MEDICAL POLICY – 1.04.503
Microprocessor-Controlled and Powered Prostheses and Orthoses for the Lower Limb

BCBSA Ref. Policy: 1.04.05
Effective Date: June 1, 2020
Last Revised: May 5, 2020
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
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| 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 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. |

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powered knee</td>
<td>A powered knee is considered investigational.</td>
</tr>
<tr>
<td>Microprocessor-controlled or powered ankle-foot</td>
<td>A microprocessor-controlled or powered ankle-foot is considered investigational.</td>
</tr>
<tr>
<td>Additions to a conventional prosthesis:</td>
<td>Orthotics, prosthetics, or prosthetic components added to a conventional prosthesis are considered investigational when used for experimental or investigational therapy or interventions.</td>
</tr>
<tr>
<td>• Orthotics</td>
<td></td>
</tr>
<tr>
<td>• Prosthetics</td>
<td></td>
</tr>
<tr>
<td>• Prosthetic components</td>
<td></td>
</tr>
</tbody>
</table>
### Service

<table>
<thead>
<tr>
<th>Microprocessor stance controlled orthoses</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>A microprocessor or electronic stance controlled orthosis is considered investigational (eg, Ottobock C-Brace™ Orthotronic Mobility System, Ottobock the Sensor Walk™ stance control KAFO, Becker E-Knee™microprocessor knee joint).</td>
<td></td>
</tr>
</tbody>
</table>

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

### Additional Guidelines

Microprocessor-controlled prosthetic knees are programmable devices 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 (see Table 1). These lower limb prosthetics will most likely include a prosthetic foot that may or may not be powered or controlled by a microprocessor.

Microprocessor-controlled prosthetic feet have sensors that control the flexion angle of the ankle. This programmable ankle/foot prosthetic is considered investigational (see Table 2). Other conventional types of prosthetic feet do not require review under this medical policy.

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 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 (eg, 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.
Additional Guidelines

Patient Selection and Identification

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.

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.¹

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

- 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 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 device
Additional Guidelines

- Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed.
- The 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 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 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 K 3—unlimited community ambulator.
- Medicare Level K 4—active adult, athlete who has the need 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 socket.
- Immediate postoperative fit is possible.
- Must have potential to return to an active lifestyle.

Table 1. Microprocessor-Controlled Knee Prosthetics

<table>
<thead>
<tr>
<th>Names of Microprocessor-Controlled Knee Prosthetics (company)</th>
<th>include but are not limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive (Endolite, Blatchford Inc. United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>C-Leg Compact (Otto Bock Orthopedic Industry, Minneapolis, MN)</td>
<td></td>
</tr>
<tr>
<td>Endolite Intelligent/Smart Prosthesis (Endolite, Blatchford Inc. United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>Genium Bionic Prosthetic system (Otto Bock Orthopedic Industry, Minneapolis, MN)</td>
<td></td>
</tr>
</tbody>
</table>
Names of Microprocessor-Controlled Knee Prosthetics (company) include but are not limited to:

<table>
<thead>
<tr>
<th>Name</th>
<th>Company, Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intelligent Prosthesis (IP)</td>
<td>Blatchford, United Kingdom</td>
</tr>
<tr>
<td>Linx</td>
<td>Endolite, Blatchford Inc. United Kingdom</td>
</tr>
<tr>
<td>Orion 2</td>
<td>Endolite, Blatchford Inc. United Kingdom</td>
</tr>
<tr>
<td>Power Knee™</td>
<td>Ossur, Iceland</td>
</tr>
<tr>
<td>RheoKnee®</td>
<td>Ossur, Iceland</td>
</tr>
</tbody>
</table>

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 Foot Prosthetics (company) include but are not limited to:

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>élan Foot</td>
<td>Endolite</td>
</tr>
<tr>
<td>iPED</td>
<td>Martin Bionics LLC and licensed to College Park Industries</td>
</tr>
<tr>
<td>Proprio Foot®</td>
<td>Össur, Iceland</td>
</tr>
<tr>
<td>PowerFoot BiOM®</td>
<td>developed at MIT and licensed to iWalk</td>
</tr>
</tbody>
</table>

Documentation Requirements

Clinical documentation supporting ALL of the following:

- Patient 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

- Patient 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
Documentation Requirements

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

AND

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

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>L2006</td>
<td>Knee-ankle-foot (KAF) device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (eg, sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated (new code effective 1/1/20)</td>
</tr>
<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type</td>
</tr>
<tr>
<td>L5859</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee shin system, powered and programmable flexion/extension assist control, includes any type motor(s)</td>
</tr>
<tr>
<td>L5973</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

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 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 May 2020

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 patients 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 patient’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 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 (eg, 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 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 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. This technology is designed 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 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 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.

**Microprocessor-Controlled KAFOs**

The C-brace™ (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.

The Becker E-Knee™ “is a foot force activated, computer controlled electromechanical orthotic knee joint”. A pressure sensitive adjustable footplate signals the microprocessor to lock the knee joint when pressure is applied and unlock when there is no pressure to the knee joint.
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, an increase in 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 be able to use the advanced technology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, 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 a powered knee prosthesis with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a tibial amputation who receive a prosthesis with a powered ankle-foot, the evidence includes no data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 patients 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 the effects of the technology on health outcomes.

**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**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02089880</td>
<td>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</td>
<td>24</td>
<td>May 2020</td>
</tr>
<tr>
<td>NCT03204513</td>
<td>Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction</td>
<td>15</td>
<td>Apr 2021</td>
</tr>
<tr>
<td>NCT03906656</td>
<td>Clinical Trial Comparing C-Brace to Knee Ankle Foot Orthosis (KAFO) /Stance Control Orthosis (SCO)</td>
<td>53</td>
<td>April 2020</td>
</tr>
<tr>
<td>NCT03930056</td>
<td>Micro-Processor Controlled Knee-Ankle-Foot Orthosis (C-Brace) Usage in a Spinal Cord Injury (SCI) Population Compared to Traditional Rehabilitation Methods: Determining Functional Outcome Differences of Recovery</td>
<td>30</td>
<td>Nov 2025</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02864693</td>
<td>Comparative Effectiveness of Microprocessor Controlled and Carbon Fiber Energy Storing and Returning Prosthetic Feet in Persons with Unilateral Transtibial Amputation</td>
<td>30</td>
<td>Apr 2018 (Results submitted, pending quality control review)</td>
</tr>
<tr>
<td>NCT02892760</td>
<td>Clinical Algorithm for Post-Stroke Gait Training with C-Brace</td>
<td>14</td>
<td>Dec 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Practice Guidelines and Position Statements

**Veteran’s Affairs Prosthetic and Sensory Aids Strategic Healthcare Group**

The Veteran’s Affairs Prosthetic and Sensory Aids Strategic Healthcare Group established a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive practices. A subgroup of the Pre-Post National Amputation Workgroup met in 2004 to define the patient selection and identification criteria for microprocessor prosthetic knees. Their proposal was based on recommendations arising from the 2003 Microprocessor Prosthetic Knee Forum. The resulting Department of Veteran’s Affairs clinical practice recommendations for microprocessor knees are listed above.

**Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation**

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

> 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.

**Medicare National Coverage**

Durable medical equipment regional carriers are responsible for creating coverage policies for Medicare. There is no specific coverage policy on microprocessor-controlled knee prosthesis, in part because there is no specific HCPCS code describing this prosthesis. However, the durable medical equipment regional carriers document has noted that a determination of medical necessity for certain components and additions to the prosthesis is based on the patient’s potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to:

- The patient’s past history
• The patient’s current condition including the status of the residual limb and the nature of other medical problems

• The patient’s desire to ambulate

The document has also provided the following classification of rehabilitation potential (see **Table 4**).

### Table 4. Classification of Rehabilitation Potential

<table>
<thead>
<tr>
<th>Level</th>
<th>Rehabilitation Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0</td>
<td>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.</td>
</tr>
<tr>
<td>Level 1</td>
<td>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.</td>
</tr>
<tr>
<td>Level 2</td>
<td>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.</td>
</tr>
<tr>
<td>Level 3</td>
<td>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.</td>
</tr>
<tr>
<td>Level 4</td>
<td>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.</td>
</tr>
</tbody>
</table>

### 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 patients 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.
References


28. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): Lower Limb Prostheses (L33787); https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?UCM=1719897&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&keyword=prostheses&keyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=EAAAABAAAAA&A. Accessed May 2020.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/10/04</td>
<td>Add to Durable Medical Equipment Section - New Policy PR.1.01.113 replaces BCBSA 1.01.25 (Issue 3:2003).</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.1.01.113. No date changes.</td>
</tr>
<tr>
<td>02/08/05</td>
<td>Replace Policy - Policy reviewed with literature search through December 2004; no change to policy statement; references added.</td>
</tr>
<tr>
<td>02/14/06</td>
<td>Replace Policy - Policy reviewed with literature search; no change to policy statement; reference added.</td>
</tr>
<tr>
<td>02/22/06</td>
<td>Codes updated - No other changes, effective date unchanged.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>03/13/07</td>
<td>Replace Policy - Policy updated with literature review; reference added. No change in policy statement.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>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.</td>
</tr>
<tr>
<td>05/12/09</td>
<td>Replace Policy - Policy updated with literature search. Policy statements added regarding ankle-foot and powered knee prostheses as investigational. References added.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Code Update - New 2010 codes added.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>06/13/11</td>
<td>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.</td>
</tr>
<tr>
<td>01/27/12</td>
<td>HCPCS code L5312 added.</td>
</tr>
<tr>
<td>05/22/12</td>
<td>Replace policy. Policy updated with literature review through December 2011; Rationale revised; references 3, 16, 17, 22 added; some references removed. Policy statements unchanged.</td>
</tr>
<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>05/28/13</td>
<td>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.</td>
</tr>
<tr>
<td>08/14/13</td>
<td>Update Related Policies. Change title to policy 1.04.04.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. 1.04.04 was deleted and replaced with 1.04.502.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>08/11/14</td>
<td>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.</td>
</tr>
<tr>
<td>06/17/15</td>
<td>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.</td>
</tr>
<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy reviewed with literature search; policy statement unchanged.</td>
</tr>
<tr>
<td>09/22/17</td>
<td>Policy moved to new format. No changes to policy statements.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Minor update, updated the title of Related Policy 1.04.502.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 5, 2018. Policy updated with literature review through February 2018; references 10 and 26 added; Policy statements unchanged.</td>
</tr>
<tr>
<td>06/01/19</td>
<td>Annual Review, approved May 7, 2019. Policy updated with literature review through February 2019; references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>06/01/20</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit
booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**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.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111

To file a complaint please call 855-332-4535, or write to: U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Email AppealsDepartmentInquiries@Premera.com

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at


Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Getting a Grievance

You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at

https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Email AppealsDepartmentInquiries@Premera.com

If you file a complaint and the Office for Civil Rights makes a decision on your complaint, the Office for Civil Rights will send you a letter about the decision. You can also file a complaint with a federal, state, or local agency. You can also file a complaint with a federal, state, or local agency.

If you believe that Premera has failed to provide these services or discriminate in another way on the basis of race, color, national origin, age, disability, or sex, you can file a complaint with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111

To file a complaint please call 855-332-4535, or write to: U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Email AppealsDepartmentInquiries@Premera.com

You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at

https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Email AppealsDepartmentInquiries@Premera.com

If you file a complaint and the Office for Civil Rights makes a decision on your complaint, the Office for Civil Rights will send you a letter about the decision. You can also file a complaint with a federal, state, or local agency. You can also file a complaint with a federal, state, or local agency.