Regence

Back to Site Print Page

Medical Policy

Introduction | Table of Contents | Recent Updates | Contact Medical Policy Staff

Durable Medical Equipment Section - Microprocessor-Controlled Prosthetic Knees

Topic: Microprocessor-Controlled Prosthetic Knees
Section: DME
Approved Date: 07/03/2007
Next Review Date: 03/2008

Date of Origin: 02/03/2004
Policy No: 68
Effective Date: 07/03/2007

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

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.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

There are over 100 different prosthetic knee designs currently available. The choice of the most appropriate design depends 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 person. 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 intended 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 of 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 prosthetist to set a pace that is adjusted to the individual amputee 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, Intelligent Prosthesis Plus, and The Adaptive (Endolite North America), the Ossur's Rheo Knee? (Ossur-Flexfoot, Iceland), and the C-Leg? and Compact? (Otto Bock Orthopedic Industry, Minneapolis, MN). The C-Leg? was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA, K991590). According to Otto Bock, the life expectancy of the C-Leg? is 2 to 5 years. 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.

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.

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

Functional Classification 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 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.
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.

Indications for use of the microprocessor knee include:

- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence
- Adequate strength and balance to stride to activate the knee unit
- Should not exceed the weight or height restrictions of the device
- Adequate cognitive ability to master technology and gait requirements of device
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral lower extremity amputees are candidates if they meet functional criteria as listed
- Patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue
- Daily activities or job tasks that do not permit full focus of concentration on knee control and stability?such as uneven terrain, ramps, curbs, stairs, repetitive lifting and/or carrying
- Medicare Functional Levels K3, K4, and selected K2 as follows:
  - Medicare Level K2?limited community ambulator, but only if improved stability in stance permits increased independence, decreased risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to utilize the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.
  - Medicare Level K3?unlimited community ambulator
  - Medicare Level K4?active adult, athlete, who has the need to function at a K3 level in daily activities
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable
- Potential to unload and decrease stress on remaining limb
- Potential to return to an active lifestyle

Policy/Criteria

1.	All of the following general criteria must be met for a microprocessor-controlled knee prosthesis to be considered for benefits. Following this section there are specific patient selection guidelines.		
	A.	At least one of the following criteria are met:	
		1)	Demonstrated need for long distance ambulation at variable rates (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
		2)	Demonstrated 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)
	B.	Adequate physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed	
	C.	Adequate cognitive ability to master use and care requirements for the technology	
	D.	New amputees may be considered if they meet the criteria below. Pre-morbid and current functional assessment are important determinants	
		1)	Stable wound
		2)	Ability to fit socket
		3)	Must have potential to return to active lifestyle
2.	A microprocessor-controlled prosthetic knee is considered not medically necessary when any of the following apply:		
	A.	Medicare Functional Levels K0, K1, and selected K2	
		1)	Medicare Level K0?no ability or potential to ambulate or transfer.
		2)	Medicare Level K1?limited ability to transfer or ambulate on level ground at fixed cadence
		3)	Medicare Level 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.	Any condition which prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear	
	D.	Inability to tolerate the weight of the prosthesis	
	E.	Inability to utilize swing and stance features of the knee unit	
	F.	Poor balance or ataxia that limits ambulation	
	G.	Significant hip flexion contracture (over 20 degrees)	
	H.	Significant deformity of remaining limb that would impair ability to stride	
	I.	Limited cardiovascular and/or pulmonary reserve or profound weakness	
	J.	Limited cognitive ability to understand gait sequencing or care requirements	
	K.	Long distance or competitive running	
	L.	Patient falls outside of recommended weight or height guidelines of manufacturer	
	M.	Specific environmental factors?such as excessive moisture or dust, or inability to charge the prosthesis	
	N.	Extremely rural conditions where maintenance ability is limited	

Scientific Background

The Veteran?s Administration?s Prosthetic and Sensory Aids Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive practices. The New Technology Subgroup of the Pre-Post National Amputation Workgroup met in April 2004 to develop a proposal to define patient selection and identification criteria for Microprocessor Prosthetic Knees. Their proposal was based on recommendations arising from the May 2003 Microprocessor Prosthetic Knee Forum hosted at Walter Reed Army Medical Center and sponsored and funded by the American Academy of Orthotists and Prosthetists. The above patient selection criteria are based on these recommendations.

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 analysis may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis. There are minimal published data on the microprocessor-controlled knee prostheses. Kirker and colleagues reported on the gait symmetry, energy expenditure, and subjective impression of the Intelligent Prosthesis 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 Intelligent Prosthesis (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. However, no objective measurements were provided to support these subjective findings.

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 two 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. Again, no objective data was reported.

Buckley and colleagues focused on a comparison of the energy cost of an IP with a pneumatic swing phase control unit in three patients. (4) Two subjects showed a decrease in energy consumption, while a third showed no change. In another study of one patient, Taylor and colleagues also reported lower oxygen consumption with an IP prosthesis. (5) Datta and colleagues studied oxygen consumption at different walking speeds in ten 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. No significant difference was found in oxygen cost at normal walking speed, subjective gait evaluation or temporal and spatial gait parameters. Few conclusions can be drawn from these small trials. Specifically, the clinical significance of decreased oxygen consumption at lower walking speeds is uncertain.

Schmalz and colleagues, Otto Bock Research and Development Biomechanics Laboratory, Germany, reported the results of gait analysis on twelve subjects during two-step stair descent. (7) Measurements of vertical and horizontal forces and flexion angles of the following were compared:

The C-Leg? versus two mechanical knee joint systems, the Otto Bock 3R45 and the 3R80

The three prosthetic knee joints versus the amputees? sound (contralateral) knee function

The three prosthetic knee joints and the sound leg function versus the gait of non-amputees

Subjectively, all twelve subjects preferred the C-Leg?. The force and flexion measurements with the C-Leg? were closest to non-amputee measurements for both the prosthetic leg and the contralateral leg. The authors conclude that, of these three prosthetic knee joints, the C-Leg? more closely approximated normal gait on two-step descent. However, there is no discussion as to the impact of these findings on long-term functional outcomes.

Chin and colleagues measured oxygen uptake to evaluate energy expenditure during walking with the IP microprocessor-controlled knee and with the Otto Bock 3R15 mechanical knee. (8) Three patients were tested; all had a unilateral endoskeletal hip disarticulation prosthesis, the Otto Bock 7E7 hip. Two patients showed decreased oxygen uptake with the IP at all three speeds. The remaining patient showed decrease oxygen uptake with the IP at the medium and higher speeds, and no significant difference at the slower speed. There was no further follow-up and no measures of the impact of the changes in oxygen consumption on long-term functional outcomes.

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. (9) 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 greater with the microprocessor-controlled prosthesis as measured by the Prosthesis Evaluation Questionnaire (PEQ). Fourteen subjects preferred the microprocessor-controlled prosthesis, two 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 (non-significant) 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).

Two small studies of high functioning amputees (functional level 3 to 4, n = 8 and 10, respectively) compared performance with the subject?s own C-Leg? to a mechanical model. (10,11) These 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. However, there was little or no acclimation time for the mechanical knee. A survey of eight amputees who had previously switched to a C-Leg? found that this group of patients felt less fatigued, safer due to a reported reduced incidence from falls, and more motivated and self-confident when using the C-Leg? in comparison with their previous mechanical model. (12) 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.

Department of Veteran?s Affairs

According to the Department of Veteran?s Affairs (VA) Fact Sheet, all lower-limb amputees returning from Operation Iraqi Freedom and Operation Enduring Freedom currently receive a microprocessor-controlled prosthesis from the VA. (13)

In 2000, the Veteran?s Administration Technology Assessment Program issued a ?short report? on computerized lower limb prostheses. (14) 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 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.

In 2006, a series of papers from the VA reports results from a within-subject comparison of the C-Leg? to a hydraulic Mauch SNS knee. (15-16) Eight (44%) of the 18 functional level 2 to 3 subjects recruited completed the study; most withdrew due to the time commitment of the study or other medical conditions, two could not be adequately fit, and one could not acclimate to the C-Leg?. Of the eight 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. (15) 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. (16) 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. (17) 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 can not 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 eight subjects preferred to keep the microprocessor-controlled prosthesis at the end of the study. The authors noted that without any prompting, all of the subjects had mentioned that stumble recovery was their favorite feature of the C-Leg?.

Summary

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 patient preference for prosthetic knees that control 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.? (14) It is concluded that a microprocessor-controlled knee may provide incremental benefit for those individuals who meet the criteria listed above and have both the potential and need for frequent ambulation at variable cadence, on uneven terrain or on stairs.

References

BlueCross BlueShield Association Medical Policy Reference Manual, Policy No. 1.01.25

Kirker S, Keymer S, Talbot J et al. An assessment of the intelligent knee prosthesis. *Clin Rehabil* 1996;10(3):267-73

Datta D, Howitt J. Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: user?s verdict. *Prosthet Orthot Int* 1998;22(2):129-35

Buckley JG, Spence WD, Solomonidis SE. Energy cost of walking: comparison of "Intelligent Prosthesis" with conventional mechanism. *Arch Phys Med Rehabil* 1997;78(3):330-3

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):116-21

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;16:255-63

Chin T, Sawamura S, Shiba R, et. al. Energy expenditure during walking in amputees after disarticulation of the hip. A microprocessor-controlled swing-phase control knee versus a mechanical-controlled stance-phase control knee. *J Bone Joint Surg Br* 2005;87(1):117-9

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):207-17

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):563-75

. 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):563-75

. Seymour R, Engbretson B, Kott K et al. Comparison between the C-leg(R) 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

. Swanson E, Stube J, Edman P. Function and body image levels in individuals with transfemoral amputations using the C-Leg. *J Prosth Orthotics* 2005;17(3):80-4

. Department of Veterans Affairs Fact Sheet, VA?s Prosthetics and Sensory Aids. February 2006, available at: www1.va.gov/OPA/fact/docs/pros-sensory.doc (Verified 3/8/07)

. U.S. Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Service Research and Development Service, Management Decision and Research Center, Technology Assessment Program. Computerized lower limb prosthesis. VA Technology Assessment Program Short Report No. 2. Boston, Mass: MDRC, March 2000 available online at: www.va.gov/vatap/pubs/ta_short_3_00.pdf (Verified 7/25/07)

. Orendurff MS, Segal AD, Klute GK, et al. Gait efficiency using the C-Leg. *J Rehabil Res Dev* 2006;43(2):239-46

. Williams RM, Turner AP, Orendurff MS, et al. Does having a computerized prosthetic knee influence cognitive performance during amputee walking? *Arch Phys Med Rehabil*. 2006;87(7):989-94

. Klute GK, Berge JS, Orendurff MS, et al. Prosthetic intervention effects on activity of lower-extremity amputees. *Arch Phys Med Rehabil*. 2006;87(5):717-22

Cross References

Lower Limb Prostheses, Regence Medical Policy Manual, Durable Medical Equipment, Policy No. 18

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

DME Section Table of Contents GO »

BACK TO TOP »