09-L0000-06

Original Effective Date: 02/15/04

Reviewed: 08/25/22

Revised: 09/15/22

Subject: Lower Limb Microprocessor-Controlled Prosthetics

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions | Related Guidelines | Other | References | Updates

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 individual.

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 simpler designs that 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 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; therefore, these prostheses are generally prescribed to athletic or physically 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 (computerized) Prosthetic Knees

Microprocessor-controlled (computerized) prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, United Kingdom), the Adaptive (Endolite, England), the Rheo

Knee® (Ossur, Iceland) and the C-LEG®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN) and Seattle Power Knees (3 models include Single Axis, 4-bar and Fusion, 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 use control in both the swing and stance phases of gait The C-LEG Compact provides only stance control. By improving stance control, such devices may provide increased safety, stability, and function; for example, the sensors are designed to recognize a stumble, stiffen the knee, and avoid 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. In 1999, the C-Leg was cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use additional environmental input (eg, gyroscope and accelerometer) and more sophisticated processing that are 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 in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Powered Knee Prostheses

The Power Knee™ (Össur, Iceland), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot 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.

Microprocessor-Controlled Ankle-Foot Prostheses

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Ossur) and the iPED (developed by Martin Bionics LLC and licensed to College Park Industries) and the Elan Foot (Endolite). Sensors in the feet 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 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 prosthesis that are commercially available at this time, and is a class I device that is exempt from 510(k) marketing clearance. Information on the Össur website indicates the use of the Proprio Foot® for low- to moderate-impact for transtibial amputees who are classified as level K3 (ie, community ambulatory, with the ability or potential for ambulation with variable cadence).

Powered Ankle-Foot Prostheses

In development are lower-limb prostheses that also replace muscle activity 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. 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.

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the U.S. Food and Drug Administration (FDA) and is exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of FDA prior to marketing. FDA product codes: ISW, KFX.

POSITION STATEMENT:

A microprocessor-controlled knee **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- The member has a demonstrated need for long distance ambulation at variable rates (i.e., 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 has a demonstrated need for regular ambulation on uneven terrain or for regular use on stairs (i.e., 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**
- The member has the physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; **AND**
- The member has adequate cognitive ability to master use and care requirements for the technology.

A microprocessor-controlled knee **does not meet the definition of medical necessity** when the above criteria are not met.

A powered knee (myoelectric lower limb prosthetic designed to replace muscle activity of the quadriceps and uses artificial proprioception with sensors) is considered **experimental or investigational**. There is insufficient published clinical evidence to support the efficacy of these prosthetic devices or their effects on health outcomes.

A microprocessor-controlled or powered ankle-foot is considered **experimental or investigational**. The available clinical evidence is insufficient to evaluate the health benefits of microprocessor-controlled ankle-foot prostheses.

BILLING/CODING INFORMATION:

HCPCS Coding:

L2006	Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
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
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for lower limb microprocessor.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative note	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Lower Limb Prosthetics (L33787) located at cgsmedicare.com.

DEFINITIONS:

Cadence: the rate at which a person walk, expressed in steps per minute. The average cadence is 100 - 115 steps/min.

RELATED GUIDELINES:

None applicable.

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Adaptive

C-Leg

Genium™ Bionic Prosthetic System

Intelligent Prosthesis

iPED

Microprocessor-controlled knee prosthesis

Otto Bock C-LEG Knee-Shin System

PowerFoot BiOM®

Power Knee™

Proprio Foot®

Rheo Knee

Seattle Power Knees

X2 and X3 prostheses

REFERENCES:

1. Agrawal V, Gailey RS, Gaunaurd IA et al. Comparison of four different categories of prosthetic feet during ramp ambulation in unilateral transtibial amputees. Prosthet Orthot Int. 2015 Oct;39(5):380-389.
2. Agrawal V, Gailey RS, Gaunaurd IA et al. Comparison between microprocessor-controlled ankle/foot and conventional prosthetic feet during stair negotiation in people with unilateral transtibial amputation. Journal of Rehabilitation Research and Development 2013;50(7):941-950.
3. Bellmann M, Schmalz T, Ludwigs E, et al. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Archives of Physical Medicine and Rehabilation 2012 March;93(3):541-549.

4. Blue Cross Blue Shield Association Medical Policy Microprocessor-Controlled Prostheses for the Lower Limb 1.04.05, 04/22.
5. 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. Prosthetics and Orthothics International 2012 March;36(1):95-104.
6. Carse B, Scott H, Brady L, et al. Evaluation of gait outcomes for individuals with established unilateral transfemoral amputation following the provision of microprocessor controlled knees in the context of a clinical service. Prosthet Orthot Int. 2021 Jun 1;45(3):254-261. [Abstract]
7. 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. Prosthetics and Orthothics International 2014 Dec;38(6):447-455.
8. Ernst M, Altenburg B, Bellmann M et al. Standing on slopes-how current microprocessor-controlled prosthetic feet support transtibial and transfemoral amputees in an everyday task. Journal of Neuroengineering and Rehabilitation November 2017;14(1):117.
9. 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. Journal of Rehabilitation Research & Development 2012;49(4):597-612.
10. 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. Journal of Rehabilation Research Development 2009;46(3):417-433.
11. Herr HM, Grabowski AM. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. Proceedings. Biological Sciences. 2012 Feb 7;279(1728):457-464.
12. Kaufman KR, Levine JA, Brey RH, McCrady SK, Padgett DJ, Joyner MJ. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. Arch Phys Med Rehabil. 2008 Jul;89(7):1380-5.
13. Martin CW, Senior Medical Advisor for the WCB Evidence Based Practice Group. Otto Bock C-leg: a review of its effectiveness for Special Care Services. WorkSafe Workers' Compensation Board of British Columbia. Compensation and Rehabilitation Services Division. 2003:30.
14. Medicare Region C DMERC Local Coverage Determination (L33787) for Lower Limb Prosthetics, 01/01/18.
15. Miller WC, Speechley M, Deathe B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. Archives of Physical Medicine and Rehabilitation. August 2001; 82(8):1031–1037.
16. Orendurff MS, Segal AD, Klute GK, McDowell ML, Pecoraro JA, Czerniecki JM. Gait efficiency using the C-Leg. J Rehabil Res Dev. 2006; 43(2): 239-46.
17. Rosenblatt NJ, Bauer A; CPO, Rotter D; CPO, Grabiner MD. Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibial amputation. Journal of Rehabilitation & Development 2014;51(8):1229-42.
18. State of Washington Department of Labor and Industries, Office of the Medical Directory, Technology Assessmen: Microprocessor-Controlled Prosthetic knees. Last revised. 08/16/02.

19. Struchkov V, Buckley JG. Biomechanics of ramp descent in unilateral trans-tibial amputees: Comparison of a microprocessor controlled foot with conventional ankle-foot mechanisms. Clinical Biomechanics 2016 Feb;32:164-70.
20. 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. Journal Rehabilation Medicine 2012 May;44(5):454-461.
21. 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. Journal of Rehabilation Medicine 2011 Oct;43(10):906-915.
22. Thomas-Pohl M, Villa C, Davot J, Bonnet X, Facione J, Lapeyre E, Bascou J, Pillet H. Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope. Disabil Rehabil Assist Technol. 2021 Jan;16(1):17-26. [Abstract]
23. Wurdeman SR, Stevens PM, Campbell JH. Mobility analysis of AmpuTees (MAAT 5): impact of five common prosthetic ankle-foot categories for individuals with diabetic/dysvascular amputation. Journal of Rehabilitation and Assistive Technologies Engineering. 2019 Feb; 6:2055668318820784.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/25/22.

GUIDELINE UPDATE INFORMATION:

02/15/04	New Medical Coverage Guideline.
03/15/05	Scheduled review; no change in coverage statement.
04/01/05	2nd quarter HCPCS coding update; added K0670.
01/01/06	Annual HCPCS coding update; added L5858, and removed K0670.
03/15/06	Scheduled review; no change in coverage statement.
05/15/07	Scheduled review; reformatted guideline; coverage position changed from investigational; added criteria for medical necessary.
05/15/08	Schedule review; no charge in position statement; references updated.
01/01/10	Annual HCPCS coding update: title change to include other lower limb microprocessor-controlled prosthetics; added new code L5973.
05/15/10	Scheduled review; position statement unchanged; descriptive information added for microprocessor-controlled ankle/foot prosthetics; references updated.
05/15/12	Scheduled review; position statement revised; Program Exception added for Medicare Advantage products; references updated.
01/01/13	Annual HCPCS coding update: added L5859.
01/01/14	Annual HCPCS coding update: added L5969. Updated Program Exceptions section.
06/15/18	Review; revise position statement. Updated description and references.
06/15/19	Review; no change in position statement. Updated references.
01/01/20	Annual HCPCS code update. Added code L2006.
06/15/20	Review; no change in position statement. Updated references.
09/15/22	Review; no change in position statement. Updated references.