Premera Blue Cross	Corporate Medical Policy

Title	**Microprocessor-Controlled Prosthetic Knees**
Number	**CP.MP.PR.1.01.513***
Revision Date(s)	03/13/07; 02/14/06; 02/08/05; 02/10/04
Effective Date	March 13, 2007
Replaces	1.01.25
Cross References	None

Description

There are over 100 different prosthetic knee designs that 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 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 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) 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 prosthesis 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.

Scope	Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply.*
Policy	A microprocessor controlled knee prosthesis for the treatment of individuals with a transfemoral amputation may be considered **medically necessary** when all the functional requirements identified in the Policy Guidelines section are met.
Policy Guidelines	**Functional Requirements for Use of a Microprocessor Controlled Knee Prosthesis** ∑ Patient has adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking speed. ∑ Patient must demonstrate the ability to ambulate at a faster than baseline rate using a standard prosthetic application with a swing and stance control knee. For new amputees without a prosthesis, the patient must have the potential to ambulate at a faster than baseline rate. ∑ There must be a demonstrated patient need for long distance ambulation at variable rates (greater than 400 yards) on a daily basis. Use of the limb in the home or for basic community ambulation is not sufficient to justify the computerized limb over a standard limb. ∑ There must be a 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 the use of a computerized limb over a standard limb.
Benefit Application	Contractual or benefit limitations on durable medical equipment or prostheses upgrades may be applicable.
Rationale/ Source	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; the bulk of the literature focuses on the Intelligent Prosthesis which, while similar to the C-LEG, is not distributed in this country. 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. 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.

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. All patients were otherwise fit and fairly active. The questionnaire focused on functional attributes of the two prostheses, such as speed of walking, and 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. Two subjects showed a decrease in energy consumption, while a third showed no change. Another study of one patient also reported lower oxygen consumption with an IP prosthesis. Obviously, few conclusions can be drawn from these small trials.

Additional Information

Otto Bock, the manufacturer of the C-LEG has provided the following potential patient selection criteria.

Amputees with mobility level "able to walk outdoors without limitations" and "able to walk outdoors without limitations plus engage in high performance activities" with at least one of the following findings:

- diseases and/or complications, due to an injury, that increase the disability caused by the amputation;
- neuromuscular deficiencies of the extremities, including deficiencies of the residual limb motor system;
- employees with professional activities requiring a high level of safety or long walking and standing;
- people having parental authority for children up to an age of 6 years;
- people with unilateral hip disarticulation amputation, and patients with hemipelvectomy amputation with good walking ability;
- people climbing stairs often (>100 per day), walking on slopes or uneven ground; or
- active amputee able to walk fast (>5 kmph or 3 mph) and/or walking long distances (.5 km or 3 miles per day).

	Medicare Policy DMERC (durable medical equipment regional carriers) is responsible for crediting coverage policies for Medicare regarding durable medical equipment. There is no specific coverage policy on microprocessor-controlled knee prosthesis, in part because there is no specific HCPCS code describing this prosthesis. However, the DMERC document does note that a determination of the medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to: ∑ the patient's past history; and ∑ the patients current condition including the status of the residual limb and the nature of other medical problems; and ∑ the patient's desire to ambulate. The document also provides the following classifications of rehabilitation potential. **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 ambulatory. **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 ambulatory. **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 demand of the child, active adult or athlete. **Veteran's Administration** In 2000, the Veteran's Administration Technology Assessment Program issued a "short report" on computerized lower limb prostheses. This report, which considered the same

data as that referenced above, 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 recreation 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.
- The VA has also developed a set of functional requirements necessary for the prescription of a microprocesser-controlled knee prosthesis instead of a standard prosthesis.
- 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 recognizable 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.

2004-2005 Update

Chin et al reported on a comparative study of energy expenditure and walking speeds between able-bodied people and young Intelligence Prosthesis (IP) users and to demonstrate the effect of IP on the walking ability of young amputees. The test subjects were eight young traumatic transfemoral amputees and fourteen able-bodied persons served as controls. They concluded that, after a prosthetic rehabilitation program for eight weeks, the young IP users could walk at the normal speeds of able-bodied people, with only around a 24% increase in energy expenditure.

An evidence review prepared by the Evidence Based Group of the Workers Compensation Board of British Columbia concluded that, "[t]o date, the published research on computerized knee prosthesis is very limited. Less than 3 % of published

	and indexed research represents structured research. Most published articles are purely descriptive or promotional in nature." The evidence review noted: Published studies enrolled highly selected sample of amputees who did not have additional medical problems and who were fit and active. These characteristics have been shown to be independently predictive of successful rehabilitation or return to 'normal' living after amputation. Thus, these variables are most likely to confound the results of the non-randomized, uncontrolled studies on microprocessor controlled knee prosthesis that have been published to date. The evidence review concluded that, "at present, the small number of studies on computerized knee prostheses does not conclusively show the effectiveness of the prostheses" in reducing energy expenditure particularly in normal speed walking, improving ability to walk on uneven terrain, improving ability to climb and descend stairs, and increasing walking distance. Nonetheless, the Workers Compensation Board of British Columbia decided to accept the microprocessor-controlled knee prosthesis using the guidelines and parameters developed by the U.S. Department of Veteran Affairs. **2006 Update** Wetz and colleagues reported the C-Leg microprocessor-controlled knee-shin system for the above-knee amputees was introduced as a dramatic improvement over all other prosthetic knees. This is due to its combination of on-board microprocessor and the hydraulic controls acting both on the swing and stance phase. A more secure, natural and efficient gait is expected. Following the recommendations of Otto Bock the indications for the prescription of the C-leg are: Amputees with mobility level "able to walk outdoors without limitations: and "able to walk outdoors without limitations plus engage in high performance activities" if they face at least one extra obstacle as listed in the Otto Bock catalogue of indications. Their testing compared the C-Leg against the regular knee, which is assumed to be an adequate choice for the patient and to which he is accustomed. They concluded that multi-handicapped patients of all activity levels generally experience substantial improvement due to this system. Some patients may show significant functional improvement. Active patients benefit in the majority of cases. However, some highly active patients complain about interferences between their intended movement and the microprocessor control of knee movements. **2007 Update** Orendurff and colleagues reported on a randomized controlled trial comparing the C-Leg versus the Mauch SNS on eight transfemoral (TF) amputees. The purpose of the study was to investigate whether microprocessor controlled prosthetic knees improved gait efficiency over mechanically controlled prosthetic knee joints in TF amputees. Net oxygen costs (mL/kg/m) was measured while the TF amputees walked over ground at four speed in random order: the authors found that the C-Let compared to the Mauch

	SNS but did not incur higher oxygen costs, suggesting greater efficiency only at higher walking speeds. References: 1. Kirker S, Keymer S, Talbot J et al. An assessment of the intelligent knee prosthesis. *Clin Rehabil* 1996; 10(3):267-73. 2. Datta D, Howitt J. Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: user's verdict. *Prosthet Orhot Int* 1998; 22(2):129-35. 3. 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. 4. Taylor MB, Clark E, Offord EA et al. A comparison of energy expenditure by a high level trans-formal amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. *Prosthet Orthot Int* 1996; 20(2):116-21. 5. www.ottobockus.com (Accessed January 9, 2007.) 6. www.palmettogba.com (Accessed January 9, 2007.) 7. 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 at www.va.gov/vatap/pubs/ta_short_3_00.pdf. (Accessed January 9, 2007.) 8. Endolite North America. The Intelligent Prosthesis Plus [website]. Centerville, OH: Endolite North America; 2004. Available at: http://www.endolite.com. (Accessed January 9, 2007.) 9. Martin CW; WCB Evidence Based Group. Otto Bock C-leg©: A review of its effectiveness for special care services. Assessment prepared for Workers Compensation Board of British Columbia, Compensation and Rehabilitation Services Division. Vancouver, BC: Workers Compensation Board of British Columbia; November 27, 2003. Available at: http://www.worksafebc.com/health_care_providers/Assets/PDF/Otto_Bock_Cleg.pdf . (Accessed January 9, 2007.) 10. 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. 11. Wetz HH, Hafkemeyer U, Drerup B. The influence of the C-leg knee-shin system from the Otto Bock Company in the care of above-knee amputees. A clinical-biomechanical study to define indications. *Orthopade* 2005; 34(4):298, 300-314, 316-9. 12. Orendurff MS, Segal AD, Klute GK, et al. Gait efficiency using the C-Leg. *J Rehabil Res Dev* 2006 Mar-April;43(2):239-46.

Codes	Number	Description
CPT		
ICD-9 Procedure		
ICD-9 Diagnosis	897	Traumatic amputation of leg(s) (complete) (partial) code section
	V43.65	Organ or tissue replaced by other means; knee
HCPCS	L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
	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 skin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
Type of Service	Durable Medical Equipment	
Place of Service	Inpatient	