Arkansas BlueCross BlueShield
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Coverage Policy Manual

Category:	**DME**
Intiated:	**April 2006**
Last Review:	**April 2006**

Microprocessor-Controlled Prosthetic Knees

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) 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.

Policy/ Coverage:

A microprocessor-controlled prosthetic knee is covered for members who are:
Amputees with mobility level "able to walk outdoors without limitations" or "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
- Active amputee able to walk fast (>5 kmph or 3 mph) and/or walking long distances (.5 km or 3 miles per day)

Any other use of a microprocessor-controlled prosthetic knee is not covered for members covered by Group Contracts or Individual Contracts furnished on or after July 1, 2004, based on benefit certificate primary coverage criteria.

For members with Individual Contracts issued prior to July 1, 2004 (contracts without primary coverage criteria), the use of microprocessor-controlled prosthetic knee in any circumstance not specifically stated as covered is considered investigational and is not covered. Investigational services are an exclusion in the member benefit contract.

Allowances for the microprocessor-controlled prosthetic knee, or its components, are subject to any contract limitations for DME services.

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 analysis 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, 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 2 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 1 patient also reported lower oxygen consumption with an IP prosthesis. Obviously, few conclusions can be drawn from these small trials. In summary, there are minimal published data on microprocessor-controlled knee prostheses in the English literature.

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 here, offered the following observations and conclusions:

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.

CPT/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

References:

C-Leg microprocessor knee patient evaluation protocol. www.ottobockus.com; 2006.

[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]. Wetz HH, Hafkemeyer U, Drerup B. Orthopade 2005; 34:298-319.

A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. Datta D, Heller B, Howitt J. Clin Rehabil 2005; 19:298-403.

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. Chin T, Sawamura S, et al. J Bone Joint Surg Br 2005; 87:117-9.

Energy expenditure and gait characteristics of a bilateral amputee walking with the C-leg prostheses compared with stubby and conventional articulating prostheses. Perry J, Burnfield JM, et al. Arch Phys Med Rehabil 2004; 85:1711-7.

VA Technology Assessment Program Short Report - Computerized lower limb prostheses. http://www.va.gov/vatap/topic_prosthetics.htm; 2000.

Conventional versus microchip controlled pneumatic swing phase control for transfemoral amputees: user's verdict. Datta D, Howitt J. Prosthet Orthot Int 1998; 22:129-35.

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

A comparison of energy expenditure by a high-level trans-femoral amputee using the Intelligent Prosthesis and conventionally dampted prosthetic limbs. Taylor MB, Clark E, et al. Prosthet Orthot Int 1996; 20:116-21.

An assessment of the intelligent knee prosthesis. Kirker S, Keymer S, et al. Clin Rehabil 1996; 10:267-73.

Group specific policy will supersede this policy when applicable. This policy does not apply to the Wal-Mart Associates Group Health Plan participants.