Medical Policy

Subject: Microprocessor Controlled Lower Limb Prosthesis
Policy #: OR-PR.00003 **Current Effective Date:** 02/26/2009
Status: Revised **Last Review Date:** 02/26/2009

Description/Scope

This document addresses the use of microprocessor controlled lower limb prostheses including, but not limited to, the Otto-Bock C-Leg device®, the Ossur RheoKnee® and the Endolite Intelligent Prosthesis®.

Position Statement

Medically Necessary:

The use of a microprocessor controlled lower limb prosthesis (e.g., Otto-Bock C-Leg device®, the Ossur RheoKnee® or the Endolite Intelligent Prosthesis®), is considered **medically necessary** for transfemoral (above knee) and knee disarticulation amputees when *all* of the criteria set forth in (A) and (B) below have been met:

A) Patient selection criteria:

1. Patient has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology and to allow for faster than normal walking speed; and
2. Patient has demonstrated the ability to ambulate faster than their baseline rate using a standard prosthetic application with a swing and stance control knee; and
3. Patient has a documented need for daily long distance ambulation (i.e., greater than 400 yards) at variable rates. (In other words, use within the home or for basic community ambulation is not sufficient to justify the computerized limb over standard limb applications); and
4. Patient has a demonstrated need for regular ambulation on uneven terrain or regular use on stairs. Use of limb for limited stair climbing in the home or place of employment is not sufficient to justify the computerized limb over standard limb applications.

B) Documentation and performance criteria:

1. Complete multidisciplinary assessment of patient including an evaluation by a trained prosthetic clinician. The assessment must objectively document that all of the above patient selection criteria have been evaluated and met.

Not Medically Necessary:

The use of a microprocessor controlled leg prosthesis is considered **not medically necessary** in all other cases, including when the criteria above have not been met.

Rationale

At this time, the available peer-reviewed published literature addressing the clinical benefit of microprocessor controlled lower limb prostheses is limited to non-randomized controlled clinical trials, and case series of limited size. Additionally, the majority of these studies have involved highly selected subjects who were otherwise in good health.

One publication by Hafner and others (2007) reports the findings of a small, non-randomized, cross-over controlled design study in which each subject was exposed to two different prosthetic limb conditions (mechanical and microprocessor controlled C-Leg) twice during the trial. This study included 21 patients, each of whom used both a standard mechanical knee and lower limb prosthesis and the C-Leg microprocessor controlled prosthesis. Subjects were recruited for participation from a local amputee population. Seventeen patients completed the study. Subjects were told at the time of enrollment that they would be allowed to keep the test prosthesis whether or not they completed the trial. The patients began the trial with a two month period using their standard prosthesis followed by an activity assessment and functional, performance and subjective perception evaluation. Next, all patients used the microprocessor controlled prosthesis until acclimation was demonstrated. This was then followed by a two month acclimation period with the microprocessor controlled prosthesis, ending with an activity assessment and functional, performance and subjective perception evaluation. Patients were then reverted back to the standard prosthesis for two weeks and again an activity assessment and functional, performance and subjective perception evaluation was done. In the final stage of the trial, participants were allowed to use either one or both prosthetic devices over a four month period. Daily use and activity levels were measured for each device. The study concluded with a final activity assessment and functional performance and subjective perception evaluation with the microprocessor controlled device. A variety of objective and subjective outcome measures were reported. The authors reported no significant differences between the two prosthetic devices in terms of daily activity as measured by mean daily step frequency and mean estimated step distance, in performance on level or varied surfaces, or in cognitive demand during use of the devices. They did note a significant improvement with the C-Leg prosthesis in subjects' Stair Assessment Index (SAI) scores, time to descend scores, and a surveyed preference for the microprocessor controlled C-Leg as compared with a mechanical prosthetic knee. There was no difference noted in ascending stairs, but self reported frequency of stumbles and falls was lower for the C-Leg prosthesis. Limitations of this study include its small size, lack of outcome comparisons to a group randomized to continued use of a standard prosthesis, and lack of control of the type of mechanical prosthesis used. In addition, the period of time allowed for the patient to revert back to a standard prosthesis (two weeks) for a functional assessment prior to the 4-month combined use measures was quite limited.

An article by Williams and colleagues (2006) describes a randomized two-group crossover design study of C-Leg vs. a standard hydraulic knee prosthesis (Mauch SNS® knee). Patients were given a 3 month acclimation period for each device prior to testing. This study was not blinded and was hampered by a significant drop-out rate (56%) that left only 8 participants in the evaluable study population. The findings concluded that in non-demanding walking conditions with experienced amputees, participants reported the C-Leg® required less cognitive attention than the non-computerized knee. However, this subjective experience did not translate into improved performance on neuropsychologic screening instruments or walking speed.

In another report of the same trial (Orendurf, 2006) the authors report that they found no significant difference between the groups in either oxygen efficiency or gait efficiency. It is noted in the discussion section of this article that the programming of each C-Leg requires a high degree of tailoring to meet the needs of the user. The authors comment that the parameters that were used by each of the study participants varied widely, with some preferring their C-Leg to operate in a manner not too dissimilar to that of a standard non-computerized limb, and others preferring significantly different functional parameters. With this degree of variation, even within such a small study population, it would indicate that a much larger study population should be used in further studies of the C-Leg in order to control for this potential source of bias.

A non-randomized cross over study conducted by Kaufman and colleagues (2007) compared the computerized prosthetic knee to the standard hydraulic prosthesis in gait and balance parameters. The study included 15 participants, who were allowed an average of 4.5 months of acclimation time with each device. The authors indicate that there was a significant ($p< 0.01$) improvement in objective, standardized measures of both gait (knee flexor movement) and balance (Sensory Organization test) with the computerized prosthesis. The investigators point out that the study included a select group of healthy, highly effective ambulators with no additional musculoskeletal conditions. It is unclear what impact the use of computerized prosthetic knee devices may have on individuals with lower functional classifications.

Seymour and colleagues published a study comparing energy expenditure, obstacle course negotiation and quality of life (QOL) measures in 10 highly effective healthy ambulators who use both a C-Leg and a non-computerized prosthesis (2007). This study had a 23% drop out rate. A subset of participants (10 of 13) in this study underwent an eight minute energy consumption test on a treadmill using one of their prostheses, and then again using the other device after a 10 minute rest. They were then asked to undergo a walking obstacle course eight times, four holding a laundry basket containing a 10 lb weight, and four times unencumbered. Finally, they were asked to complete a standardized quality of life questionnaire (SF-36v2). The authors report a statistically significant lower energy consumption rate for participants when wearing their C-Leg devices at both typical and fast paces. On the obstacle course, statistical differences were noted in the number of steps taken, elapsed time, and the number of times participants stepped out of bounds during the unencumbered portion of the trial. During the encumbered trial, the elapsed time (11.5 sec vs. 15.5 sec) was shorter for the C-Leg prosthesis group ($p=0.007$). No stumbles or falls were reported in either group. The results of the QOL questionnaire associated with wearing the C-Leg indicated that the participants were at or above the normative data available for the general population.

A study by Kahle and colleagues (2008) investigated the impact of the C-Leg on several functional parameters, including stumbles, falls, performance in walking and stair descent and QOL. The study involved 21 patients, with 19 completing the study and utilized a simple pre-test post-test design. Participants in the study had a wide variation in physical status and health, but were all community ambulators. Some participants utilized assistive devices for ambulation. This is the first published study to include a mixed population. The authors report significant improvement in the number of stumbles (p=0.006), but no significant improvement in the number of falls. No statistical analysis was provided for either walking or stair descent performance. Finally, there was a significant improvement (20%, p=0.007) in QOL scores with the C-Leg prosthesis.

The U.S. Department of Veterans Affairs Technology Assessment Program (VATAP, 2000) completed a systematic review of 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 chose not to return to their conventional prostheses.

The U.S. Department of Veterans Affairs (VA) Veterans Health Administration (VHA) has published a document outlining the VA's prescribing guidelines for the computerized lower limb prosthesis. In this document they set forth the criteria for both patient selection and patient performance parameters, to identify patients who are both highly active, healthy, capable of managing the use of a computerized lower limb, and who have a clear need for this type of prosthesis on a routine basis.

Although the evidence continues to evolve, it is reasonable to consider microprocessor controlled lower limb prostheses appropriate for a select group of patients meeting strict criteria for fitness, health, and daily utilization expectations. However, these devices may not be appropriate for all potential users. Since the device produces definite but marginal improvements in functional capacity by reducing oxygen consumption and improving walking speed and safety when ambulating in more challenging environments (e.g., long distances, uneven terrain, regular use of stairs) the device is appropriate for users who face those challenges regularly. In addition, the device requires substantial training to allow for faster than normal walking speed and a user should have adequate cognitive learning ability to master the higher level technology. The criteria set forth above identify the potential users for whom the device may represent an improvement in functional capacity.

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 amputation as the result of 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 the knee or above, 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.

Microprocessor controlled lower limb prostheses use computer-controlled knee mechanisms to detect step time and alter knee extension level to suit walking speed. 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 on uneven terrains and/or during sports activities.

The claimed advantages of the 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 document 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 may be Medically Necessary when criteria are met:

HCPCS

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

ICD-9 Diagnosis

	All diagnoses, including, but not limited to, the following:
897.2	Traumatic amputation of leg, unilateral, at or above knee, without mention of complication
897.3	Traumatic amputation of leg, unilateral, at or above knee, complicated
897.6-897.7	Traumatic amputation of leg, bilateral [when specified at or above knee]
V49.76	Lower limb amputation status, above knee

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, or when the code(s) describes a procedure indicated in the Position Statement section as not medically necessary.

References

Peer Reviewed Publications:

1. Chin T, Sawamura S, Shiba R, et al. Effect of an Intelligent Prosthesis (IP) on the walking ability of young transfemoral amputees: Comparison of IP users with able-bodied people. Am J Phys Med Rehabil. 2003; 82(6): 447-451.
2. Chin T, Machida K, Sawamura S, et al. Comparison of different microprocessor controlled knee joints on the energy consumption during walking in trans-femoral amputees: intelligent knee prosthesis (IP) versus C-leg. Prosthet Orthot Int. 2006; 30(1):73-80.
3. 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.
4. Hafner BJ, Willingham LL, Buell NC, et al. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabil. 2007; 88(2):207-217.
5. Johansson JL, Sherrill DM, Riley PO, et al. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil. 2005; 84(8): 563-575.
6. Kahle JT, Highsmith MJ, Hubbard SL. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. JRRD. 2008; 45(1):1–14.
7. Kaufman KR, Levine JA, Brey RH, et al. Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. Gait Posture. 2007; 26(4):489-493.

8. Klute GK, Berge JS, Orendurff MS, Williams RM, Czerniecki JM. Prosthetic intervention effects on activity of lower-extremity amputees. Arch Phys Med Rehabil. 2006; 87(5):717-722.
9. Orendurff MS, Segal AD, Klute GK, et al. Gait efficiency using the C-leg. Journal of Rehabilitation Research and Development. 2006; 43(2):239-246.
10. Schmalz T, Blumentritt S, Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. Gait Posture. 2002; 16:255-263.
11. Segal AD, Orendurff MS, Klute GK, et al. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. J Rehabil Res Dev. 2006; 43(7):857-870.
12. Seymour R, Engbretson B, Kott K, et al. Comparison between the C-leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: a preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthet Orthot Int. 2007; 31(1):51-61.
13. Taylor MB, Clark E, Offord EA, et al. A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. Prosthet Orthot Int. 1996; 20(2):116-121.
14. Williams RM, Turner AP, Orendurff M, Segal AD, Klute GK, Pecoraro J, Czerniecki J. Does having a computerized prosthetic knee influence cognitive performance during amputee walking? Arch Phys Med Rehabil. 2006; 87(7):989-994.

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 February 25, 2009.
2. U.S. Department of Veteran's Affairs. VHA Prosthetic and Sensory Aids Service Strategic Healthcare Group's Prescribing Guidelines for Computerized Lower Extremity Prosthesis. Available at: http://www.va.gov/vatap/publications/cleg_guideline.doc. Accessed on February 25, 2009.
3. Washington State Department of Labor and Industries, Office of the Medical Director. Microprocessor-controlled prosthetic knees. Technology Assessment. 2002.
4. Workers' Compensation Board of British Columbia, Evidence Based Practice Group. A Review of Microprocessor-Controlled Knee Prostheses. 2003.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	02/26/2009	Medical Policy & Technology Assessment Committee (MPTAC) review. Added medically necessary position and criteria for microprocessor controlled lower limbs. Updated Rationale, Coding and Reference sections.
Revised	08/28/2008	MPTAC review. Changed position statement from Investigational and Not Medically Necessary to Not Medically Necessary. Updated Rationale, Coding and Reference sections.
Reviewed	05/15/2008	MPTAC review. No change to position statement. Updated Rationale and Reference sections
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. No change to position statement. Updated Rationale and Reference sections. Coding updated; removed HCPCS L5846 and L5847 deleted 12/31/2004, and K0670 deleted 12/31/2005.

Reviewed	06/08/2006	MPTAC review. No change to position; updated references.
	01/01/2006	Updated coding section with 01/01/2006 CPT/HCPCS changes
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document 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)
