



Medical Policy

Subject: Microprocessor Controlled Lower Limb Prosthesis	
Policy #: OR-PR.00003	Current Effective Date: 08/11/2006
Status: Reviewed	Last Review Date: 06/08/2006

Description/Scope

This policy addresses the use of microprocessor controlled lower limb prostheses, including the Otto-Bock C-Leg device[®].

Policy Statement

Investigational/Not Medically Necessary:

The use of a computerized leg prosthesis, such as the Otto-Bock, Inc. C-Leg Knee-Shin System[®] (C-Leg[®]), is considered **investigational/not medically necessary** in all cases.

Rationale

As is expected with many new technologies, there is a paucity of peer-reviewed, randomized studies evaluating the effectiveness of microprocessor controlled lower limb prostheses. Most of the articles published have enrolled small numbers, have been case reports (not randomized-controlled trials), and have utilized highly selected subjects who were otherwise in good health and without any additional medical problems.

The U.S. Department of Veteran Affairs Technology Assessment Program (VATAP) completed a systematic review on computerized lower limb prostheses in March 2000 and concluded that the:

- Energy requirements of ambulation (compared to requirements when using conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed, but are not significantly different at customary speeds.
- Results on the potential to improve ambulation on uneven terrain, stairs, or inclines were mixed; a study of 22 patients by Datta and Howitt found that 77% found no difference in ascending or descending stairs but 59% found it easier to walk on slopes.
- Patients did have a favorable perception of computerized prostheses and the vast majority of study participants choose not to return to their conventional prostheses.

The State of Washington Department of Labor and Industries published another systematic review of microprocessor-controlled prosthetic limbs in 2002. This review analyzed nearly the identical articles as the VATAP review and concluded that due to the small number of studies and study participants, the evidence supporting the broad effectiveness of microprocessor-controlled prosthetic knees remains inconclusive.

Otto Bock, Inc, the manufacturer of the C-Leg[®] prosthetic, cites three studies in support of the benefits of their device, but none of the studies have been published in peer-reviewed journals.

Microprocessor controlled lower limb prostheses represent a promising new technology but more studies, involving more patients, are required to determine if they offer significant (and reproducible) benefits over conventional lower limb prostheses.

Background/Overview

Prostheses are devices that are used to replace or compensate for the absence of a body part. Such absence may be present at birth or due to illness or trauma. Prosthetic devices have been used to replace body parts from individual fingers to entire limbs. Additionally, prostheses may include replacements for other body parts including breasts, eyes, and teeth. There are a wide variety of prostheses for the replacement of limbs made from various materials using a wide range of technologies.

For prostheses used to replace lower limbs where the leg is missing from above the knee, there is a need for a device to replace the normal function of the knee. In people with intact legs, the knee naturally and automatically adjusts its action to the speed and stride of the person. Conventional prosthetic legs use a pneumatic or hydraulic return mechanism to mimic the natural pendulum action of the knee. This mechanism is usually set by a prosthetist to work at the patient's normal walking speed, and does not allow any room for variation in speed. Changes in a patient's walking speed requires the patient to compensate for any delay in knee action through a variety of means including altering stride length and body position, among others. Such maneuvers lead to an abnormal gait and require extra effort and concentration for what is normally an unconscious act.

Computerized leg prostheses are now becoming available in the United States. These devices use computer-controlled knee mechanisms to detect step time and alter knee extension level to suit walking speed. Some more advanced models, such as the Otto-Bock C-Leg[®], have multiple sensors that gather and calculate data on various parameters such as the amount of vertical load, ankle movement, and knee joint movement in an attempt to mimic more natural leg function to provide stability and gait fluidity as needed (even on uneven terrains and/or during sports activities).

The claimed advantages of computerized leg prosthesis include a decreased level of effort in walking, improved symmetry of movement between legs leading to more natural movement, and the avoidance of falls.

Definitions

Computerized leg prosthesis: a prosthetic device for individuals with above the knee amputations which uses a computer microprocessor to detect walking speed in order to adjust knee-swing speed to compensate for differences in stride

Prosthesis: for the purposes of this policy, a device used to replace or compensate for the absence of a limb; prostheses may be artificial replacements for a wide variety of body parts

Coding

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational/Not Medically Necessary:

HCPCS

K0670	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type (code deleted 12/31/2005)
L5846	Addition, endoskeletal knee-shin system; microprocessor control feature, swing phase only (deleted 01/01/2005)
L5847	Addition, endoskeletal knee-shin system; microprocessor control feature, stance phase (deleted 01/01/2005)
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-shin system, microprocessor

control feature, stance phase only, includes electronic sensor(s), any type (code effective 01/01/2006)

ICD-9 Diagnosis

All Diagnoses

References

Peer Reviewed Publications:

1. Datta D, Heller B, Howitt J. A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. Clin Rehabil. 2005; 19(4):398-403.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Department of Veteran's Affairs Technology Assessment Program. Short Report – Computerized lower limb prostheses. March 2000. http://www.va.gov/vatap/pubs/ta_short_3_00.pdf Accessed March 9, 2006.
2. Washington State Department of Labor and Industries, Office of the Medical Director. Microprocessor-controlled prosthetic knees. Technology Assessment. 2002.
3. Workers' Compensation Board of British Columbia, Evidence Based Practice Group. A Review of Microprocessor-Controlled Knee Prostheses. 2003.

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Adaptive Prosthesis

C-Leg Microprocessor Controlled Knee Prosthesis

Endolite Intelligent Prosthesis

Lower Limb Prostheses, Microprocessor-Controlled

Microprocessor Controlled Lower Limb Prostheses (Above Knee Prosthetics)

Prostheses, Microprocessor-Controlled Lower Limb

Seattle Limb Systems Power Knee

Policy History

Status	Date	Action
Reviewed	06/08/2006	Medical Policy & Technology Assessment Committee (MPTAC) review. No change to policy position; updated references.
Reviewed	01/01/2006	Updated coding section with 01/01/2006 CPT/HCPCS changes
Revised	07/14/2005	MPTAC review. Revision based on Policy Harmonization: Pre-merger Anthem and Pre-merger WellPoint.

Pre-Merger Organizations	Last Review Date	Policy Number	Title
Anthem, Inc.	09/19/2003	OR-PR.00003	Computerized Limbs
WellPoint Health Networks, Inc.	06/24/2004	9.01.07	Microprocessor Controlled Lower Limb Prosthesis (Above Knee Prosthetics)

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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