthetic knee is a computer controlled knee joint system equipped with sensors to detect changes in gait and adjust resistance with every step allowing a more natural walking pattern of various speeds. The sensors detect when the knee is in full extension and adjust the swing phase automatically resulting in greater stability and less energy expenditure than traditional prostheses. Microprocessor controlled prosthetic knees include the C-Leg®, Genium Bionic Prosthetic System and Seattle Power Knees (3 models include Single Axis, 4-bar and Fusion). In addition, these devices use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.)

Microprocessor-Controlled Ankle-foot Prostheses:

Microprocessor controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot®, the iPED and the Elan Foot. Sensors 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 Proprio Foot is the only commercially available microprocessor controlled foot prosthesis and is a class I device that is exempt from FDA 510(k) marketing clearance.

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Description: (cont.)

Powered Prostheses:

The powered knee has been investigated to replace muscle activity of the quadriceps to bend and straighten the knee as needed to propel the user forward. The prosthesis is designed to lift the heel from the ground, support the user while ascending inclines and power them up stairs. Sensors within the prosthesis monitor and regulate gait.

The powered foot has been investigated for transtibial amputees to generate energy for walking by using multiple springs and a small battery-powered motor. The prosthesis uses muscle activity from the remaining limb for control of ankle movement and is designed to propel the foot forward as it pushes off the ground during the gait cycle. The energy produced from the forward motion is stored in the power-assisted spring and then released as the foot pushes off.

Helix3D Hip Joint System:

The Helix3D Hip Joint System produces a three-dimensional hip movement to compensate for pelvic rotation and promotes a symmetrical and natural gait pattern. The Helix3D Hip Joint System can only be used with the C-Leg and prosthetic feet specified for use with the C-Leg.

Definitions:

Functional Levels:

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 improved stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.
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.



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Criteria:

Knee Prostheses:

All requests for microprocessor controlled knee prosthesis will be reviewed by the medical director(s) and/or clinical advisor(s).

- Microprocessor controlled knee prosthesis is considered **medically necessary** with documentation of **ALL** of the following:
 1. Demonstrates success utilizing and maintaining a hydraulic swing and stance control knee prosthesis to walk at a faster than baseline rate
 2. Demonstrates potential for improved gait efficiency (e.g., functionality, performance and safety) as determined by gait analysis.
 3. Documented current and potential functional level and, if applicable, an explanation for the difference
 4. Potential functional level of 3 or 4
 5. No additional medical conditions that would interfere with maintaining functional level 3 or 4 (e.g., decreased pulmonary reserve, disabling cardiovascular, neuromuscular, peripheral vascular or musculoskeletal conditions)
 6. Meets the manufacturer's specifications and limitations for a microprocessor controlled knee prosthesis **AND** must be fitted by a prosthetist certified by the manufacturer
 7. Ambulates greater than 400 yards daily **OR** ambulates regularly on uneven terrain or stairs for specific activities other than basic home or community purposes
 8. Individual does not live or work in a wet environment
 9. Adequate cognitive ability to master use and care requirements
- If above criteria not met, microprocessor controlled knee prosthesis is considered **not medically necessary**.
- Power Knee is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.



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Criteria: (cont.)

Foot Prostheses:

- The following foot prostheses are considered ***experimental or investigational*** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These foot prostheses include, *but are not limited to*:

- Microprocessor controlled ankle-foot prosthesis
- Power foot

Helix3D Hip Joint System:

All requests for Helix3D Hip Joint System will be reviewed by the medical director(s) and/or clinical advisor(s).

- Helix3D Hip Joint System is considered ***medically necessary*** with documentation of **ALL** of the following:
1. Individual has undergone hip disarticulation or hemipelvectomy
 2. Used in combination with the C-Leg and the prosthetic feet specified for use with the C-Leg



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Resources:

1. 1.04.05 BCBS Association Medical Policy Reference Manual. Microprocessor-Controlled Prostheses for the Lower Limb. Re-issue date 03/13/2014, issue date 10/09/2003.
2. California Technology Assessment Forum. Microprocessor Controlled Prosthetic Knees. *Blue Shield of California Foundation*. 10/17/2007.
3. Centers for Medicare & Medicaid Services. DMERC Manual Region B Chapter 17. Accessed 01/20/2005.
4. Hangar Prosthetics. Inservice: Advances in Prostheses. 01/11/2005.
5. Otto Bock. C-Leg Microprocessor Knee Patient Evaluation Protocol. October 2003.
6. Veteran's Health Administration Prosthetic Clinical Management Program. Clinical Practice Recommendations Microprocessor Knees. 09/24/2004.
7. Wall Street Journal. Bionic Knee 'Learns' How to Walk. 07/06/2004.

FDA 510K Summary for C-Leg® (Otto Bock Orthopedic Industry, Inc.):

- FDA-approved indication: For use in the fitting of lower limb prostheses. It can be used for highly mobile individuals as well as those who need additional stance stability