Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Microprocessor-Controlled Prostheses for the Lower Limb

Policy Number: 1.04.05 **Last Review:** 12/2025
Origination: 12/2005 **Next Review:** 12/2026

Blue KC has developed medical policies that serve as one of the sets of guidelines for coverage decisions. Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the medical policies. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and/or federal law. Medical policy does not constitute plan authorization, nor is it an explanation of benefits.

When reviewing for a Medicare beneficiary, guidance from National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) supersede the Medical Policies of Blue KC. Blue KC Medical Policies are used in the absence of guidance from an NCD or LCD.

NCDs
https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=NCD&contractOption=all

LCDs
https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=F,P&contractOption=all

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for microprocessor-controlled lower limb prostheses when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

A microprocessor-controlled knee may be considered **medically necessary** in individuals with transfemoral amputation who meet the following requirements:

- demonstrated need for long distance ambulation at variable rates (use of the limb in the home or for basic community ambulation is not sufficient to

justify provision of the computerized limb over standard limb applications) OR demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application); AND
- physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation at faster than normal walking speed; AND
- adequate cognitive ability to master use and care requirements for the technology.

When Policy Topic is not covered

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

A powered knee is considered **investigational.**

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

Considerations

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

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 (eg, gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, 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 (>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

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: • With transfemoral amputation	Interventions of interest are: • Prosthesis with a microprocessor-controlled knee	Comparators of interest are: • Prosthesis with a conventional knee	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life
Individuals: • With transfemoral amputation	Interventions of interest are: • Prosthesis with a powered knee	Comparators of interest are: • Prosthesis with a conventional knee	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life
Individuals: • With tibial amputation	Interventions of interest are: • Prosthesis with a microprocessor-controlled ankle-foot	Comparators of interest are: • Prosthesis with a conventional foot-ankle	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life
Individuals: • With tibial amputation	Interventions of interest are: • Prosthesis with a powered ankle-foot	Comparators of interest are: • Prosthesis with a conventional ankle-foot	Relevant outcomes include: • Functional outcomes • Health status measures • Quality of life

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.

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 and systematic reviews of these studies. Relevant outcomes are functional outcomes, health status measures, and quality of life. For K3- and K4-level amputees, studies have shown an objective improvement in function on some outcome measures, particularly for hill and ramp descent, and strong patient preference for microprocessor-controlled prosthetic knees. Benefits include a more normal gait, increased stability, and a decrease in falls. The evidence in Medicare level K2 ambulators suggests that a prosthesis with stance control only can improve activities that require balance and improve walking in this population. For these reasons, a microprocessor-controlled knee may provide incremental benefit for these individuals. The potential to achieve a higher functional level with a microprocessor-controlled knee includes having the appropriate physical and cognitive ability to use the advanced technology. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have a tibial amputation who receive a prosthesis with a microprocessor-controlled ankle-foot, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using microprocessor-controlled ankle-foot prostheses compared with standard prostheses although quality of life improvements were noted in 1 small study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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.

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

This evidence review was created in October 2003 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 5, 2025.

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 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 (eg, gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 (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[1,] 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 (MPK) in patients with lower limb amputation.[2,] 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 MPKs , but it remains unclear whether there are differences among various models of microprocessor prosthetic knees.

In a systematic review and meta-analysis of MPKs in limited community ambulators, Hahn et al (2022) identified 13 studies (N=2366; n=704 limited community ambulators).[3,] 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 (NMPKs).

Randomized Controlled Trials

Morgan et al (2025) conducted an RCT evaluation of the effects of MPKs compared to NMPKs in patients with recent transfemoral amputation.[4,] Patients (N=18) were randomized to either MPKs (n=10) or NMPKs (n=8) as their first prosthesis; 15 patients completed the 3 month trial after receiving their prosthesis. Performance based outcomes (ie, 6 minute walk test, amputee mobility predictor score, timed-up and go speeds, average daily step count, and mean stride velocity) were not statistically significant between groups (p>.05 for all outcomes). Participants with MPKs demonstrated significantly better self-reported outcomes including mobility, balance confidence, and return to normal living scores compared to those with NMPKs. Specifically, participants with an MPK had significantly higher Prosthetic Limb Users Survey of Mobility (Hedges' g: 1.70; 95% CI, 0.38 to 2.96; p=.01), Activity-specific Balance Confidence (Hedges' g: 1.75; 95% CI, 0.51 to 2.94; p=.01), and Return to Normal Living Index (Hedges' g: 0.54; 95% CI, 0.44 to 1.50; p=.05) scores.

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
K2 ambulators							
Theeven et al (2011, 2012)[5,6,]	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
Burnfield et al (2012)[7,]	Level and ramp walking	U.S.	10	Functional level K2	C-Leg compact 3-mo acclimation	Own NMPK	
K2 to K3 ambulators							
VA (2006)[8,9,10,]	Lab and home	U.S.	8	Functional level K2 to K3	C-Leg	Hydraulic	1 wk
Hafner and Smith (2009)[11,]	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)[12,]	Ramp		21	Independent community ambulator	C-leg with 3-mo acclimation	Own NMPK	
Howard et al (2018)[13,]	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)[14,]	A-B-A-B design in lab and city sidewalk	U.S.	17	Proficient community ambulator		Own mechanical	
Kaufman et al (2018)[15,]	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
K3 to K4 ambulators							
Kaufman et al	Lab and home	U.S.	15	Functional level K3 or	MPK acclimation	Own NMPK	10 d

(2007, 2008)[16,17,]				K4	of 10-39 wk		
Johansson et al (2005)[18,]	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	
K2 to K4 ambulators							
Carse et al (2021) [19,]	Laboratory and 12m indoor walkway	Scotland	• 5 K2 • 17 K3 • 10 K4	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
K2 ambulators				
Theeven et al (2011, 2012)[5,6,]	Improved simulated ADLs for		• Subjective benefit on PEQ	No difference in objectively measured

	activities requiring balance		• No preference for C-Leg over C-Leg compact	activity level
Burnfield et al (2012)[7,]	Improved walking on level ground, ramps, and faster TUG (17.7 s vs. 24.5 s)		• PEQ • All wanted to keep the C-Leg compact	•
K2 to K3 ambulators				
VA (2006)[8,9,10,]		Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009)[11,]	Improved mobility and speed			Decrease in self-reported stumbles and falls
Highsmith et al (2013)[12,]	Improved hill descent time (6.0 s vs. 7.7 s) and HAI			
Howard et al (2018)[13,]	Improved 6MWT, BBS, and AMP, but inconsistent for normal walking speed and L test	Improved Physiological Cost Index	• Preference for MPK in 6 of 7 participants • PEQ superior in 5 of 7	•
Hafner et al (2007)[14,]	Improved for descent of stairs and hills only		Subjective improvement with MPK	
Kaufman et al (2018)[15,]	Reduction in falls			Subjective improvement in PEQ satisfaction with MPK
K3 to K4 ambulators				
Kaufman et al (2007, 2008)[16,17,]	More natural gait	No significant difference	Preferred MPK	Increased
Johansson et al (2005)[18,]	More natural gait and decrease in hip work	Oxygen consumption reduced for Rheo but not C-Leg	Preferred MPK	
K2 to K4 ambulators				
Carse et al		Improved GPS and walking		

(2021)[19,]		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.[20,] 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® (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® and Elan are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing

clearance. Information on the Össur website indicates the use of the Proprio Foot® for low- to moderate-impact for transtibial amputees who are classified as level K3 (ie, 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.[21,] Also, reviewers noted that most clinical studies on human walking have used standardized gait assessment protocols (eg, 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.[22,23,] 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.[24,]

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).[25,] 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.[26,] 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. [27,] 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.[28,] 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® (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.[29,]

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.[30,] 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.[31,]

In a conference proceeding, Mancinelli et al (2011) described a comparison of a passive-elastic foot and the PowerFoot BiOM in 5 transtibial amputees.[32,] 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.[33,] 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 2024 , the updated Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations (Table 3).).[34,]

Table 3. VA/DoD Clinical Practice Recommendations for Lower Limb Amputation

Recommendation	Strength
For prosthetic ambulators, we suggest prescribing microprocessor knee units over non-microprocessor knee units for reducing falls, optimizing functional mobility, and improving patient satisfaction.	Weak for
For prosthetic ambulators, there is insufficient evidence to prescribe any specific energy storing and return (ESAR) or microprocessor foot and ankle component over another.	Neither for nor against
For prosthetic ambulators, we suggest energy storing and return (ESAR) or microprocessor-controlled foot and ankle components over solid ankle cushioned heel (SACH) feet to improve ambulation and patient satisfaction	Weak for

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 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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
Unpublished			
NCT04112901	Activity, Mobility, Social Functioning, Mental Health and Quality of Life Outcomes in Limited Mobility Transfemoral and Knee Disarticulation Amputees Using Microprocessor-Controlled Knees or Non-Microprocessor Controlled Knees in the United Kingdom: A Cohort Study	330	May 2020
NCT05267639	Clinical Outcomes With Passive MPKs vs. Powered Prosthetic Knees	13	Aug 2024

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, Beaudart 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. Morgan SJ, Friedly JL, Nelson IK, et al. The effects of microprocessor prosthetic knee use in early rehabilitation: A pilot randomized controlled trial. PM R. Feb 02 2025. PMID 39895150
5. 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
6. 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
7. 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

8. 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
9. 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
10. 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
11. 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
12. 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
13. 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
14. 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
15. 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). Oct 2018; 58: 116-122. PMID 30077128
16. 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
17. 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
18. 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
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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
25. Gailey RS, Gaunaurd 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

26. 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
27. 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
28. 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
29. 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
30. 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
31. 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
32. Mancinelli C, Patritti 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
33. 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.
34. VA/DOD Clinical Practice Guideline, Work Group. VA/DOD Clinical Practice Guideline for Rehabilitation of Individuals With Lower Limb Amputation. U.S. Government Printing Office; 2024:2-162. https://www.healthquality.va.gov/guidelines/Rehab/amp/LLA-CPG_2024-Guideline_final_20250110.pdf

Billing Coding/Physician Documentation Information

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. 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. Other Policies and Guidelines may apply.

L5615 Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control

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 skin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type.

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

ICD-10 Codes

S78.011-S78.929 Traumatic amputation of hip and thigh; code range

Z96.651-Z96.659 Presence of artificial knee joint; code range

Additional Policy Key Words

N/A

Policy Implementation/Update Information

12/1/05 New policy; considered investigational.

12/1/06 No policy statement changes.

12/1/07 Policy statement revised; may be medically necessary for some patients.

12/1/08 No policy statement changes.

12/1/09 Policy statements added regarding ankle-foot and powered knee prostheses; these are investigational. Title changed to "prostheses for the lower limb" to include ankle-foot

12/1/10 No policy statement changes.

12/1/11 Policy revised to include PAVET scoring as a requirement for determining medical necessity for microprocessor knees. Not medically necessary statements added regarding batteries. Policy number changed from 1.01.25 to 1.04.05 (prosthetics).

12/1/12 No policy statement changes.

12/1/13 No policy statement changes.

12/1/14 No policy statement changes.

12/1/15 No policy statement changes.

12/1/16 No policy statement changes.

12/1/17 No policy statement changes.

12/1/18 No policy statement changes.

8/1/19 Removed all current Medically Necessary Statements. Added: A microprocessor-controlled knee may be considered medically necessary in individuals with transfemoral amputation who meet criteria. Removed: A microprocessor-controlled knee is considered not medically necessary for the following patients: Those who have a PAVET score less than 40; or Those who have a PAVET score 73 or greater as this high is unrealistic and indicates possible scoring discrepancy (these patients should be re-evaluated); or Those who do not meet all of the above criteria. Removed: Microprocessor knees that have only swing-phase microprocessors are considered not medically necessary. Removed: Spare or extra lithium ion batteries for the microprocessor knee are considered not medically necessary, as they are convenience items. Removed: More than one (1) lithium ion battery charger is considered

not medically necessary. Added: A microprocessor-controlled knee is considered not medically necessary in individuals who do not meet these criteria.

12/1/19 No policy statement changes.
12/1/20 No policy statement changes.
12/1/21 Added K1014 new eff 4/1/21. No policy statement changes.
12/1/22 No policy statement changes.
12/1/23 No policy statement changes.
12/1/24 No policy statement changes.
12/1/25 No policy statement changes.

Material ID: Y0126_23_2001_C