Protocol	**Microprocessor-Controlled Prostheses for the Lower Limb**

(10405)

Medical Benefit		**Effective Date**: 07/01/13	**Next Review Date**: 05/18
Preauthorization	Yes	**Review Dates**: 09/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Description

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. Active joint control is intended to improve safety and function, particularly for patients who have the capability to maneuver on uneven terrain and with variable gait.

Summary of Evidence

Microprocessor-controlled prostheses use feedback from sensors to adjust joint movement on a real-time as-needed basis. The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees versus hydraulic knee joints. For K3- and K4-level amputees, studies show an objective improvement in function on some outcome measures and a strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, an increase in stability, a decrease in falls, and a decrease in the cognitive burden associated with monitoring the prosthesis. It is concluded that a micropro-cessor-controlled knee may provide incremental benefit for these 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.

Evidence is insufficient to permit conclusions regarding the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators. Evidence is also insufficient to permit conclusions regarding the effect of a next-generation microprocessor-controlled prosthesis on health outcomes. Therefore, these are considered investigational.

The limited evidence available to date does not support an improvement in functional outcomes with a micro-processor-controlled or powered ankle-foot prostheses compared with standard prostheses. Therefore, microprocessor-controlled or powered ankle-foot prostheses are considered investigational.

Policy

A microprocessor-controlled knee may be considered **medically necessary** in amputees who meet the following requirements:

- 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) 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

- physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; AND

- adequate cognitive ability to master use and care requirements for the technology.

A microprocessor-controlled knee is considered **not medically necessary** in individuals who do not meet these criteria.

A powered knee is considered **investigational**.

A microprocessor-controlled or powered foot is considered **investigational**.

Policy Guidelines

Amputees should be evaluated by an independent qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor-knees involve multiple factors including activity levels as well as the patient's physical and cognitive ability. A patient's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (e.g., gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, daily and frequent need of two or more of these activities would be needed to show benefit.

For patients in whom the potential benefits of the microprocessor knees are uncertain, patients may first be fitted with a standard prosthesis to determine their level of function with the standard device.

The following are guidelines from the Veteran's Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees.[1]

Patient Selection and Identification

1. Contraindications for use of the microprocessor knee should include:

   - Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear.

   - Inability to tolerate the weight of the prosthesis.

   - Medicare Level K0—no ability or potential to ambulate or transfer.

   - Medicare Level K1—limited ability to transfer or ambulate on level ground at fixed cadence.

   - Medicare Level K2—limited community ambulator that does not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, less risk of falls, and potential to advance to a less-restrictive walking device.

   - Inability to use swing and stance features of the knee unit.

   - Poor balance or ataxia that limits ambulation.

   - Significant hip flexion contracture (over 20°).

- Significant deformity of remaining limb that would impair ability to stride.

- Limited cardiovascular and/or pulmonary reserve or profound weakness.

- Limited cognitive ability to understand gait sequencing or care requirements.

- Long distance or competitive running.

- Falls outside of recommended weight or height guidelines of manufacturer.

- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.

- Extremely rural conditions where maintenance ability is limited.

2. Indications for use of the microprocessor knee should include:

- Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.

- Adequate strength and balance in 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 Level K2—limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance to a less restrictive walking device, and patient has cardiovascular reserve, strength, and balance to use 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 as 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.

3. Physical and Functional Fitting Criteria for New Amputees:

- New amputees may be considered if they meet certain criteria as outlined above.

- Premorbid and current functional assessment important determinant.

- Requires stable wound and ability to fit socket.

- Immediate postoperative fit is possible.

- Must have potential to return to active lifestyle.

Medicare Advantage

For Medicare Advantage a lower limb prosthesis would only be considered **medically necessary** when the member:

1. Will reach or maintain a defined functional state within a reasonable period of time; and

2. Is motivated to ambulate.

Knee

A fluid, pneumatic, or electronic/microprocessor knee may be **medically necessary** for patients whose functional level is three or above (see Medicare Advantage Policy Guidelines).

The powered and programmable flexion/extension assist control addition is **medically necessary** only when the patient meets all of the criteria below:

- Has a microprocessor (swing and stance phase type controlled electronic) knee

- K3 functional level

- Weight greater than 110 lbs. and less than 275 lbs.

- Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K3 level function with the use of a microprocessor-controlled knee alone

- Is able to make use of a product that requires daily charging

- Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

Foot

A microprocessor controlled ankle foot system may be **medically necessary** for patients whose functional level is three or above (see Medicare Advantage Policy Guidelines).

Medicare Advantage Policy Guidelines

Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

1. The member's past history (including prior prosthetic use if applicable); and

2. The member's current condition including the status of the residual limb and the nature of other medical problems; and

3. The member's desire to ambulate.

Rehabilitation Classification Levels

Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.

Level 1: Has the ability or potential to use 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.

Background

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may 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 person. In general, key elements of a prosthetic knee 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 prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees 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 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 for 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.

Microprocessor-Controlled Prosthetic Knees

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, England), the Adaptive (Endolite, England), the Rheo Knee® (Össur, Iceland), the C-Leg®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN), and Seattle Power Knees (three models include Single Axis, 4-bar and Fusion, from Seattle Systems). 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. In addition, these devices (with the exception of the IP) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control.) 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. The C-Leg was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA; K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses utilize additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used, for example, in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Microprocessor-Controlled Ankle-Foot Prostheses

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot's movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. The intent of the technology is to make ambulation more efficient and prevent falls in patients ranging from the young active amputee to the elderly diabetic patient. The Proprio Foot™ and Elan Foot are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates use of the Proprio Foot™ for low- to moderate-impact for transtibial amputees who are classified as level K3 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence).

Powered Prostheses

In development are lower-limb prostheses that also replace muscle activity in order to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM® (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement (see the Myoelectric Prosthetic Components for the Upper Limb Protocol for a description of myoelectric technology). This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from an unnatural gait with use of a passive prosthesis. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis.

The Power Knee™ (Össur), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot in order to anticipate and respond with the appropriate movement required for the next step. The Power Knee is currently in the initial launch phase in the United States.

Regulatory Status

Microprocessor-controlled prostheses are categorized as class I, exempt devices. Manufacturers must register prostheses with the restorative devices branch of FDA and keep a record of any complaints but do not have to undergo a full FDA review. FDA product codes: ISW, KFX.

Related Protocols

Functional Neuromuscular Electrical Stimulation

Myoelectric Prosthetic Components for the Upper Limb

───────────────────────────────

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. VHA Prosthetic Clinical Management Program (PCMP). Clinical practice recommendations: microprocessor knees, 2004. See: Berry D. Microprocessor prosthetic knees. Phys Med Rehabil Clin N Am. 2006; 17:91-113.
2. 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. 2000; http://www.research.va.gov/resources/pubs/docs/ta_short_3_00.pdf. Accessed February, 2015.
3. Highsmith MJ, Kahle JT, Bongiorni DR, et al. Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature. Prosthet Orthot Int. Dec 2010; 34(4):362-377. PMID 20969495
4. Department of Veterans Affairs. VA Prosthetics and Sensory Aids. 2006; http://montgomery.md.networkofcare.org/veterans/library/article.aspx?id=1684. Accessed February, 2015.
5. Orendurff MS, Segal AD, Klute GK, et al. Gait efficiency using the C-Leg. J Rehabil Res Dev. Mar-Apr 2006; 43(2):239-246. PMID 16847790
6. Klute GK, Berge JS, Orendurff MS, et al. Prosthetic intervention effects on activity of lower-extremity amputees. Arch Phys Med Rehabil. May 2006; 87(5):717-722. PMID 16635636
7. Williams RM, Turner AP, Orendurff M, et al. Does having a computerized prosthetic knee influence cognitive performance during amputee walking? Arch Phys Med Rehabil. Jul 2006; 87(7):989-994. PMID 16813788
8. Kaufman KR, Levine JA, Brey RH, et al. Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. Gait Posture. Oct 2007; 26(4):489-493. PMID 17869114
9. Kaufman KR, Levine JA, Brey RH, et al. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil. Jul 2008; 89(7):1380-1385. PMID 18586142
10. 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. Aug 2005; 84(8):563-575. PMID 16034225
11. 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. Feb 2007; 88(2):207-217. PMID 17270519
12. Highsmith MJ, Kahle JT, Miro RM, et al. Ramp descent performance with the C-Leg and interrater reliability of the Hill Assessment Index. Prosthet Orthot Int. Oct 2013; 37(5):362-368. PMID 23327837
13. Hafner BJ, Smith DG. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. J Rehabil Res Dev. 2009; 46(3):417-433. PMID 19675993
14. Theeven P, Hemmen B, Rings F, et al. Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. J Rehabil Med. Oct 2011; 43(10):906-915. PMID 21947182
15. Theeven PJ, Hemmen B, Geers RP, et al. Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. J Rehabil Med. May 2012; 44(5):454-461. PMID 22549656
16. Burnfield JM, Eberly VJ, Gronely JK, et al. Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. Prosthet Orthot Int. Mar 2012; 36(1):95-104. PMID 22223685
17. Eberly VJ, Mulroy SJ, Gronley JK, et al. Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with a transfemoral amputation. Prosthet Orthot Int. Dec 2014; 38(6):447-455. PMID 24135259

18. Bellmann M, Schmalz T, Ludwigs E, et al. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Arch Phys Med Rehabil. Mar 2012; 93(3):541-549. PMID 22373937

19. Prinsen EC, Nederhand MJ, Olsman J, et al. Influence of a user-adaptive prosthetic knee on quality of life, balance confidence, and measures of mobility: a randomised cross-over trial. Clin Rehabil. Oct 6 2014. PMID 25288047

20. Kirker S, Keymer S, Talbot J, et al. An assessment of the intelligent knee prosthesis. Clin Rehabil 1996; 10(3):267-273.

21. Datta D, Howitt J. Conventional versus microchip controlled pneumatic swing phase control for trans-femoral amputees: user's verdict. Prosthet Orthot Int. Aug 1998; 22(2):129-135. PMID 9747997

22. Datta D, Heller B, Howitt J. A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control. Clin Rehabil. Jun 2005; 19(4):398-403. PMID 15929508

23. Hofstad C, Linde H, Limbeek J, et al. Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. Cochrane Database Syst Rev. 2004(1):CD003978. PMID 14974050

24. Alimusaj M, Fradet L, Braatz F, et al. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. Gait Posture. Oct 2009; 30(3):356-363. PMID 19616436

25. Fradet L, Alimusaj M, Braatz F, et al. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Gait Posture. Jun 2010; 32(2):191-198. PMID 20457526

26. Darter BJ, Wilken JM. Energetic consequences of using a prosthesis with adaptive ankle motion during slope walking in persons with a transtibial amputation. Prosthet Orthot Int. Feb 2014; 38(1):5-11. PMID 23525888

27. Gailey RS, Gaunaurd I, Agrawal V, et al. Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. J Rehabil Res Dev. 2012; 49(4):597-612. PMID 22773262

28. Delussu AS, Brunelli S, Paradisi F, et al. Assessment of the effects of carbon fiber and bionic foot during over-ground and treadmill walking in transtibial amputees. Gait Posture. Sep 2013; 38(4):876-882. PMID 23702342

29. Au S, Berniker M, Herr H. Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. Neural Netw. May 2008; 21(4):654-666. PMID 18499394

30. Ferris AE, Aldridge JM, Rabago CA, et al. Evaluation of a powered ankle-foot prosthetic system during walking. Arch Phys Med Rehabil. Nov 2012; 93(11):1911-1918. PMID 22732369

31. Herr HM, Grabowski AM. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. Proc Biol Sci. Feb 7 2012; 279(1728):457-464. PMID 21752817

32. Mancinelli C, Patritti BL, Tropea P, et al. Comparing a passive-elastic and a powered prosthesis in transtibial amputees. Conf Proc IEEE Eng Med Biol Soc. Aug 2011; 2011:8255-8258. PMID 22256259

33. LCD for Lower Limb Prostheses (L11464). http://www.medicarenhic.com/viewdoc.aspx?id=1649. Accessed February, 2015.

34. Noridian Healthcare Solutions, LLC, (Jurisdiction - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont , District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania, California - Entire State, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada) Local Coverage Determination (LCD): Lower LIMB Prostheses (L33787), Revision Effective Date for services performed on or after 07/01/2016.