

1.04.05	Microprocessor-Controlled Prostheses for the Lower Limb		
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Section:	1.0 Durable Medical Equipment	Page:	Page 1 of 20

Policy Statement

A microprocessor-controlled knee may be considered **medically necessary** for an individual with transfemoral amputation who meets **all** of the following requirements:

- I. **One** of the following:
 - A. 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)
 - B. 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)
- II. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed
- III. Adequate cognitive ability to master use and care requirements for the technology

Replacement/Repair

Replacement or repair of a microprocessor-controlled knee may be considered **medically necessary** when **both** of the following criteria are met:

- I. The current prosthesis is out of warranty
- II. The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis

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

A powered knee is considered **investigational**.

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

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Prostheses Examples

Any specific products referenced in this Medical Policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

Examples of Microprocessor-Controlled Knee Prostheses:

- Endolite Intelligent Prosthesis®
- Ossur RheoKnee®
- Otto Bock C-Leg device®
- Otto Bock Genium™ Bionic Prosthetic System

Examples of Microprocessor Controlled Foot-Ankle Prostheses:

- iWalk PowerFoot BiOM®
- Ossur Proprio Foot®

Prosthetic Evaluation

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 (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 2 or more of these activities would be needed to show benefit.

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.

The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees.¹

- A. Contraindications for the 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 K0-no ability or potential to ambulate or transfer
 - Medicare level K1-limited ability to transfer or ambulate on level ground at fixed cadence
 - Medicare level K2-limited community ambulator who 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 (greater than 20°)
 - 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
- B. Indications for the 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 patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue
 - Daily activities or job tasks that do not permit full focus of concentration on knee control and stability-such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying
 - Medicare level K2-limited community ambulator, but only if improved stability in stance permits increased independence, less risk of falls, and potential to advance

to a less restrictive walking device, and 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 K3-unlimited community ambulator
- Medicare level K4-active adult, athlete who needs to function as a K3 level in daily activities
- Potential to lessen back pain by providing more secure stance control, using less muscle control to keep the knee stable
- Potential to unload and decrease stress on remaining limb
- Potential to return to an active lifestyle

C. 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

Coding

The following specific HCPCS codes describe the microprocessor-controlled knee prosthesis:

- **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)

The following is a specific HCPCS code for ankle-foot system with a microprocessor control feature:

- **L5973:** Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Effective April 1, 2021, there is a new HCPCS code that represents the ALLUX microprocessor-controlled knee (MPK) by Proteor USA. Per the manufacturer, this device is intended for use by amputees that are missing their leg through knee joint or higher. They state it is the only microprocessor-controlled knee, utilizing a 4-bar geometry with hydraulic control of both stance and swing phases of gait called the Safety Lock. This feature will automatically lock knee flexion when the user maintains a load on a flexed, stationary knee. Upon knee extension, the lock is released, and the knee returns to normal function.

- **K1014:** Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control

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.

Related Policies

- Functional Neuromuscular Electrical Stimulation

- Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 FDA prior to marketing. FDA product codes: ISW, KFX.

Rationale

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 1 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Microprocessor-Controlled Prosthetic Knees for Individuals with Transfemoral Amputation Clinical Context and Therapy Purpose

The purpose of microprocessor-controlled prosthetic knees in patients who have transfemoral amputation is to improve activity and function.

The question addressed in this evidence review is: Does microprocessor-controlled prosthetic knees improve the net health outcome in individuals with transfemoral amputations?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is people with transfemoral amputation.

Interventions

The therapies being considered are prostheses with a microprocessor-controlled knee.

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 U.S. 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 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.

Comparators

The relevant comparator is prosthesis with a conventional knee.

Outcomes

Relevant outcomes for microprocessor-controlled lower-limb prostheses may include the patient's perceptions of subjective improvement attributable to the prosthesis and level of activity or function. Also, the energy costs of walking or gait efficiency may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

In 2000, the Veterans Administration Technology Assessment Program issued a report on computerized lower-limb prosthesis.² This report offered the following observations and conclusions:

- Energy requirements of ambulation (vs requirements with conventional prostheses) are decreased at walking speeds slower or faster than the amputee's customary speed but do not differ significantly at customary speeds.
- Results on the potentially improved ability to negotiate uneven terrain, stairs, or inclines are mixed. Such benefits, however, could be particularly important to meeting existing deficits in the reintegration of amputees to normal living, particularly those related to decreased recreational opportunities.
- Users' perceptions of the microprocessor-controlled prosthesis are favorable. Where such decisions are recorded or reported, most study participants choose not to return to their conventional prosthesis or to keep these only as a back-up to acute problems with the computerized one.
- Users' perceptions may be particularly important for evaluating a lower-limb prosthesis, given the magnitude of the loss involved, along with the associated difficulty of designing and collecting objective measures of recovery or rehabilitation. However resilient the human organism or psyche, loss of a limb is unlikely to be fully compensated. A difference between prostheses sufficient to be perceived as distinctly positive to the amputee may represent the difference between coping and a level of function recognizably closer to the preamputation level.

The primary literature consists of small (sample range, 7 to 28 patients) within-subject comparisons of microprocessor-controlled with non-microprocessor-controlled prostheses in transfemoral amputees. These studies are described in Tables 1 and 2, divided by the Medicare Functional Level. Medicare Functional Level K2 describes a limited community ambulatory who is able to traverse low barriers such as curbs and walk with a fixed cadence. Medicare Functional Level K3 describes a community ambulatory who is able to traverse most barriers at variable cadence and may have activities beyond basic locomotion, and Medicare Functional Level K4 exceeds basic ambulation skills and includes activities with high impact or stress that would be performed by a child, athlete, or active adult. The C-Leg compact provides stance control only and has been tested primarily in the more limited Medicare Functional Level K2 amputees. The C-Leg, which provides both stance and swing control, has been tested in Medicare Functional Level K3 and K4 amputees, in addition to Medicare Functional Level K2 amputees.

About half of the studies first tested participants with their own non-microprocessor prosthesis followed by an acclimation period and testing with the microprocessor-controlled knee (Table 1). The other studies used an alternating or randomized order, with more than 1 test session for

each type of prosthesis. Most studies compared performance in laboratory activities and about half also included a period of home use.

Table 1. Within-Subject Study Characteristics of the Microprocessor Knee

Study	Study Location	Country	N	Participants	MPK	NMPK	Home Monitoring
K2 ambulators							
Theevenet al (2011, 2012) ^{3,4}	Activity at home and lab-simulated ADLs	Netherlands	28	Functional level K2	C-Leg and C-Leg compact1-wk acclimation	Own NMPK	1 wk for each prosthesis
Burnfield et al (2012) ⁵	Level and ramp walking	U.S.	10	Functional level K2	C-Leg compact 3-mo acclimation	Own NMPK	
K2 to K3 ambulators							
VA (2006) ^{6,7,8}	Lab and home	U.S.	8	Functional level K2 to K3	C-Leg	Hydraulic	1 wk
Hafner and Smith (2009) ⁹	A-B-A-(A or B) design in lab and city sidewalk	U.S.	• 8 K2 • 9 K3	Functional level K2 to K3	Retest in lab with preferred prosthesis	Retest in lab with preferred prosthesis	Prior 4 wk from 4-, 8-, and 12-mo tests
Highsmith et al (2013) ¹⁰	Ramp		21	Independent community ambulator	C-leg with 3-mo acclimation	Own NMPK	
Howard et al (2018) ¹¹	4-wk laboratory sessions for each phase (A-B-A or B-A-B)	U.S.	• 1 K2 • 6 K3	Functional level K2 or K3	Rheo Knee	Own NMPK	PROs for 3 wk prior to use
Hafner et al (2007) ¹²	A-B-A-B design in lab and city sidewalk	U.S.	17	Proficient community ambulator		Own mechanical	
Kaufman et al (2018) ¹³	Free living environment	U.S.	5048 K2	Functional level K2 or K3	One of 4 MPK devices	Own NMPK	Functional measures and PROs 10 wks
K3 to K4 ambulators							
Kaufman et al (2007, 2008) ^{14,15}	Lab and home	U.S.	15	Functional level K3 or K4	MPK acclimation of 10-39 wk	Own NMPK	10 d
Johansson (2005) ¹⁶	Laboratory and 0.25-mile indoor track	U.S.	8	Functional level K3 or K4	10-h acclimation if not owned	10-h acclimation if not owned	

ADLs: activities of daily living; MPK: microprocessor knee; NMPK non-microprocessor knee; PROs: patient-reported outcomes; VA: Veterans Administration.

Results of these studies are described in Table 2 and summarized below:

- In K2 ambulators, the C-Leg and C-Leg compact improved performance on simulated activities of daily living that required balance, for walking on level ground and ramps, and led to a faster time to stand up from a seated position and move forward (Timed Up & Go test). In the single study that measured activity levels at home, use of a microprocessor-controlled knee did not increase objectively measured activity.
- In studies that included K2 to K3 ambulators, use of a microprocessor-controlled knee increased balance, mobility, speed, and distance compared with performance using the participant's prosthesis. In studies that included independent or proficient community ambulators, the greatest benefit was for the descent of stairs and hills. Normal walking speed was not increased. In a study that primarily included K2 ambulators there was a

reduction in falls demonstrated by the change from baseline while using microprocessor knee and an increase in falls with reversion to non-microprocessor knee.

- In studies that included K3 to K4 ambulators, use of a prosthesis with a microprocessor-controlled knee resulted in a more natural gait, and an increase in activity at home. Participants voiced a strong preference for the microprocessor knee.
- Irrespective of the Medicare Functional Level from K2 to K4, all studies reported that participants preferred the C-Leg or C-Leg compact over their non-microprocessor prosthesis.

Table 2. Outcomes With Microprocessor Knee Prosthesis Versus a Non-Microprocessor Knee

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
K2 ambulators				
Theevenet et al (2011, 2012) ^{3,4}	Improved simulated ADLs for activities requiring balance		<ul style="list-style-type: none"> • Subjective benefit on PEQ • No preference for C-leg over C-leg compact 	No difference in objectively measured activity level
Burnfield et al (2012) ⁵	Improved walking on level ground, ramps, and faster TUG (17.7 s vs 24.5 s)		<ul style="list-style-type: none"> • PEQ • All wanted to keep the C-Leg compact 	
K2 to K3 ambulators				
VA (2006) ^{6,7,8}		Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009) ⁹	Improved mobility and speed			Decrease in self-reported stumbles and falls
Highsmith et al (2013) ¹⁰	Improved hill descent time (6.0 s vs 7.7 s) and HAI			
Howard et al. (2018) ¹¹	Improved 6MWT, BBS, and AMP, but inconsistent for normal walking speed and L test	Improved Physiological Cost Index	<ul style="list-style-type: none"> • Preference for MPK in 6 of 7 participants • PEQ superior in 5 of 7 	
Hafner et al (2007) ¹²	Improved for descent of stairs and hills only		Subjective improvement with MPK	
Kaufman et al (2018) ¹³	Reduction in falls			Subjective improvement in PEQ satisfaction with MPK
K3 to K4 ambulators				
Kaufman et al (2007, 2008) ^{14,15}	More natural gait	No significant difference	Preferred MPK	Increased
Johansson (2005) ¹⁶	More natural gait and decrease in hip work	Oxygen consumption reduced for Rheo but not C-Leg	Preferred MPK	

ADL: activity of daily living; AMP: amputee mobility predictor; BBS: Berg Balance Scale; HAI: Hill Assessment Index; MPK: microprocessor knee; NMPK non-microprocessor knee; PEQ: Prosthesis Evaluation Questionnaire; 6MWT: 6-minute walk test; TUG: Timed Up & Go; VA: Veterans Administration.

Section Summary: Microprocessor-Controlled Knee

The literature consists of a number of small within-subject comparisons of microprocessor-controlled knees with non-microprocessor-controlled knee joints. Studies of prostheses with microprocessor knees in Medicare Functional Level K3 and K4 amputees have shown objective improvements in function on some outcome measures and strong patient preference for the microprocessor-controlled prosthetic knees. The evidence in Medicare Functional Level K2 ambulators suggests that a prosthesis with stance control only can improve activities that require

balance and improve walking in this population. Only 1 biomechanical study of the next-generation Genium prosthesis was identified. One small study found little difference in performance between the Rheo Knee II and the user's own non-microprocessor-controlled knee.

Powered-Knee Prostheses for Individuals with Transfemoral Amputation

Clinical Context and Therapy Purpose

The purpose of powered-knee prostheses in patients who have transfemoral amputation is to improve activity and function.

The question addressed in this evidence review is: Does powered-knee prostheses improve the net health outcome in individuals with transfemoral amputation?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is people with transfemoral amputation.

Interventions

The therapies being considered are 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.

Comparators

The relevant comparator is prosthesis with a conventional knee.

Outcomes

Relevant outcomes may include the patient's perceptions of subjective improvement attributable to the prosthesis and level of activity or function. Also, the energy costs of walking or gait efficiency may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

We did not identify any literature on powered knee prostheses.

Microprocessor-Controlled Prosthetic Ankle-Foot for Individuals with Tibial Amputation

Clinical Context and Therapy Purpose

The purpose of microprocessor-controlled prosthetic ankle-foot in patients who have tibial amputation is to improve activity and function.

The question addressed in this evidence review is: Does microprocessor-controlled prosthetic ankle-foot improve the net health outcome in individuals with tibial amputation?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is people with tibial amputation.

Interventions

The therapies being considered are 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 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence).

Comparators

The relevant comparator is prosthesis with a conventional ankle/foot.

Outcomes

Relevant outcomes may include the patient's perceptions of subjective improvement attributable to the prosthesis and level of activity or function. Also, the energy costs of walking or gait efficiency may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

A Cochrane review by Hofstad et al (2004), which evaluated ankle-foot prostheses, concluded that there was insufficient evidence from high-quality comparative studies for an overall superiority of any individual type of prosthetic ankle-foot mechanism.¹⁷ Also, reviewers noted that most clinical studies on human walking have used standardized gait assessment protocols (e.g., treadmills) with limited "ecological validity," and recommended that for future research, functional outcomes be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changes in walking speed.

Proprio Foot

Gait analysis with the Proprio Foot was evaluated in 16 transtibial K3-K4 amputees during stair and ramp ascent and descent.^{18,19} Results with the adaptive ankle (allowing 4° of dorsiflexion) were compared with tests conducted with the same prosthesis but at a fixed neutral angle (similar to other prostheses) and with results from 16 healthy controls. Adaptive dorsiflexion was found to increase during the gait analysis; however, this had a modest impact on other measures of gait for either the involved or uninvolved limb, with only a "tendency" to be closer

to the controls, and the patient's speed was not improved by the adapted ankle. The authors noted that an adaptation angle of 4° in the stair mode is small compared with physiologic ankle angles, and the lack of power generation with this quasi-passive design may also limit its clinical benefit. For walking up and down a ramp, the adapted mode resulted in a more normal gait during ramp ascent, but not during ramp descent. Some patients reported feeling safer with the plantar flexed ankle (adaptive mode) during ramp descent. Another small within-subject study (2014; N =6) found no benefit of an active Proprio Foot compared with the same prosthesis turned off with level walking or with slope ascent or descent.²⁰

Self-reported and objective performance outcomes for 4 types of prosthetic feet, including the Proprio Foot, were evaluated in a randomized within-subject crossover study reported by Gailey et al (2012).²¹ Ten patients with transtibial amputation were initially tested with their prosthesis and tested again following training and a 2-week acclimation period with the SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux, and Proprio Foot in a randomized order. No differences between prostheses were detected by the self-reported Prosthesis Evaluation Questionnaire and Locomotor Capabilities Index, or for the objective 6-minute walk test. Steps per day and hours of daily activity between testing sessions did not differ by type of prosthesis.

In another study by Delussu et al (2013) found a lower energy cost of floor walking with the Proprio Foot compared with a dynamic carbon fiber foot in 10 transtibial amputees.²² However, the study found no significant benefit for walking stairs or ramps, for the Timed Up & Go test, or for perceived mobility or walking ability.

Section Summary: Microprocessor-Controlled Ankle-Foot Prostheses

Several small studies have been reported with microprocessor-controlled prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes compared with the same device in the off-mode or compared with energy-storing and energy returning prostheses. Larger, higher quality studies are needed to determine the impact of these devices on health outcomes with greater certainty.

Powered Ankle-Foot Prostheses for Individuals with Tibial Amputation

Clinical Context and Therapy Purpose

The purpose of powered ankle-foot prostheses in patients who have tibial amputation is to improve activity and function.

The question addressed in this evidence review is: Does powered ankle-foot prostheses improve the net health outcome in individuals with tibial amputations?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is people with tibial amputation.

Interventions

The therapies being considered are powered ankle-foot prostheses.

In development are lower-limb prostheses that also replace muscle activity to bend and straighten the prosthetic joint. For example, the PowerFoot BiOM® (developed at the Massachusetts Institute of Technology and licensed to iWalk) is a myoelectric prosthesis for transtibial amputees that uses muscle activity from the remaining limb for the control of ankle movement (see Blue Shield of California Medical Policy: Myoelectric Prosthetic and Orthotic Components for the Upper Limb for a description of myoelectric technology). This prosthesis is designed to propel the foot forward as it pushes off the ground during the gait cycle, which in addition to improving efficiency, has the potential to reduce hip and back problems arising from

an unnatural gait with use of a passive prosthesis. This technology is limited by the size and the weight required for a motor and batteries in the prosthesis.

Comparators

The relevant comparator is prosthesis with a conventional ankle/foot.

Outcomes

Relevant outcomes may include the patient's perceptions of subjective improvement attributable to the prosthesis and level of activity or function. Also, the energy costs of walking or gait efficiency may be a more objective measure of the clinical benefit of the microprocessor-controlled prosthesis.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

PowerFoot BiOM

Au et al (2008) reported on the design and development of the powered ankle-foot prosthesis (PowerFoot BiOM); however, clinical evaluation of the prototype was performed in a single patient.²³

Ferris et al (2012) reported on a pre-post comparison of the PowerFoot BiOM with the patient's own energy-storing and energy returning foot in 11 patients with transtibial amputation. Results for both prostheses were also compared with 11 matched controls who had intact limbs.²⁴ In addition to altering biomechanical measures, the powered ankle-foot increased walking velocity compared with the energy-storing and energy returning prosthesis and increased step length compared with the intact limb. There appeared to be an increase in compensatory strategies at proximal joints with the PowerFoot; the authors noted that normalization of gait kinematics and kinetics might not be possible with a uniarticular device. Physical performance measures did not differ significantly between the prostheses, and there were no significant differences between conditions on the Prosthesis Evaluation Questionnaire. Seven patients preferred the PowerFoot and 4 preferred the energy-storing and energy returning. Compared with controls with intact limbs, the PowerFoot had reduced range of motion but provided greater ankle peak power.

In another similar, small pre-post study (7 amputees, 7 controls), Herr and Grabowski (2012) found gross metabolic cost and preferred walking speed to be more similar to nonamputee controls with the PowerFoot BiOM than with the patient's own energy-storing and energy returning.²⁵

In a conference proceeding, Mancinelli et al (2011) described a comparison of a passive-elastic foot and the PowerFoot BiOM in 5 transtibial amputees.²⁶ The study was supported by the U.S. Department of Defense, and, at the time of testing, the powered prosthesis was a prototype and subjects' exposure to the prosthesis was limited to the laboratory. Laboratory assessment of gait biomechanics showed an average increase of 54% in the peak ankle power generation during late stance. Metabolic cost, measured by oxygen consumption while walking on an indoor track, was reduced by an average of 8.4% ($p=0.06$).

Section Summary: Powered Ankle-Foot Prostheses

Several small studies have been reported with powered ankle-foot prostheses for transtibial amputees. The evidence to date is insufficient to support an improvement in functional outcomes.

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 versus 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 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. 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.

Supplemental Information

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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.

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:[27](#)

“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).”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03204513	Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction	15	Apr 2021
NCT04630457	Safety and Effectiveness of Electronically Controlled Prosthetic Ankle in Patients With Transtibial Amputation	42	Dec 2024
<i>Unpublished</i>			
NCT02864693	Comparative Effectiveness of Microprocessor Controlled and Carbon Fiber Energy Storing and Returning Prosthetic Feet in Persons With Unilateral Transtibial Amputation	30	Apr 2018 (Results submitted, pending quality control review)
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

NCT: national clinical trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Date of amputation
 - Physical and cognitive status
 - Current functional K level and level patient is expected to attain including patient's desired level of ambulation
 - Reason for needing a microprocessor controlled prosthesis
- Prescription for the prosthesis from referring physician (Physiatrist or Orthopedist)
- Name of ordering prosthetist, fax and phone number
- Activities that will require long distance ambulation at variable rates, uneven terrain, or stairs
- All prosthetist's clinical/office notes including (as applicable):
 - Current make, model, components in use
 - Describe daily activities and needs related to daily activities
 - Previous prosthesis use history
 - Recent rehabilitation the patient has received
 - Physical or mental conditions limiting the use of a microprocessor controlled prosthesis
- Clearly list all HCPCS codes with descriptions of generic codes

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control (Code effective 4/1/2021)
	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

Type	Code	Description
	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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/07/2006	BCBSA Medical Policy adoption
01/11/2008	Policy revision with position change
04/02/2010	Policy Revision with title changed from Microprocessor - Controlled Prosthetic Knee
02/22/2013	Coding Update
09/27/2013	Policy Review
07/14/2014	Policy title change from Microprocessor-Controlled Lower Limb Prostheses Policy revision with position change
05/29/2015	Coding update
10/30/2015	Policy revision without position change
04/01/2017	Policy revision without position change
12/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement. Policy guidelines and literature updated. Coding update.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Microprocessor-Controlled Prostheses for the Lower Limb 1.04.05</p> <p>Policy Statement: A microprocessor-controlled knee may be considered medically necessary for an individual with transfemoral amputation who meets all of the following requirements:</p> <ul style="list-style-type: none"> • One of the following: <ul style="list-style-type: none"> ○ 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) ○ 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) • Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed • Adequate cognitive ability to master use and care requirements for the technology <p>Replacement/Repair Replacement or repair of a microprocessor-controlled knee may be considered medically necessary when both of the following criteria are met:</p> <ul style="list-style-type: none"> • The current prosthesis is out of warranty • The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis <p>A microprocessor-controlled knee is considered not medically necessary in individuals who do not meet the medical necessity criteria.</p> <p>A powered knee is considered investigational.</p>	<p>Microprocessor-Controlled Prostheses for the Lower Limb 1.04.05</p> <p>Policy Statement: A microprocessor-controlled knee may be considered medically necessary for an individual with transfemoral amputation who meets all of the following requirements:</p> <ol style="list-style-type: none"> I. One of the following: <ol style="list-style-type: none"> A. 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) B. 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) II. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed III. Adequate cognitive ability to master use and care requirements for the technology <p>Replacement/Repair Replacement or repair of a microprocessor-controlled knee may be considered medically necessary when both of the following criteria are met:</p> <ol style="list-style-type: none"> I. The current prosthesis is out of warranty II. The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis <p>A microprocessor-controlled knee is considered not medically necessary in individuals who do not meet the medical necessity criteria.</p> <p>A powered knee is considered investigational.</p>

POLICY STATEMENT

(No changes)

BEFORE

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

AFTER

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