

Medical Affairs Policy & Procedure

Title/Service: Microprocessor Controlled Lower Limb Prosthesis (Adaptive Prosthesis, Endolite, Intelligent Prosthesis, Otto-Bock C-Leg, Ossur Rheo, Power Knee)

Revised	
Reviewed	07/28/06, 05/18/07, 05/16/08, 07/27/10, 09/16/2011
Developed	07/28/06
Policy Committee Approval	09/16/2011

Description:

Microprocessor-controlled lower limb prosthetics are equipped with sensors that record information 50 times per second to detect the individual's speed of ambulation and adjust the performance of the prosthetic knee based on that speed and the terrain (for example, uneven surfaces or stairs). This may result in a more natural pattern of walking at different speeds. A conventional lower limb prosthetic is set to the individual's usual speed of ambulation and requires manual intervention to be reset. The microprocessor-controlled prosthesis may improve the patient's level of function and decrease the patient's energy expenditure during ambulation.

Indications of Coverage:

A microprocessor controlled lower limb prosthesis is considered medically necessary for an above-the-knee amputee when **all** of the following criteria are met:

- A. The individual has expressed a willingness to ambulate and the individual's current activities exceed the capabilities of a standard lower limb prosthetic device on a daily basis
- B. The patient has used a standard lower limb prosthetic device for independent daily activities for a minimum of three months
- C. Records from a physician (orthopedist or physical medicine and rehabilitation) report that the use of the device will enable the individual to reach a minimum of functional level 3 (see table below) within three months of obtaining the device. The records must document the individual's current functional level, the expected functional level, and why the expected functional level cannot be achieved with the current device.
- D. There is no documentation of a significant cardiovascular, musculoskeletal, or neuromuscular condition that would prohibit maximal use of the device (for example, a cardiac, vascular, orthopedic, or muscular condition that would prevent the individual from achieving a fast walking pace)

- E. Gait analysis documents that the individual has the ability to ambulate at a rate faster than what can currently be achieved with a standard prosthesis despite appropriate adjustments to the current prosthesis

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. Microprocessor controlled ankle and foot prosthetic devices are considered investigational as there is insufficient peer-reviewed scientific literature supporting the use of these devices.
- E. Microprocessor controlled lower limb prosthesis are considered not medically necessary (not the most cost-effective prosthetic) if the patient's medical needs could be met with a standard non-electronic prosthetic.

Documentation Required:

- Office notes
- Gait analysis report

Rationale:

At this time, there is limited peer-reviewed scientific literature documenting improved function using a microprocessor controlled prosthetic. Much of the literature that is available is of poor quality, includes few subjects, selectively includes individuals who would be more likely to report improved results, does not include control groups, and does not objectively measure changes in function with the use of the microprocessor controlled prosthetic. Several studies evaluating oxygen consumption (a measure of effort) in individuals using a standard prosthetic and a microprocessor controlled prosthetic were equivocal. However, improvement in outcomes is reported, including a decreased effort required for ambulation, improved and more natural gait patterns, and improvement in negotiating inclines and significantly uneven surfaces. Unless these conditions are presented to the individual on a daily basis, the standard lower limb prosthetic device is generally adequate for ambulation across flat and minimally uneven surfaces.

The Centers for Medicare and Medicaid Services (CMS) has defined the following functional levels:

Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

(Note: the use of a microprocessor controlled prosthetic over a standard prosthetic for home use (for example, to climb stairs at home) or for the community ambulator (for example, to climb stairs at work) is generally not medically necessary.)

Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

References:

1. Centers for Medicare and Medicaid (CMS). National Government Services Inc. Local coverage determination (LCD) for lower limb prosthesis (L27013) Revision effective date: 01/01/2011. Available at: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=27013&ContrId=138&ver=15&ContrVer=1&Date=&DocID=L27013&bc=iAAAAAgAAAA&>. Accessed: 25 Aug 11.
2. Segal AD, Orendurff MS, Klute GK, McDowell ML, Pecoraro JA, Shofer J, Czerniecki JM. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J Rehabil Res Dev. 2006 Nov-Dec; 43(7): 857-870.
3. U.S. Department of Veteran's Affairs Technology Assessment Program. Short Report – Computerized lower limb prostheses. March 2000.
4. Washington State Department of Labor and Industries, Office of the Medical Director. Microprocessor-controlled prosthetic knees. Technology Assessment. 2002.

