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MEDICAL POLICY – 1.04.503

Microprocessor-Controlled and Powered Prostheses and Orthoses for the Lower Limb

BCBSA Ref. Policy:	1.04.05
Effective Date:	April 1, 2024
Last Revised:	Mar. 11, 2024
Replaces:	1.01.25, 1.01.513 and 1.04.05

RELATED MEDICAL POLICIES:

1.04.502	Myoelectric Prosthetic and Orthotic Components for the Upper Limb
8.03.01	Functional Neuromuscular Electrical Stimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

After a person has had a limb amputated, an artificial limb (prosthesis) may be used. Computerized, microprocessor controlled prosthetic joints have been developed that contain sensors to automatically adjust movement of the joint. When the prosthesis involves a knee joint, a microprocessor controlled prosthetic joint is thought to help a person walk more safely and smoothly. This policy describes when a microprocessor controlled prosthetic device may be medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Microprocessor-controlled knee	**A microprocessor-controlled knee may be considered medically necessary in individuals with transfemoral amputation (above the knee) who meet ALL of 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 individual 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.**

Service	Investigational
Powered knee	**A powered knee is considered investigational.**
Microprocessor-controlled or powered ankle-foot	**A microprocessor-controlled or powered ankle-foot is considered investigational.**
Additions to a conventional prosthesis: • **Orthotics** • **Prosthetics** • **Prosthetic components**	**Orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are considered investigational when used for experimental or investigational therapy or interventions.**
Microprocessor stance controlled orthoses	**A microprocessor or electronic stance controlled orthosis is considered investigational (e.g., Ottobock C-Brace Orthotronic**

Service	Investigational
	Mobility System, Ottobock the Sensor Walk stance control KAFO).

Service	Not Covered
Additions to a conventional prosthesis: • **Orthotics** • **Prosthetics** • **Prosthetic components**	**Orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are not covered when:** • It is used only for recreational, sports or athletic activities • It is available over-the-counter or off-the-shelf without a prescription from the treating physician or consultation with a prosthetist

Additional 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 and the individual's physical and cognitive ability. An individual'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.

Patient Selection and Identification

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

Veterans Health Administration Prosthetic Clinical Management Program (VHA PCMP) Recommendations

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees.

Contraindications for use of the microprocessor knee should include the following:

Additional Guidelines

- 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 K 0—no ability or potential to ambulate or transfer
- Medicare Level K 1—limited ability to transfer or ambulate on level ground at fixed cadence
- 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
- Inability to use swing and stance features of the knee unit
- Poor balance or ataxia that limits ambulation
- Significant hip flexion contracture (> 20 degrees)
- Significant deformity of remaining limb that would impair the 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 the manufacturer
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis
- Extremely rural conditions where maintenance ability is limited

Indications for use of the microprocessor knee should include the following:

- 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 the device
- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- The individual 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 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 the individual has the 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

Additional Guidelines
• Medicare Level K 3—unlimited community ambulator • Medicare Level K 4—active adult athlete who needs to function as a K 3 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 **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 the socket • Immediate postoperative fit is possible • Must have potential to return to an active lifestyle

Table 1. Microprocessor-Controlled or Powered Knee Prosthetics

Names of Microprocessor-Controlled or Powered Knee Prosthetics (company) include but are not limited to:
Adaptive (Endolite, Blatchford Inc. United Kingdom)
C-Leg Compact (Otto Bock Orthopedic Industry, Minneapolis, MN)
Endolite Intelligent/Smart Prosthesis (Endolite, Blatchford Inc. United Kingdom)
Genium Bionic Prosthetic system (Otto Bock Orthopedic Industry, Minneapolis, MN)
Intelligent Prosthesis (IP) (Blatchford, United Kingdom
Linx (Endolite, Blatchford Inc. United Kingdom)
Orion 2 (Endolite, Blatchford Inc. United Kingdom)
Power Knee (Ossur, Iceland)
RheoKnee (Ossur, Iceland)
Seattle Power Knees (Seattle Systems) 3 models include: • 4-bar • Fusion • Single Axis
X2 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN)
X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN)

Table 2. Microprocessor-Controlled or Powered Foot Prosthetics

Names of Microprocessor-Controlled or Powered Foot Prosthetics (company) include but are not limited to:
élan Foot (Endolite)
iPED (developed by Martin Bionics LLC and licensed to College Park Industries)
Proprio Foot (Össur, Iceland)
PowerFoot BiOM (developed at MIT and licensed to iWalk)

Documentation Requirements

Clinical documentation supporting ALL of the following:

- Individual has a need for long-distance walking at variable speed (in other words, use within the home or for basic community ambulation is not sufficient to justify the computerized limb over standard limb applications)

OR

- Individual has a demonstrated need for regular walking on uneven terrain or regular use on stairs. Use of limb for limited stair climbing in the home or place of employment is not sufficient to justify the computerized limb over standard limb applications

AND

- Individual has physical ability, including adequate cardiovascular and pulmonary reserve, to allow for faster than normal walking speed

AND

- Individual is mentally fit to master use and care requirements for the technology

Coding

Note: If any of the addition codes below are used on other types of prostheses other than a microprocessor-controlled or powered prosthetic, this policy may not apply (e.g., a mechanical hydraulic or pneumatic control prosthesis) (See **Definition of Terms**).

Code	Description
HCPCS	

Code	Description
K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control (code termed 1/1/2024)
L2006	Knee-ankle-foot (KAF) 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 (e.g., C-Brace Orthotronic Mobility System)
L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control (new code effective 1/1/2024) (when used as an additional component to a microprocessor-controlled knee)
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)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Related Information

Definition of Terms

Hydraulic system consists of pistons inside cylinders containing fluid and use a liquid medium (usually silicone oil) instead of air to respond to a wide range of walking speeds. These systems provide gaits close to normal knee function. These systems are heavier than pneumatic systems. These systems can be added to mechanical or microprocessor (computerized) prostheses. This system works well for more active individuals.

Mechanical prosthesis uses a mechanical hinge to replace the knee joint which uses friction, hydraulics, pneumatics, or a locking mechanism to control the flexion and extension capability

of the prosthesis. These can be single-axis or polycentric, and may be weight activated or other mechanical controls such as hydraulic or pneumatic systems.

Microprocessor prosthesis receives feedback from sensors and other parameters inside the joint to adjust the flexion, extension, and speed to mimic the user's natural gait pattern. The internal computer controls the mechanical mechanism, which can be single axis, pneumatic, or hydraulic.

Pneumatic system consists of pistons inside cylinders containing air. Pneumatic control compresses air as the knee is flexed, stores the energy, and then returns the energy as the knee moves into extension. They provide better swing control than friction knees but are considered less effective than hydraulic systems.

Powered prosthesis is a motor activated prosthesis that uses sensors to control and generate flexion and extension movements imitating the biomechanical function of the missing limb.

Benefit Application

Contractual or benefit limitations on durable medical equipment or prostheses upgrades may be applicable.

New technologies that use microprocessor control are being developed. Based on the currently available evidence, no microprocessor-controlled device has been shown to have better outcomes than other (e.g., earlier) models. If more costly, the prosthesis would be considered not medically necessary using the Plan's definition of medical necessity. Benefit or contract language describing the "least costly alternative" may also be applicable to prostheses.

C-Brace Microprocessor-Controlled Orthosis

Source: https://www.ottobockus.com/orthotics/solution-overview/c-brace/ Accessed April 17, 2023

Evidence Review

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 individuals who can maneuver on uneven terrain and with variable gait.

Background

Lower-Extremity Prosthetics

More than 100 different prosthetic ankle-foot and knee designs are currently available. The choice of the most appropriate design may depend on the individual's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from 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 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 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 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 (Blatchford); the Adaptive, (Endolite); the Rheo Knee (Össur); the C-Leg, Genium Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry); 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. The prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. Also, these devices (except 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, such devices 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. In 1999, the C-Leg was cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process (K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use 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 (Genium 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), 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

Microprocessor-controlled ankle-foot prostheses have been developed for transtibial amputees. These include the Proprio Foot (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), Meridium (Ottobock), Freedom Kinnex 2.0 (Proteor), and the Elan Foot (Blatchford). 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. This technology is designed to make ambulation more efficient and prevent falls in individuals ranging from the young, active amputee to the elderly diabetic patient. The Proprio Foot and Elan 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 the 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 Ankle-Foot 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 **Related Policies**). 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. Empower (Ottobock) is a commercially available powered ankle-foot prosthesis.

Microprocessor-Controlled KAFOs

The C-brace Orthotronic Mobility System (Ottobock) is a microprocessor stance and swing control knee-ankle-foot orthosis (KAFO) that is custom made for each individual user. Per the manufacturer, "the C-brace consists of individually fabricated thigh, calf and foot components. An ankle joint, unilateral or bilateral fitting, or an individual spring element connects the foot and calf components. The sensor system continuously measures the flexion of the knee joint and its angular acceleration." The C-brace enables the user's walking phase and hydraulic resistances to be detected and controls the flexion and extension of the knee joint. It is intended to reportedly increase mobility in individuals with leg paresis and allows for more natural movement on stairs, inclines, and rough terrain. A rechargeable lithium ion battery powers the microprocessor, which is then controlled by the user via a mobile app.

The FDA describes the Sensor Walk (Ottobock) as "a microprocessor-controlled knee-ankle-foot orthosis (KAFO) designed to help wearers achieve a safer, more physiologically correct gait. It does this by unlocking the knee joint when the wearer is ready for swing phase and locking it again for stability during stance phase." The system includes an onboard microprocessor, a clutch spring knee joint, foot pressure sensors, a knee angle sensor, a battery (which lasts for 12 hours), and a battery charger. It is designed for community ambulators who exhibit knee instability in the sagittal plane while bearing weight during the stance phase of their gait cycle.

Summary of Evidence

For individuals who have a transfemoral amputation who receive a prosthesis with a microprocessor-controlled knee, the evidence includes a number of within-subject comparisons of microprocessor-controlled knees vs non-microprocessor-controlled knee joints. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures, particularly for hill and ramp descent, and strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, increased stability, and a decrease in falls. The evidence in Medicare level K2 ambulators suggests that a

prosthesis with stance control only can improve activities that require balance and improve walking in this population. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. The potential to achieve a higher functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using microprocessor-controlled ankle-foot prostheses compared with standard prostheses although quality of life improvements was noted in one small study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using powered ankle-foot prostheses compared with standard prostheses. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with neuromuscular lower-limb deficits using a microprocessor stance-controlled knee-ankle-foot orthosis, the evidence includes limited data. Pröbsting, et al (2017) in a before and after trial of individuals who were previous users of orthoses due to lower limb paresis were then fitted with the Ottobock C-brace microprocessor stance-controlled KAFO and questionnaire scores on their performance of various activities of daily living using both devices were compared. The authors noted that the microprocessor stance and swing control orthosis may facilitate improvements in performing activities of daily living such as ambulation at varying speeds and descending stairs compared with use of a stance control orthosis. Limitations of the study include small sample size (n=13), no randomization, no blinding, self-reported outcome measures were not validated, and authors of the study were employed by Otto Bock Healthcare which could result in a high risk of bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some ongoing and currently unpublished trials that might influence this policy are listed in **Table 3** below.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05407545	Evaluation of a Motorised Prosthetic Knee	10	Aug 2023
NCT03204513	Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction	15	Dec 2023
NCT04630457	Safety and Effectiveness of Electronically Controlled Prosthetic Ankle in Patients With Transtibial Amputation	42	Dec 2024
NCT04784429	Assessing Outcomes With Microprocessor Knee Utilization in a K2 Population (ASCENT K2)	107	Dec 2026
NCT03930056	C-Brace II Spinal Cord Injury	30	Nov 2025
NCT02089880	Micro-processor Controlled Knee-Ankle Foot Orthosis (C-Brace) Versus Stance Control Knee-Ankle-Foot Orthosis (SCO: Functional Outcomes in Individuals with Lower Extremity Impairment	24	Dec 2023
Unpublished			
NCT04112901	Activity, Mobility, Social Functioning, Mental Health and Quality of Life Outcomes in Limited Mobility Transfemoral and Knee Disarticulation Amputees Using Microprocessor-Controlled Knees or Non-Microprocessor Controlled Knees in the United Kingdom: A Cohort Study	330	May 2020
NCT03906656	Multinational Randomized Controlled Cross-over Trial Comparing C-Brace to Conventional Knee Ankle Foot Orthosis (KAFO) with Respect to Balance, Fall Risk and Activities of Daily Living.	108	Aug 2022 Completed

NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

U.S Department of Veterans Affairs/Department of Defense

In 2019, the Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations:[33]

> "We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces. (From Table 3. Clinical practice guideline evidence-based recommendations and evidence strength)."

Medicare National Coverage

There is no national coverage determination (NCD).

Table 4. Classification of Rehabilitation Potential for Centers for Medicare and Medicaid Services (CMS).

Level	Rehabilitation Potential
K-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.
K-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 ambulatory.

Level	Rehabilitation Potential
K-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 ambulatory.
K-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.
K-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.

Regulatory Status

According to the manufacturers, microprocessor-controlled prostheses are considered a class I device by the FDA and are exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing.

FDA product codes: ISW, KFX.

Sensor Walk (Otto Bock HealthCare LP) an electronic stance control KAFO is considered a class 1 orthosis, limb brace by the FDA. In 2006 it was cleared for 510(k) marketing as equivalent to the Otto Bock Free Walk exempt device. (K052771). Indications for use are solely for the orthotic fitting of the lower limbs of individuals who are community ambulators who exhibit knee instability in the sagittal plane while bearing weight during the stance phase of their gait cycle when walking forward on level surfaces.

FDA product code: IQI

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History

Date	Comments
02/10/04	Add to Durable Medical Equipment Section - New Policy PR.1.01.113 replaces BCBSA 1.01.25 (Issue 3:2003).
09/01/04	Replace Policy - Policy renumbered from PR.1.01.113. No date changes.
02/08/05	Replace Policy - Policy reviewed with literature search through December 2004; no change to policy statement; references added.
02/14/06	Replace Policy - Policy reviewed with literature search; no change to policy statement; reference added.
02/22/06	Codes updated - No other changes, effective date unchanged.
05/26/06	Update Scope and Disclaimer - No other changes.
03/13/07	Replace Policy - Policy updated with literature review; reference added. No change in policy statement.
05/13/08	New BC Policy - Replaces PR.1.01.513, status changed from PR to BC. A microprocessor-controlled knee may be considered medically necessary in amputees who meet the criteria listed. When criteria are not met, it is considered not medically necessary.
05/12/09	Replace Policy - Policy updated with literature search. Policy statements added regarding ankle-foot and powered knee prostheses as investigational. References added.
02/09/10	Code Update - New 2010 codes added.
04/13/10	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
06/13/11	Replace Policy - Policy updated with literature review through January 2011; reference 21 added; policy number changed from 1.01.25 to 1.04.05 (prosthetics); policy statements unchanged. ICD-10 codes added to policy.
01/27/12	HCPCS code L5312 added.
05/22/12	Replace policy. Policy updated with literature review through December 2011; Rationale revised; references 3, 16, 17, 22 added; some references removed. Policy statements unchanged.
08/24/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
05/28/13	Replace policy. Policy updated with literature review through February 1, 2013; Rationale revised; references 12, 15, 17, 23, 26-27 added and references reordered; policy statements unchanged.
08/14/13	Update Related Policies. Change title to policy 1.04.04.

Date	Comments
03/21/14	Update Related Policies. 1.04.04 was deleted and replaced with 1.04.502.
06/13/14	Annual Review. Policy updated with literature review through February 24, 2014. References 17, 25, 27 added; others renumbered/removed. Policy statements unchanged.
08/11/14	Interim Update. Policy Guidelines added with details about when orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are not covered. No new references added. Policy statements unchanged. HCPCS codes L5845 removed from policy; this is not reviewed.
06/17/15	Annual Review. Two tables added to the Policy Guidelines section that list examples of microprocessor-controlled prosthetic knees and feet for the lower limb. Policy Guideline statement added that conventional prosthetic foot is not subject to review under this medical policy. Policy updated with literature review through January 29, 2015. Reference 19 added; others renumbered. Policy statements unchanged. ICD-9 diagnosis codes removed; no utilized in adjudication. HCPCS codes L5312 and L5856 removed; these are not reviewed.
06/01/16	Annual Review, approved May 10, 2016. Policy reviewed with literature search; policy statement unchanged.
09/22/17	Policy moved to new format. No changes to policy statements.
12/01/17	Annual Review, approved November 21, 2017. Policy updated with literature review through August 2017; no references added. Policy title changed to "Microprocessor-Controlled and Powered Prostheses for the Lower Limb". Policy statements unchanged.
05/01/18	Minor update, updated the title of Related Policy 1.04.502.
07/01/18	Annual Review, approved June 5, 2018. Policy updated with literature review through February 2018; references 10 and 26 added; Policy statements unchanged.
06/01/19	Annual Review, approved May 7, 2019. Policy updated with literature review through February 2019; references added. Policy statements unchanged.
03/01/20	Interim Review, approved February 11, 2020. Policy title changed from "Microprocessor-Controlled and Powered Prostheses for the Lower Limb" to "Microprocessor-Controlled and Powered Prostheses and Orthoses for the Lower Limb". Policy updated with literature search. Policy statement added regarding microprocessor stance-controlled orthoses are considered investigational. References added. Added HCPCS code L2006 (new code effective 1/1/20).
06/01/20	New policy number (1.04.503), approved May 5, 2020, effective June 1, 2020. Policy 1.04.503 replaces policy 1.04.05 which is now deleted. Policy updated with literature review through February 2020; references added, Policy statements unchanged.
06/01/21	Annual Review, approved May 4, 2021. Policy updated with literature review through January 25, 2021; no references added. Policy statements unchanged.

Date	Comments
06/01/22	Annual Review, approved May 9, 2022. Policy updated with literature review through January 24, 2022; references added. Policy statements unchanged. Added HCPCS code K1014.
06/01/23	Annual Review, approved May 5, 2023. Policy updated with literature review through January 26, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/24	Coding update. Added new HCPCS code L5615 and termed HCPCS code K1014.
04/01/24	Interim Review, approved March 11, 2024. Added a clarifying coding note and definition of terms to indicate some addition components may be used on other types of prostheses, such as mechanical, which do not apply to this policy.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

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