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Medical Policy

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Section: Medicine

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Type: MN and I/E

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.

Subject: **Microprocessor - Controlled Prosthetic Knee**

Description

More than 100 different prosthetic knee designs are currently available. The choice of the most appropriate design will depend on the patient's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will be quite different than a younger, active subject. In general, key elements of a prosthetic design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees also vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces.

In contrast to more simple designs, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow the amputee to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing phase controls allow the amputee to set a pace from very slow to a race walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons these prostheses are generally prescribed to athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing phase features.

Most recently, microprocessor-controlled prosthetic knees have become available, including the Intelligent Prosthesis (Blatchford, United Kingdom), the Adaptive (Endolite, England), the Rheo Knee (Ossur Americas, Aliso Viejo, CA), and the C-LEG® (Otto Bock Orthopedic Industry, Minneapolis, MN). These devices 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. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. The C-LEG is also designed to improve the stance control; for example, it may be possible for the sensors to recognize a stumble, stiffen the knee, and avoid a fall.

With the exception of the Intelligent Prosthesis, these devices use microprocessor control in both the swing and stance phases of gait. By improving stance control, they may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble and stiffen the knee, thus avoiding a fall. Other potential benefits of microprocessor-controlled knee prostheses are improved ability to navigate stairs, slopes, and uneven terrain, and reduction in energy expenditure and concentration required for ambulation.

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The criteria below apply to the use of the Otto Bock C-Leg microprocessor-controlled prosthetic knee only. Use of all other microprocessor controlled prosthetic knees including but not limited to the Intelligent Prosthesis, the Adaptive, and the Rheo Knee is considered **investigational/experimental.**

1. The use of the Otto Bock C-Leg microprocessor-controlled prosthetic knee only, in healthy, active **K3-K4** ambulating adults with a trans-femoral amputation from a non-vascular cause is considered **medically necessary** in patients that meet **all** of the following criteria (A to E):

A. Patient must be evaluated and the device prescribed by a Physiatrist.
B. At least one of the following criteria are met:

- Demonstrated need for long distance ambulation at variable rates on a daily basis - greater than 400 yards (Use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications) **or**
- Demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application); **and**

C. Adequate physical ability (the patient should not have any major cardiovascular, musculoskeletal or neuromuscular problems), including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; **and**

D. Adequate cognitive learning ability to master use and care requirements for the technology; **and**

E. The patient must meet the manufacturer's specifications and limitations for a microprocessor-controlled system and must be fitted by a prosthetist with the appropriate expertise (see policy guidelines).

2. A microprocessor-controlled prosthetic knee is considered **<u>not medically necessary</u>** for the following criteria:

A. In amputees with the following functional levels:

- K0 - no ability or potential to ambulate or transfer, **or**
- K1 - limited ability to transfer or ambulate on level ground at fixed cadence, **or**
- K2 - limited community ambulator who does <u>not</u> have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, decreased risk of falls and potential to advance to a less restrictive walking device.

B. When the primary benefit is to allow the patient to perform leisure or recreational activities.
C. Significant deformity of remaining limb that would impair ability to stride
D. Patient falls outside of recommended weight guidelines of Manufacturer (≤275lbs).
E. Extremely rural conditions where maintenance ability is limited.

3. Requests for the **replacement** of the microprocessor−controlled prosthetic knee in use for > 6 yrs are eligible for coverage when all of the following criteria are met:

- Adjustments/repair options no longer effective; **or**
- Adjustments/repair would cost > 60% of the cost of replacement; **and**
- Documented compliance with manufacturer's required maintenance

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Policy Guidelines

The following are the functional classification levels used to determine patient rehabilitation potential:

<u>Manufacturer Indications for Otto Bock C- Leg®</u>

Amputees (knee disarticulation amputation level and higher) at mobility 3 “non restricted outdoor walker” or 4 “non restricted outdoor walker with especially rigorous demands” with at least one of the following findings:

- Amputees who have the ability or the potential to vary their cadence and to walk fast (>5 kmph or 3 mph) and/or walk long distances (>5km or 3 miles per day);
- Patients walking on uneven ground or slopes or climbing/descending stairs often (>100 steps per day);
- Amputees with professional activities requiring a high level of stance safety, particularly efficient swing phase control and who walk for extended periods;
- Amputees who have to change their movements and speed quickly in sudden, unexpected situations (e.g. people responsible for young children);
- Amputees who require the additional modes (e.g. for standing with the knee slightly flexed while weight bearing).

Other indications when considering an Otto Bock Microprocessor Knee include:

- Other diseases and/or complications due to an injury which increase the disability caused by amputation (e.g. contralateral joint instabilities, arthritis of lower extremity joints, contralateral amputation below the knee, amputation of upper extremities, complicated post-traumatic conditions, multiple disabilities);
- Serious neuromuscular deficiencies of the extremities (e.g. plexus paralysis) including deficiencies of the residual limb motor system;
- Cognitive ability or living situations that do not allow proper care of Microprocessor Knees.

Medicare Functional Levels	
K0	No ability or potential to ambulate or transfer.
K1	Limited ability to transfer or ambulate on level ground at fixed cadence
K2	Limited community ambulator who does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, decreased risk of falls and potential to advance to a less restrictive walking device.
K3	Unlimited community ambulatory.
K4	Active adult, athlete, who has the need to function at a K3 level in daily activities.

See below for additional information regarding the replacement and maintenance of the microprocessor controlled prosthetic knee and its components:

Maintenance

Regular annual maintenance may be required to keep the warranty valid. Regular maintenance may include an assessment of the electronics and other knee components and replacement of worn parts.

Rationale

Relevant outcomes for microprocessor-controlled knee prostheses may include the patient's perceptions of subjective improvement attributable to the prosthesis and level of activity/function. In addition, the energy costs of walking or gait efficiency may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis.

Published data on the microprocessor-controlled knee prostheses are minimal; the bulk of the literature focuses on the Intelligent Prosthesis (IP), which is similar to the C-Leg, but is not distributed in this country. Kirker and colleagues reported on the gait symmetry, energy expenditure, and subjective impression of the IP in 16 patients with an above-knee amputation related to trauma or congenital anomaly. (2) The patients had previously functioned adequately with a pneumatic swing-phase control unit and were offered a trial of an IP. At the beginning of the study, the patients had been using the IP for between 1 and 9 months. The patients responded to a questionnaire using a visual analog scale regarding how much effort was needed to walk at their normal, faster, and slower speeds on smooth level surfaces, outdoors or at work, up and down a slope, and up and down steps. The patients also indicated their overall preference for one or the other. Subjects reported that significantly less effort was required when using the IP prosthesis to walk at normal or high speeds, but there was no difference for a slow gait. Effort was reduced walking outdoors or at work. Subjects reported a strong preference for the IP versus the standard pneumatic leg.

Datta and Howitt reported on the results of a questionnaire survey of 22 amputees who were switched from pneumatic swing-phase control prostheses to an IP device. (3) All patients were otherwise fit and fairly active. The questionnaire focused on functional attributes of the 2 prostheses, such as speed of walking, walking up and down stairs, energy levels, and naturalness of the gait. All subjects reported that the IP was an improvement over the conventional prosthesis. The main benefits suggested by this subjective study were the ability to walk at various speeds, reduction of effort of walking, and patients' perception of improvement of walking pattern.

Buckley and colleagues focused on a comparison of the energy cost of an IP with a pneumatic swing-phase control unit in 3 patients. (4) Two subjects showed a decrease in energy consumption, while a third showed no change. Another study of 1 patient also reported lower oxygen consumption with an IP prosthesis. (5) Finally, Datta and colleagues studied oxygen consumption at different walking speeds in 10 patients using an IP and a pneumatic swing gait prosthesis. (6) Similar to the Kirker study, the IP was associated with less oxygen consumption at lower walking speeds only. Studies of gait analyses did not identify any other significant differences. Obviously, few conclusions can be drawn from these small trials. Specifically, the clinical significance of decreased oxygen consumption at lower walking speeds is uncertain.

In 2000, the Veteran's Administration Technology Assessment Program issued a "short report" on computerized lower limb prostheses. (7) This report, which considered the same data as those referenced here, offered the following observations and conclusions:

Energy requirements of ambulation (compared to requirements with 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 potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficit in the reintegration of amputees to normal living, particularly those related to decreased recreational opportunities.

Users' perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, the vast majority of study participants choose not to return to their conventional prosthesis or to keep these only as back-up to acute problems with the computerized one.

Users' perceptions may be particularly important for evaluating a lower limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the preamputation level.
Mechanical failure is recorded in some of the studies, but seems to be rare. The manufacturer indicates that some C-Legs have been used for extended periods (up to 5 years) without mechanical or electrical problems.
The UK Medical Devices Agency has conducted an evaluation of the Endolite Intelligent Prosthesis, with generally favorable results. Recognizing constraints related to the substantial cost of the prosthesis, the UK National Health Service makes it available to a wide range of patients, and has arranged with the manufacturer for a program to lend critical components, should these components of the prosthesis require factory repair.

2006 Update

A literature search performed for the period of 2003 through February 2006 did not identify any additional published clinical trials; therefore, the policy statement was unchanged.

2007 Update

A search of the MEDLINE database from February 2006 through September 2007 identified a number of reports comparing mechanical and microprocessor-controlled prostheses.

Few of the studies report on functional outcomes; those that do, while not without limitations, present positive results for improved function with use of a microprocessor-controlled prosthesis. As noted above, Seymour et al conducted observations of participants ability to traverse an obstacle course meant to replicate walking tasks that they would encounter in real-life (14). Participants were able to complete the obstacle course faster, with few steps and with fewer step-offs from the course while wearing the C-Leg. These results were retained when the participants carried a ten pound laundry basket while walking the course, except the difference in step-offs from the course was no longer significant. This study had some significant limitations. Similar to all of the included studies, there were only a small number of participants, limiting their ability to measure characteristics of participants predicting the most benefit when wearing a microprocessor-controlled prosthesis. The investigators did not randomize the order in which the participants wore the two different prostheses, nor were they blinded to the prosthesis being worn. When they analyzed the data, they did not conduct an analysis that accounted for the fact that each participant traversed the obstacle course multiple times while wearing each prosthesis (repeated-measure analysis). Despite these limitations, the functional results of this study are promising.

Hafner et al also assessed functional outcomes (8). These investigators found improved function on both stair descent and hill descent with the C-Leg. In addition, the participants reported fewer falls and stumbles as well as less frustration with falls and higher overall satisfaction with the C-Leg compared to their NMC. However, neither this study nor another which examined cognitive function (12), found any difference between the two prostheses in performance on a cognitive test while walking. The Hafner study suffers from some of the same limitations as the Seymour study. While it is the largest study of the group, it is still quite small. The investigators chose not to randomize the order of prosthesis evaluation, explaining that they wanted to replicate clinical practice in which patients usually have used an NMC for many years and then switch to a microprocessor-controlled prosthesis. Like the Seymour study, the investigators were not blinded to the type of prosthesis being worn during a given test, possibly introducing bias to the results. However, their analysis was appropriate for their repeated-measures design.

Kaufman et al assessed functional outcomes and found improved function in gait biomechanics and validated balance measures (18). Balance was objectively tested using a computerized dynamic posturography moveable dual force platform that can translate or rotate along with a moveable visual surround. The Sensory Organization Test (SOT) was used to assess the three sensory components of balance (visual, somatosensory, and vestibular inputs) under a variety of altered visual and surface support conditions. The Kaufman study is also small and the investigators did not randomize the order of the prosthesis evaluation presumably because all subjects were previously NMC knee users.

Despite the limitations cited above, use of a microprocessor-controlled prosthetic knee does appear to improve both intermediate markers and functional outcomes for the select group of patients which has been studied. Although three microprocessor-controlled knees have been studied (IP, Rheo, C-Leg), the only one to be studied for actual functional outcomes is the C-Leg. The other two appear to be equivalent to the C-Leg in the few intermediate markers studied – energy expenditure and walking dynamics – but their equivalence in gait analysis, balance, obstacle course and cognitive demand functional outcomes has not been published.

One industry-sponsored study assessed function, performance, and preference for the C-Leg in 21 unilateral transfemoral amputees using an A-B-A-B design. (8) Subjects were fully accustomed to a mechanical knee system (various types) and were required to show proficiency in ambulating on level ground, inclines, stairs, and uneven terrain prior to enrollment. Of the 17 subjects (81%) who completed the study, patient satisfaction was significantly better with the microprocessor-controlled prosthesis as measured by the Prosthesis Evaluation Questionnaire (PEQ). Fourteen preferred the microprocessor-controlled prosthesis, 2 preferred the mechanical system, and one had no preference. Subjects reported fewer falls, lower frustration with falls, and an improvement in concentration. Objective measurements on the various terrains were less robust, showing improvements only for descent of stairs and hills. Average performance on stair descent improved from a step-to pattern with a rail to a step-over-step with a rail and assistive device. The C-Leg improved hill descent from requiring an assistive device to using a step-to pattern without an assistive device. Unaffected were stair ascent, step frequency, step length, and walking speed. The subjective improvement in concentration was reflected by a small (nonsignificant) increase in walking speed while performing a complex cognitive task (reversing a series of numbers provided by cell phone while walking on a city sidewalk).

All lower-limb amputees returning from Operation Iraqi Freedom and Operation Enduring Freedom currently receive a microprocessor-controlled prosthesis from the Department of Veterans Affairs (VA); 155 veterans were provided with a C-Leg in 2005. (9) A series of papers from the VA reports results from a within-subject comparison of the C-Leg to a hydraulic Mauch SNS knee. (10-12) Eight (44%) of the 18 functional level 2–3 subjects recruited completed the study; most withdrew due to the time commitment of the study or other medical conditions, 2 could not be adequately fit, and 1 could not acclimate to the C-Leg. Of the 8 remaining subjects, half showed a substantial decrease in oxygen cost when using the C-Leg, resulting in a marginal improvement in gait efficiency for the group. (10) The improvement in gait efficiency was hypothesized to result in greater ambulation, but a 7-day activity monitoring period in the home/community showed no difference in the number of steps taken per day or the duration of activity. (11) Cognitive performance, assessed by standardized neuropsychological tests while walking a wide hallway in 5 of the subjects, was not different for semantic or phonemic verbal fluency, and not significantly different for working memory when wearing the microprocessor-controlled prosthesis. (12) Although the study lacked sufficient power, results showed a 50% decrease in errors on the working memory task (1.63 vs. 0.88). Thus, the effect of this device on objective measures of cognitive performance cannot be determined from this study. Subjective assessment revealed a perceived reduction in attention to walking while performing the cognitive test (effect size of 0.79) and a reduction in cognitive burden with the microprocessor-controlled prosthesis (effect size of 0.90). Seven of the 8 subjects preferred to keep the microprocessor-controlled prosthesis at the end of the study. (11) The authors noted that without any prompting, all of the subjects had mentioned that stumble recovery was their favorite feature of the C-Leg.

Two small studies of high functioning amputees (functional level 3–4, n=8 and 10) compared performance with the subject’s own C-Leg to a mechanical model. (13, 14) With little or no acclimation time for the mechanical knee, the studies found that use of the C-Leg resulted in faster time on an obstacle course, a smoother gait, and improved efficiency of hip work. A survey of 8 amputees who had previously switched to a C-Leg found that this group of patients felt less fatigued, safer due to a reduced incidence from falls, and more motivated and self-confident when using the C-Leg in comparison with their previous mechanical model. (15) Given the highly selected patient populations and bias in experimental design, the only information provided by these studies is that some current users are satisfied with the microprocessor-controlled knees and that they perform adequately for some people.

Although the literature indicates that microprocessor-controlled knees may perform at least as well as mechanical prostheses, objective evidence of incremental improvement in activities of daily living (e.g., falls and activity levels) is lacking. This may be due, in part, to the individualized prescription of prosthetic components and the difficulty of designing and collecting objective measures of recovery or rehabilitation. The literature does indicate a strong preference for prosthetic knees that controls both stance and swing in selected patients. The perceived benefits include an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. As described in the VA short report, “users’ perceptions may be particularly important for evaluating a lower limb prosthesis, given the magnitude of the loss involved…. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the preamputation level.” (7)

It is concluded that a microprocessor-controlled knee may provide incremental benefit for some individuals. Those considered most likely to benefit from these prostheses have both the potential and need for frequent ambulation at variable cadence, on uneven terrain, or on stairs. The potential to achieve a high functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to be able to use the advanced technology.

Sources

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19. California Technology Assessment Forum. Microprocessor-Controlled Prosthetic Knees, L.Karliner et L.Bergthold. California, October 17, 2007.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

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. Some state or federal mandates (e.g., EP) prohibit Plans from denying FDA-approved technologies as investigational. In these instances, Plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design therefore contract language should be reviewed before applying the terms of the policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy.

Codes

Codes	Number	Description
CPT	None	
HCPCS	L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensors, any type
	L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensors, 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	897.2 – 897.7	Traumatic amputation of leg; code range for above the knee amputation(s)
	V43.65	Organ or tissue replaced by other means; knee
HCPCS	See Policy Guidelines	

Policy History	Date	Activity
Medical Policy Committee	12/07/2006	Policy Adopted - BCBSA MPP. All devices considered Investigational/ Experimental.
Medical Policy Committee	01/11/2008	Policy reviewed. CTAF 10/2007 assessment included. Coverage changed to allow for C-Leg (only) with certain criteria.