

<b>1.04.05</b>	<b>Microprocessor-Controlled Prostheses for the Lower Limb</b>		
<b>Original Policy Date:</b>	December 7, 2006	<b>Effective Date:</b>	May 1, 2024
<b>Section:</b>	1.0 Durable Medical Equipment	<b>Page:</b>	Page 1 of 21

## Policy Statement

- I. A microprocessor-controlled knee may be considered **medically necessary** for an individual with transfemoral amputation who meets **all** of the following requirements:
  - A. **One** of the following:
    1. 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)
    2. 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)
  - B. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed
  - C. Adequate cognitive ability to master use and care requirements for the technology

### Replacement/Repair

- II. Replacement or repair of a microprocessor-controlled knee may be considered **medically necessary** when **both** of the following criteria are met:
  - A. The current prosthesis is out of warranty
  - B. The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis
- III. A microprocessor-controlled knee is considered **investigational** in individuals who do not meet the medical necessity criteria.
- IV. A powered knee is considered **investigational**.
- V. 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<sup>®</sup>
- Ossur RheoKnee<sup>®</sup>
- Otto Bock C-Leg device<sup>®</sup>
- Otto Bock Genium™ Bionic Prosthetic System

#### *Examples of Microprocessor Controlled Foot-Ankle Prostheses:*

- iWalk PowerFoot BiOM<sup>®</sup>
- Ossur Proprio Foot<sup>®</sup>

### 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 individual's physical and cognitive ability. An individual's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (e.g., gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, the daily and frequent need of 2 or more of these activities would be needed to show benefit.

### Individual Selection and Identification

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

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

- 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 individual is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue
  - Daily activities or job tasks that do not permit full focus of concentration on knee control and stability-such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying
  - Medicare level 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 individual has the cardiovascular reserve, strength, and

balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator

- 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

See the [Codes table](#) for details.

### 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 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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

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

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 (Genium X3) is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

### *Comparators*

The relevant comparator is a prosthesis with a conventional knee.

### *Outcomes*

Relevant outcomes are functional outcomes, health status measures, and quality of life. 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 prostheses<sup>1</sup>. 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 backup 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.

## Systematic Reviews

Thibaut et al (2022) conducted a systematic review including studies of microprocessor prosthetic knees in patients with lower limb amputation.<sup>2</sup> The authors identified 18 studies (7 RCTs [later determined 5 RCTs were the same study reporting different outcomes], 6 cross-sectional studies, and 5 follow-up studies). All RCTs were cross-over studies. Overall the authors found better functional status and mobility with microprocessor prosthetic knees, but it remains unclear whether there are differences among various models of microprocessor prosthetic knees.

In a systematic review and meta-analysis of microprocessor prosthetic knees in limited community ambulators, Hahn et al (2022) identified 13 studies (N=2366; n=704 limited community ambulators).<sup>3</sup> In limited community ambulators, microprocessor prosthetic knees had improved outcomes in terms of falls, fear of falling, risk of falling, and mobility grade when compared with non-microprocessor prosthetic knees.

## Nonrandomized Trials

The primary literature consists of small (sample range, 7 to 50 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 ambulator who is able to traverse low barriers, such as curbs, and walk with a fixed cadence. Medicare Functional Level K3 describes a community ambulator who is able to traverse most barriers at variable cadence and may have activities beyond basic locomotion. 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
<i>K2 ambulators</i>							
<b>Theeven et al (2011, 2012)<sup>4,5</sup></b>	Activity at home and lab-simulated ADLs	Netherlands	28	Functional level K2	C-Leg and C-Leg compact 1-wk acclimation	Own NMPK	1 wk for each prosthesis
<b>Burnfield et al (2012)<sup>6</sup></b>	Level and ramp walking	U.S.	10	Functional level K2	C-Leg compact 3-mo acclimation	Own NMPK	
<i>K2 to K3 ambulators</i>							
<b>VA (2006)<sup>7,8,9</sup></b>	Lab and home	U.S.	8	Functional level K2 to K3	C-Leg	Hydraulic	1 wk
<b>Hafner and Smith (2009)<sup>10</sup></b>	A-B-A-(A or B) design in lab and city sidewalk	U.S.	<ul style="list-style-type: none"> <li>• 8</li> <li>• 9</li> <li>• 9</li> </ul>	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
<b>Highsmith et al (2013)<sup>11</sup></b>	Ramp		21	Independent community ambulator	C-leg with 3-mo acclimation	Own NMPK	
<b>Howard et al (2018)<sup>12</sup></b>	4-wk laboratory sessions for each phase (A-B-A or B-A-B)	U.S.	<ul style="list-style-type: none"> <li>• 1</li> <li>• 6</li> <li>• 6</li> </ul>	Functional level K2 or K3	Rheo Knee	Own NMPK	PROs for 3 wk prior to use
<b>Hafner et al (2007)<sup>13</sup></b>	A-B-A-B design in lab and city sidewalk	U.S.	17	Proficient community ambulator		Own mechanical	
<b>Kaufman et al (2018)<sup>14</sup></b>	Free living environment	U.S.	50 K2	Functional level K2 or K3	One of 4 MPK devices	Own NMPK	Functional measures and PROs 10 wks
<i>K3 to K4 ambulators</i>							
<b>Kaufman et al (2007, 2008)<sup>15,16</sup></b>	Lab and home	U.S.	15	Functional level K3 or K4	MPK acclimation of 10-39 wk	Own NMPK	10 d
<b>Johansson et al (2005)<sup>17</sup></b>	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	
<i>K2 to K4 ambulators</i>							
<b>Carse et al (2021)<sup>18</sup></b>	Laboratory and 12m indoor walkway	Scotland	<ul style="list-style-type: none"> <li>• 5</li> <li>• 17</li> <li>• 10</li> <li>• 10</li> </ul>	Functional level K2, K3 or K4		Own NMPK	

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 ambulatory, there was a reduction in falls demonstrated by the change from baseline while using a microprocessor knee and an increase in falls with reversion to a 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
<i>K2 ambulators</i>				
Theeven et al (2011, 2012) <sup>4,5</sup>	Improved simulated ADLs for activities requiring balance		<ul style="list-style-type: none"> <li>• Subjective benefit on PEQ</li> <li>• No preference for C-Leg over C-Leg compact</li> </ul>	No difference in objectively measured activity level
Burnfield et al (2012) <sup>6</sup>	Improved walking on level ground, ramps, and faster TUG (17.7 s vs. 24.5 s)		<ul style="list-style-type: none"> <li>• PEQ</li> <li>• All wanted to keep the C-Leg compact</li> </ul>	•
<i>K2 to K3 ambulators</i>				
VA (2006) <sup>7,8,9</sup>		Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009) <sup>10</sup>	Improved mobility and speed			Decrease in self-reported stumbles and falls
Highsmith et al (2013) <sup>11</sup>	Improved hill descent time (6.0 s vs. 7.7 s) and HAI			
Howard et al (2018) <sup>12</sup>	Improved 6MWT, BBS, and AMP, but inconsistent for normal walking speed and L test	Improved Physiological Cost Index	<ul style="list-style-type: none"> <li>• Preference for MPK in 6 of 7 participants</li> <li>• PEQ superior in 5 of 7</li> </ul>	•
Hafner et al (2007) <sup>13</sup>	Improved for descent of stairs and hills only		Subjective improvement with MPK	
Kaufman et al (2018) <sup>14</sup>	Reduction in falls			Subjective improvement in PEQ satisfaction with MPK
<i>K3 to K4 ambulators</i>				



Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
Kaufman et al (2007, 2008) <sup>15,16</sup> ,	More natural gait	No significant difference	Preferred MPK	Increased
Johansson et al (2005) <sup>17</sup> ,	More natural gait and decrease in hip work	Oxygen consumption reduced for Rheo but not C-Leg	Preferred MPK	
<b>K2 to K4 ambulators</b>				
Carse et al (2021) <sup>18</sup> ,		Improved GPS and walking velocity, step length, vertical ground reaction force symmetry index, and center of mass deviation		

ADL: activity of daily living; AMP: amputee mobility predictor; BBS: Berg Balance Scale; GPS, gait profile score; 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.

A cross-sectional study by Alzeer et al (2022) identified 38 patients who had been fitted with microprocessor prosthetic knees (Genium) and 38 patients fitted with various non-microprocessor prosthetic knees.<sup>19</sup> Patient-reported outcomes were measured with the Prosthesis Evaluation Questionnaire (PEQ). Total average PEQ scores were higher among patients with microprocessor prostheses (82.14 vs. 73.53;  $p=.014$ ). Utility (78.41 vs. 68.20;  $p=.025$ ) and ambulation (75.61 vs. 59.11;  $p=.003$ ) were also significantly improved. This study indicates improved quality of life outcomes in patients with microprocessor prosthetic knees compared with non-microprocessor varieties, but is limited by its small size and observational nature.

### Section Summary: Microprocessor-Controlled Knee

The literature consists of systematic reviews and 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.

### Powered-Knee Prostheses for Individuals with Transfemoral Amputation

#### Clinical Context and Therapy Purpose

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

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 a prosthesis with a conventional knee.

### ***Outcomes***

Relevant outcomes are functional outcomes, health status measures, and quality of life. 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 powered 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 individuals who have tibial amputation is to improve activity and function.

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 have been developed for transtibial amputees. These include the Proprio Foot<sup>®</sup> (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), Meridium (Ottobock), Freedom Kinnex 2.0 (Proteor), and the Elan (Blatchford). With sensors in the feet that determine the direction and speed of the foot's movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. This technology is designed to make ambulation more efficient and prevent falls in patients ranging from the young, active amputee to the elderly, diabetic patient. The Proprio Foot<sup>®</sup> and Elan are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates the use of the Proprio Foot<sup>®</sup> 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 a prosthesis with a conventional ankle/foot.

### ***Outcomes***

Relevant outcomes are functional outcomes, health status measures, and quality of life. 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.<sup>20</sup> 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.<sup>21,22</sup> 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 plantarflexed 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.<sup>23</sup>

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).<sup>24</sup> 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.

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.<sup>25</sup> 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.

Thomas-Pohl et al (2021) compared 3 different types of ankle-foot prostheses, including the Proprio Foot, in a within-subject crossover study.<sup>26</sup> The primary outcome was to evaluate the ability of these prostheses to adapt to ground inclination. Six patients tested each of the 3 devices; each data

acquisition was preceded with a 2-week acclimation period and was followed by a 3-week wash-out period with the patient's energy storing and returning foot. Overall the study found that microprocessor prostheses allowed for better posture and a reduction of residual knee moment on positive and/or negative slope when compared to the patients' energy storing and returning feet. Patients exhibited the most symmetric balance when they wore the Proprio Foot compared to the other microprocessor feet, but clinical functional tests between microprocessor prostheses and other feet did not differ greatly.

Colas-Ribas et al (2022) conducted a cross-over study in 45 patients with ankle prosthesis at 2 centers in France.<sup>27</sup> Recruited patients had a prosthetic foot for more than 3 months and were able to walk outdoors. After randomization, each foot (Proprio Foot or non-microprocessor) was worn for a total of 34 days (2 weeks of adaptation/adaptation confirmation and 20 days in everyday life). Energy expenditure was similar between prostheses (19.4 mL/kg/min with Proprio Foot and 19.1 mL/kg/min with other prostheses). Mean Short Form 36 (SF-36) physical scores with Proprio Foot were significantly better than with other prostheses (68.5 vs. 62.1;  $p=.005$ ) as were mental scores (72.0 vs. 66.2;  $p=.006$ ).

### **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 individuals who have tibial amputation is to improve activity and function.

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<sup>®</sup> (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 evidence review 1.04.04 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. Empower (Ottobock) is a commercially available powered ankle-foot prosthesis.

#### ***Comparators***

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

#### ***Outcomes***

Relevant outcomes are functional outcomes, health status measures, and quality of life. 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.<sup>28</sup> 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.<sup>29</sup> 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 prostheses. Compared with controls with intact limbs, the PowerFoot had a 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 prostheses.<sup>30</sup>

In a conference proceeding, Mancinelli et al (2011) described a comparison of a passive-elastic foot and the PowerFoot BiOM in 5 transtibial amputees.<sup>31</sup> 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% ( $p=.06$ ).

#### Empower

Cacciola et al (2022) conducted a survey of 57 individuals who were current or ( $n=41$ ) or former ( $n=16$ ) users of a powered ankle-foot.<sup>32</sup> All survey respondents were male with an average age of 53.5 years and an average of 13.1 years since amputation. Among the current users, numeric rating scale pain scores were significantly improved with Empower compared with a passive foot in terms of sound knee pain (1 vs. 2;  $p=.001$ ), amputated side knee pain (1 vs. 2;  $p=.001$ ), and low-back pain (1 vs. 3;  $p<.001$ ). Although the differences were statistically significant, the small numeric differences between groups is questionably clinically relevant.

### 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.

### 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.

### U.S Department of Veterans Affairs/Department of Defense

In 2019, the updated Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations:<sup>33</sup> "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	Dec 2024
NCT04630457	Safety and Effectiveness of Electronically Controlled Prosthetic Ankle in Patients With Transtibial Amputation	42	Dec 2024
NCT04784429	Assessing Outcomes With Microprocessor Knee Utilization in a K2 Population (ASCENT K2)	107	Dec 2026
NCT05267639	Clinical Outcomes With Passive MPKs vs. Powered Prosthetic Knees	12	Apr 2024
<i>Unpublished</i>			
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.

## References

1. Flynn K. Short Report: Computerized lower limb prosthesis (VA Technology Assessment Program). No. 2. Boston, MA: Veterans Health Administration; 2000.

2. Thibaut A, Beudart C, Maertens DE Noordhout B, et al. Impact of microprocessor prosthetic knee on mobility and quality of life in patients with lower limb amputation: a systematic review of the literature. *Eur J Phys Rehabil Med*. Jun 2022; 58(3): 452-461. PMID 35148043
3. Hahn A, Bueschges S, Prager M, et al. The effect of microprocessor controlled exo-prosthetic knees on limited community ambulators: systematic review and meta-analysis. *Disabil Rehabil*. Dec 2022; 44(24): 7349-7367. PMID 34694952
4. Theeven P, Hemmen B, Rings F, et al. Functional added value of microprocessor-controlled knee joints in daily life performance of Medicare Functional Classification Level-2 amputees. *J Rehabil Med*. Oct 2011; 43(10): 906-15. PMID 21947182
5. Theeven PJ, Hemmen B, Geers RP, et al. Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. *J Rehabil Med*. May 2012; 44(5): 454-61. PMID 22549656
6. Burnfield JM, Eberly VJ, Gronely JK, et al. Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. *Prosthet Orthot Int*. Mar 2012; 36(1): 95-104. PMID 22223685
7. Orendurff MS, Segal AD, Klute GK, et al. Gait efficiency using the C-Leg. *J Rehabil Res Dev*. 2006; 43(2): 239-46. PMID 16847790
8. Klute GK, Berge JS, Orendurff MS, et al. Prosthetic intervention effects on activity of lower-extremity amputees. *Arch Phys Med Rehabil*. May 2006; 87(5): 717-22. PMID 16635636
9. Williams RM, Turner AP, Orendurff M, et al. Does having a computerized prosthetic knee influence cognitive performance during amputee walking?. *Arch Phys Med Rehabil*. Jul 2006; 87(7): 989-94. PMID 16813788
10. Hafner BJ, Smith DG. Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. *J Rehabil Res Dev*. 2009; 46(3): 417-33. PMID 19675993
11. Highsmith MJ, Kahle JT, Miro RM, et al. Ramp descent performance with the C-Leg and interrater reliability of the Hill Assessment Index. *Prosthet Orthot Int*. Oct 2013; 37(5): 362-8. PMID 23327837
12. Howard CL, Wallace C, Perry B, et al. Comparison of mobility and user satisfaction between a microprocessor knee and a standard prosthetic knee: a summary of seven single-subject trials. *Int J Rehabil Res*. Mar 2018; 41(1): 63-73. PMID 29293160
13. Hafner BJ, Willingham LL, Buell NC, et al. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. *Arch Phys Med Rehabil*. Feb 2007; 88(2): 207-17. PMID 17270519
14. Kaufman KR, Bernhardt KA, Symms K. Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. *Clin Biomech (Bristol, Avon)*. Oct 2018; 58: 116-122. PMID 30077128
15. Kaufman KR, Levine JA, Brey RH, et al. Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees. *Gait Posture*. Oct 2007; 26(4): 489-93. PMID 17869114
16. Kaufman KR, Levine JA, Brey RH, et al. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. *Arch Phys Med Rehabil*. Jul 2008; 89(7): 1380-5. PMID 18586142
17. Johansson JL, Sherrill DM, Riley PO, et al. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. *Am J Phys Med Rehabil*. Aug 2005; 84(8): 563-75. PMID 16034225
18. Carse B, Scott H, Brady L, et al. Evaluation of gait outcomes for individuals with established unilateral transfemoral amputation following the provision of microprocessor controlled knees in the context of a clinical service. *Prosthet Orthot Int*. Jun 01 2021; 45(3): 254-261. PMID 34016870

19. Alzeer AM, Bhaskar Raj N, Shahine EM, et al. Impacts of Microprocessor-Controlled Versus Non-microprocessor-Controlled Prosthetic Knee Joints Among Transfemoral Amputees on Functional Outcomes: A Comparative Study. *Cureus*. Apr 2022; 14(4): e24331. PMID 35607529
20. Hofstad C, Linde H, Limbeek J, et al. Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. *Cochrane Database Syst Rev*. 2004; 2004(1): CD003978. PMID 14974050
21. Alimusaj M, Fradet L, Braatz F, et al. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. *Gait Posture*. Oct 2009; 30(3): 356-63. PMID 19616436
22. Fradet L, Alimusaj M, Braatz F, et al. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. *Gait Posture*. Jun 2010; 32(2): 191-8. PMID 20457526
23. Darter BJ, Wilken JM. Energetic consequences of using a prosthesis with adaptive ankle motion during slope walking in persons with a transtibial amputation. *Prosthet Orthot Int*. Feb 2014; 38(1): 5-11. PMID 23525888
24. Gailey RS, Gaunaud I, Agrawal V, et al. Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. *J Rehabil Res Dev*. 2012; 49(4): 597-612. PMID 22773262
25. Delussu AS, Brunelli S, Paradisi F, et al. Assessment of the effects of carbon fiber and bionic foot during overground and treadmill walking in transtibial amputees. *Gait Posture*. Sep 2013; 38(4): 876-82. PMID 23702342
26. Thomas-Pohl M, Villa C, Davot J, et al. Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope. *Disabil Rehabil Assist Technol*. Jan 2021; 16(1): 17-26. PMID 31535903
27. Colas-Ribas C, Martinet N, Audat G, et al. Effects of a microprocessor-controlled ankle-foot unit on energy expenditure, quality of life, and postural stability in persons with transtibial amputation: An unblinded, randomized, controlled, cross-over study. *Prosthet Orthot Int*. Dec 01 2022; 46(6): 541-548. PMID 36515900
28. Au S, Berniker M, Herr H. Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. *Neural Netw*. May 2008; 21(4): 654-66. PMID 18499394
29. Ferris AE, Aldridge JM, Rábago CA, et al. Evaluation of a powered ankle-foot prosthetic system during walking. *Arch Phys Med Rehabil*. Nov 2012; 93(11): 1911-8. PMID 22732369
30. Herr HM, Grabowski AM. Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. *Proc Biol Sci*. Feb 07 2012; 279(1728): 457-64. PMID 21752817
31. Mancinelli C, Patriitti BL, Tropea P, et al. Comparing a passive-elastic and a powered prosthesis in transtibial amputees. *Annu Int Conf IEEE Eng Med Biol Soc*. 2011; 2011: 8255-8. PMID 22256259
32. Cacciola CE, Kannenberg A, Hibler KD, Howell J. Impact of a Powered Prosthetic Ankle-Foot Component on Musculoskeletal Pain in Individuals with Transtibial Amputation: A Real-World Cross-Sectional Study with Concurrent and Recalled Pain and Functional Ratings. *J Prosthet Orthot*. 2022. doi: 10.1097/JPO.0000000000000442.
33. Webster JB, Crunkhorn A, Sall J, et al. Clinical Practice Guidelines for the Rehabilitation of Lower Limb Amputation: An Update from the Department of Veterans Affairs and Department of Defense. *Am J Phys Med Rehabil*. Sep 2019; 98(9): 820-829. PMID 31419214

## 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 provider (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 <sup>®</sup>	None	
HCPCS	K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control <b><i>(Deleted code effective 1/1/2024)</i></b>
	L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control <b><i>(Code effective 1/1/2024)</i></b>
	L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
	L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
	L5858	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
	L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
	L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

**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 review updated. Coding update.
05/01/2022	Annual review. No change to policy statement. Literature review updated.
05/01/2023	Annual review. Policy statement, guidelines and literature review updated.
03/01/2024	Coding update.
05/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.

## 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 and Feedback (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](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*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><b>Microprocessor-Controlled Prostheses for the Lower Limb 1.04.05</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. A microprocessor-controlled knee may be considered <b>medically necessary</b> for an individual with transfemoral amputation who meets <b>all</b> of the following requirements:                             <ol style="list-style-type: none"> <li>A. <b>One</b> of the following:                                     <ol style="list-style-type: none"> <li>1. 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)</li> <li>2. 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)</li> </ol> </li> <li>B. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed</li> <li>C. Adequate cognitive ability to master use and care requirements for the technology</li> </ol> </li> </ol> <p><b>Replacement/Repair</b></p> <ol style="list-style-type: none"> <li>II. Replacement or repair of a microprocessor-controlled knee may be considered <b>medically necessary</b> when <b>both</b> of the following criteria are met:                             <ol style="list-style-type: none"> <li>A. The current prosthesis is out of warranty</li> <li>B. The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis</li> </ol> </li> <li>III. A microprocessor-controlled knee is considered <b>investigational</b> in individuals who do not meet the medical necessity criteria.</li> <li>IV. A powered knee is considered <b>investigational</b>.</li> </ol>	<p><b>Microprocessor-Controlled Prostheses for the Lower Limb 1.04.05</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. A microprocessor-controlled knee may be considered <b>medically necessary</b> for an individual with transfemoral amputation who meets <b>all</b> of the following requirements:                             <ol style="list-style-type: none"> <li>A. <b>One</b> of the following:                                     <ol style="list-style-type: none"> <li>1. 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)</li> <li>2. 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)</li> </ol> </li> <li>B. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed</li> <li>C. Adequate cognitive ability to master use and care requirements for the technology</li> </ol> </li> </ol> <p><b>Replacement/Repair</b></p> <ol style="list-style-type: none"> <li>II. Replacement or repair of a microprocessor-controlled knee may be considered <b>medically necessary</b> when <b>both</b> of the following criteria are met:                             <ol style="list-style-type: none"> <li>A. The current prosthesis is out of warranty</li> <li>B. The current prosthesis requires repairs and the cost of such repairs would be more than 60% of the cost of a new prosthesis</li> </ol> </li> <li>III. A microprocessor-controlled knee is considered <b>investigational</b> in individuals who do not meet the medical necessity criteria.</li> <li>IV. A powered knee is considered <b>investigational</b>.</li> </ol>

**POLICY STATEMENT**

**(No changes)**

**BEFORE**

**AFTER**

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

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