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Medical Policy Bulletin

Title: Microprocessor-Controlled Prosthetic Knees

Policy#: 11.14.21a

Application of Medical Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Medical necessity determination applies only if the benefit exists and no contract exclusions are applicable. Individual member benefits must be verified.

In products where members are able to self-refer to providers for care and services, members are advised to use participating providers in order to receive the highest level of benefits.

This Medical Policy/Technology document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. If the Medical Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical Policy Department. This information can include medical literature or pertinent facts of an individual case in which extraordinary circumstances may exist. This type of information is relevant not only in considering whether current medical policy should be updated but also in applying current medical policy to requests for coverage.

Intent of Policy:

The intent of this policy is to communicate the medical necessity criteria for microprocessor-controlled prosthetic knees.

For information on policies related to this topic, refer to the Cross References Table in this policy.

Description:

Following a lower limb amputation and after the appropriate healing of the surgical site, an individual may consider the use of a prosthetic leg to begin rehabilitation efforts in learning to ambulate. There are many different component types of a prosthetic limb, with more than 100 different prosthetic knee designs currently available on the market.

Recently, prosthetic devices with a microprocessor-controlled knee have become

available, including the C-Leg® (Otto Bock HealthCare; Minneapolis, MN) and the Intelligent Prosthesis (Blatchford & Sons; UK). These devices are equipped with a sensor that can detect when the knee is in full extension and automatically adjust the swing phase of the individual's gait, allowing for a more natural walking pattern at varying speeds; the C-Leg® is also designed to improve stance control. In addition, sensors may be able to detect a stumble, and stiffen the knee to avoid a fall.

Hafner, et al (2007) investigated the differences in function, performance, and preference between mechanical and microprocessor prosthetic knees for transfemoral amputees. 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). In addition, subjects reported fewer falls, reduced frustration with falls, and improved concentration on tasks other than knee control and stability while walking. 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. Also, the C-Leg® improved hill descent from requiring an assistive device to using a step-to pattern without an assistive device.

All lower-limb amputees returning from Operation Iraqi Freedom and Operation Enduring Freedom currently receive a C-Leg® from the Department of Veterans Affairs (VA). 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®.

Although it is similar to the C-Leg®, the IP is not currently distributed in the United States. One study (Kirker, et al) reported on the gait symmetry, energy expenditure, and the subjective impression of the IP with 16 subjects who presented with an above-the-knee (AK) amputation related to trauma or congenital anomaly. These individuals had been functioning adequately with a pneumatic swing phase control unit and were offered a trial of the IP. At the commencement of the study, the subjects had been using the IP between one and nine months. A questionnaire was provided to the individuals to rate how much effort was required to walk at normal, fast, and slow speeds on multiple surfaces (eg, smooth level, outdoors or at work, up and down a slope, and up and down the stairs). Individuals indicated an overall preference for the IP over the pneumatic swing phase unit. Subjects reported that considerably less effort was required when using the IP to walk at normal or high speeds, but no difference was noted for a slow gait. Reduced effort was required when the IP

was used outdoors or at work.

Literature researching microprocessor-controlled prosthetic knees indicates that selected individuals strongly prefer prosthetic knees that control both stance and swing, with perceived benefits such as a decrease in falls, an increase in stability, and a decrease in the cognitive burden or effort associated with monitoring the prosthesis. The VA short report states, “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.”

In conclusion, microprocessor-controlled prosthetic knees may provide incremental benefits for individuals who meet the need for the technologic or design features of the device. Those individuals who are considered most likely to benefit from this prosthesis have both the potential and the need for frequent ambulation at variable cadence, frequent negotiation of uneven terrain, and/or recurrent usage of stairs. The potential to achieve a high functional level with a microprocessor-controlled prosthetic knee requires the appropriate physical and cognitive abilities to utilize the advanced technology.

Policy:

The microprocessor-controlled knee prosthesis is considered medically necessary and, therefore, covered as a component fitting in a lower limb prosthesis for individuals who meet all of the following criteria:

- The individual is motivated to ambulate.
- The individual will reach and maintain a defined functional state within a reasonable period of time.
- The individual has high mobility and stance stability needs and is at a **functional level of 3 or 4** according to Medicare's classification scale of patient potential functional ability as described below:
 - 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. (Modifier K0)
 - 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. (Modifier K1)
 - Level 2: Has the ability or potential for prosthetic ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator. (Modifier K2)
 - Level 3: Has the ability or potential for prosthetic 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. (Modifier K3)
 - 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. (Modifier K4)

The microprocessor-controlled knee prosthesis is considered not medically necessary and, therefore, not covered for those individuals who do not meet all of the criteria listed above.

DOCUMENTATION

The individual's medical record must reflect the need for the care provided. These medical records may include, but are not limited to, records from the physician's office, hospital, nursing home, home health agency, other healthcare professionals, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation must be made available to the Company upon request.

Policy Guidelines:

INDICATIONS FOR UTILIZATION OF MICROPROCESSOR-CONTROLLED PROSTHETIC KNEES SHOULD INCLUDE ALL THE FOLLOWING:

- The individual is an active walker (eg, greater than 3 miles per day) and requires a device that reduces energy consumption to permit longer distances with less fatigue.
- The individual requires a prosthesis that can accommodate sudden changes in direction and speed for work or home activities, with the potential or ability for improved gait quality and speed (eg, faster than 3 miles per hour).
- The individual participates in daily activities or job tasks that do not permit full focus of concentration on knee control and stability (eg, repetitive lifting and/or carrying, frequent negotiation of uneven terrain, ramps, curbs, and stairs).
- The prosthesis should not be initially prescribed for or utilized primarily for athletic purposes.
- The individual has adequate cognitive ability to master the technology and gait requirements of the prosthesis.
- The individual has adequate cardiovascular and pulmonary reserve to ambulate at variable cadence while using the prosthesis.
- The individual has adequate strength and balance to stride to activate the knee unit.
- The individual does not exceed the weight or height restrictions of the device.
- Use of the prosthesis gives the individual the potential to return to an active lifestyle.
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral lower extremity amputees are candidates if they meet

functional criteria as listed

DOCUMENTATION REQUIREMENTS

Reimbursement for devices may only occur if there is sufficient documentation in the medical record showing the individual's current functional capabilities and need for the technologic or design features of the microprocessor-controlled prosthetic knee. Documentation may also include expected functional potential and an explanation if there is a difference between the individual's current status and expected potential. This information should be retained in the physician's or prosthetist's files, and be available upon request.

Documentation should also include identification and compliance with all the indications for utilization of a microprocessor-controlled prosthetic knee listed above. An individual who is deemed an appropriate candidate for a microprocessor-controlled prosthetic knee should meet all the indications listed. These indications conform with the recommendations of the Veterans Administration (VA) Technology Assessment Program Short Report for Computerized Lower Limb Prostheses and the VA Clinical Practice proposal.

MEDICARE

This policy is consistent with Medicare's coverage criteria. Payment methodologies may vary.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

The US Food and Drug Administration (FDA) has approved numerous prosthetic devices for use with a microprocessor-controlled knee.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the microprocessor-controlled prosthetic knee is covered under the medical benefits of the Company's products when the medical necessity criteria listed in the medical policy are met.

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CODING TABLE

Code System	Code Number(s) and Narrative(s)
CPT	N/A
ICD Procedure	N/A
ICD Diagnosis	N/A
HCPCS Level II	<p>L5856: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</p> <p>L5857: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type</p> <p>L5858: Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type</p>
Revenue Codes	N/A
Place of Service	

Links to related Medical Policy documents:

Policy #:	Policy Name:	<i>Click on the link to access document</i>
03.00.10c	Modifiers LT/RT: Left side/Right side Procedures	

05.00.45b

Repair and Replacement of an
External Prosthetic Device



05.00.59a

Lower Limb Protheseses



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