BlueCross BlueShield
of North Carolina

An independent licensee of the Blue Cross and Blue Shield Association

Corporate Medical Policy

Microprocessor-Controlled Prostheses for the Lower Limb

File Name: microprocessor_controlled_prostheses_for_the_lower_limb
Origination: 6/2009
Last CAP Review: 2/2022
Next CAP Review: 2/2023
Last Review: 2/2022

Description of Procedure or Service

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

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 those of a younger, active person. 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 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; 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 have been developed, including the Intelligent Prosthesis (Blatchford, U.K.), the Adaptive (Endolite, England), the Rheo Knee® (Ossur, Iceland), 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, 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 Intelligent Prosthesis) 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

Microprocessor-Controlled Prostheses for the Lower Limb

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.

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.

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Ossur), the iPED (developed by Martin Bionics LLC 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 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 class I devices that are exempt from 510(k) marketing clearance. Information on the Ossur 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).

In development are lower-limb prostheses that also replace muscle activity in order to bend and straighten the prosthetic joint. For example, the Power Foot 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.

Related Policy:
Myoelectric Prosthesis for the Upper Limb

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for microprocessor-controlled prostheses of the lower limb when it is determined to be medically necessary because the criteria and guidelines shown below have been met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Microprocessor-Controlled Prostheses of the Lower Limb are covered

A microprocessor-controlled knee may be considered **medically necessary** in individuals with transfemoral amputation 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.

Reimbursement for microprocessor-controlled knees may only occur if there is a documented evaluation by a trained prosthetic clinician. The clinician performing the evaluation may not be an employee of or have a financial relationship with the supplier of the device.

When Microprocessor-Controlled Prostheses of the Lower Limb are not covered

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 ankle-foot is considered **investigational**.

Policy Guidelines

Decisions about the potential benefits of microprocessor-controlled knees involve multiple factors including activity levels as well as physical and cognitive ability. For patients in whom the potential benefits of microprocessor-controlled knees are uncertain, they 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 for patient selection and identification:

1. Contraindications for use of the microprocessor knee should include:
    a. any condition which prevents socket fitting, such as a complicated wound or intractable pain,
    b. inability to tolerate the weight of the prosthesis,
    c. Medicare Level K 0 - no ability or potential to ambulate or transfer,
    d. Medicare Level K 1 - limited ability to transfer or ambulate on level ground at fixed cadence,
    e. Medicare Level K 2 - 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,
    f. inability to utilize swing and stance features of the knee unit,
    g. poor balance or ataxia that limits ambulation,
    h. significant hip flexion contracture (over 20 degrees),
    i. significant deformity of remaining limb that would impair ability to stride,
    j. limited cardiovascular and/or pulmonary reserve or profound weakness,
    k. limited cognitive ability to understand gait sequencing or care requirements,
    l. long distance or competitive running,
    m. falls outside of recommended weight or height guidelines of manufacturer,
    n. specific environmental factors--such as excessive moisture or dust, or inability to charge the prosthesis,
    o. extremely rural conditions where maintenance ability is limited.

2. Indications for use of the microprocessor knee should include:
    a. adequate cardiovascular and pulmonary reserve to ambulate at variable cadence,
    b. adequate strength and balance in stride to activate the knee unit,

Microprocessor-Controlled Prostheses for the Lower Limb

c. should not exceed the weight or height restrictions of the device,

d. adequate cognitive ability to master technology and gait requirements of device,

e. hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed,

f. patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue,

g. 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,

h. Medicare Level K 2 - 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 utilize 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.*

i. Medicare Level K 3 - unlimited community ambulator,

j. Medicare Level K 4 - active adult, athlete, who has the need to function as a K 3 level in daily activities,

k. potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable,

l. potential to unload and decrease stress on remaining limb,

m. potential to return to an active lifestyle.

3. Physical and functional fitting criteria for new amputees:

a. new amputees may be considered if they meet certain criteria as outlined above,

b. premorbid and current functional assessment important determinant,

c. requires stable wound and ability to fit socket,

d. immediate postoperative fit is possible,

e. must have potential to return to active lifestyle.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: K1014, K1022, L2006, L5848, L5856, L5857, L5858, L5859, L5969, L5973, L7367, L7368

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.25. 2/12/09

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 prostheses. VA Technology Assessment Program short Report No. 2. Boston, Mass: MDRC, March 2000. Retrieved 1/22/09 from http://www.va.gov/ VATAP/pubs/ta_short_3_00.pdf

An Independent Licensee of the Blue Cross and Blue Shield Association

Microprocessor-Controlled Prostheses for the Lower Limb

California Technology Assessment Forum (October 2007). Microprocessor-Controlled Prosthetic Knees. Retrieved 1/22/09 from http://www.ctaf.org/sites/default/files/assessments/777_file_Microprocessor_W.pdf

LCD for Lower Limb Prostheses (L11464). Available online at: http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11464_2009-01-01_PA_2008-10.pdf.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05. 2/11/10

Specialty Matched Consultant Advisory Panel review 7/2010

Specialty Matched Consultant Advisory Panel review 2/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/10/11

Specialty Matched Consultant Advisory Panel review 2/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/8/12

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 2011; 43(10):906-15. Retrieved from http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-0861&html=1

Specialty Matched Consultant Advisory Panel review 2/2013

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 2012; 44(5):454-61. Retrieved from http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-0969

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 2012; 93(3):541-9. Retrieved from http://www.archives-pmr.org/article/S0003-9993(11)00944-0/fulltext

Herr HM, Grabowski AM. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. Proc Biol Sci 2012; 279(1728):457-64. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3234569/

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/14/13

Specialty Matched Consultant Advisory Panel review 2/2014

Medical Director review 2/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/13/14

Specialty Matched Consultant Advisory Panel review 2/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 4/23/15

Specialty Matched Consultant Advisory Panel review 2/2016

Specialty Matched Consultant Advisory Panel review 2/2017

Microprocessor-Controlled Prostheses for the Lower Limb

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 10/12/2017

Specialty Matched Consultant Advisory Panel review 2/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 4/12/2018

Specialty Matched Consultant Advisory Panel review 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/14/2019

Specialty Matched Consultant Advisory Panel review 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/12/2020

Specialty Matched Consultant Advisory Panel review 2/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.04.05, 3/11/21

Specialty Matched Consultant Advisory Panel review 2/2022

Policy Implementation/Update Information

7/20/09	New policy issued. Microprocessor-controlled prosthetic knees may be considered medically necessary in amputees who meet the criteria and guidelines outlined in the policy. (adn)
1/5/10	HCPCS Code L5973 added to Billing/Coding section.
4/13/10	Description section updated. (adn)
08/17/10	Specialty Matched Advisory Panel review 7/2010. Added the following statements to the When Covered section: "Reimbursement for microprocessor-controlled knees may only occur if there is a documented evaluation by a trained prosthetic clinician. The clinician performing the evaluation may not be an employee of or have a financial relationship with the supplier of the device." Medical Policy number removed. (mco)
3/15/11	Specialty Matched Consultant Advisory Panel review 2/2011. No changes to policy statement. (mco)
5/24/11	References updated. No changes to policy statements or coverage criteria. (mco)
3/20/12	Specialty Matched Consultant Advisory Panel review 2/2012. References updated. No changes to policy statements. (mco)
11/13/12	Added HCPCS codes L5848, L7274, L7367, L7368 to the Billing/Coding section. These codes were previously located in the Prosthetic Appliances policy which was archived.(lpr)
1/1/13	Added HCPCS code L5859 to Billing/Coding section. (mco)
3/12/13	Deleted code L7274 from Billing/Coding section. Revised Related Policies and added new devices to Description section. References updated. Specialty Matched Consultant Advisory Panel review 2/2013. (mco)
5/14/13	Description section updated. References updated. No changes to Policy Statements. (mco)

Microprocessor-Controlled Prostheses for the Lower Limb

12/31/13   L5969 added to Billing/Coding section. (mco)

3/11/14   Specialty Matched Consultant Advisory Panel review 2/2014. Medical Director review 2/2014. No changes to the Policy Statements. (mco)

4/29/14   References updated. No changes to Policy Statements. (mco)

4/28/15   Specialty Matched Consultant Advisory Panel review 2/2015. No change to Policy statements. (sk)

7/1/15   Reference added. (sk)

4/1/16   Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)

3/31/17   Specialty Matched Consultant Advisory Panel review 2/22/2017. (sk)

1/12/18   Reference added. (sk)

4/27/18   Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)

6/29/18   Reference added. (sk)

3/12/19   Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)

5/14/19   Reference added. (sk)

12/31/19   HCPCS code L2006 added to Billing/Coding section. (sk)

3/10/20   Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)

8/25/20   Reference added. (sk)

3/9/21   Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)

3/31/21   New HCPCS code K1014 added to Billing/Coding section, effective 4/1/2021. (sk)

10/1/21   New HCPCS code K1022 added to Billing/Coding section, effective 10/1/2021. (sk)

12/30/21   Reference added. (sk)

3/8/22   Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)