Medical Policy

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Title: Microprocessor-Controlled Prostheses for the Lower Limb

Prior Authorization of Services may be required by Member's Contract.

Related Policies:	▪ *Myoelectric Prosthetic Components for the Upper Limb*

Professional / Institutional
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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

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.

OBJECTIVE

The objective of this evidence review is to determine whether powered prostheses improve the net health outcome in individuals with lower-extremity amputations.

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.

POLICY

A. Electronic prosthetics meeting criteria below may be allowed when provided by a certified Orthopedic / Prosthetic Device Supplier.

B. **Knee**

1. A microprocessor-controlled knee may be considered **medically necessary** in individuals with transfemoral amputation who meet **all** of the following requirements:
    a. Functional level of K3 or K4:
        i. Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion (K3)
        OR
        ii. Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete (K4)
    AND
    b. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation
    AND
    c. Adequate cognitive ability to master use and care requirements for the technology

2. A microprocessor-controlled knee is **not covered** in individuals who do not meet the criteria in B1.

3. A powered knee may be considered **medically necessary** in individuals with transfemoral amputation who meet **all** of the following requirements:
    a. Has a microprocessor-controlled knee (meeting the criteria in B1)
    AND
    b. Has K3 functional level only
    (Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion [K3])
    AND
    c. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K3 level function with the use of a microprocessor-controlled knee alone
    AND
    d. Is able to make use of a product that requires daily charging
    AND
    e. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

4. A powered knee is **not covered** in individuals who do not meet the criteria in B 3.

C. **Ankle**

1. A microprocessor-controlled ankle may be considered **medically necessary** in individuals with tibial amputation who meet **all** of the following requirements:
    a. Functional level of K3 or K4:
        i. Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion (K3)

        OR

        ii. Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete (K4)

    AND

    b. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation

    AND

    c. Adequate cognitive ability to master use and care requirements for the technology

2. A microprocessor-controlled ankle is **not covered** in individuals who do not meet the criteria in C 1.

D. **Ankle-Foot**

1. A microprocessor-controlled ankle foot system may be considered **medically necessary** in individuals with tibial amputation who meet **all** of the following requirements:
    a. Functional level of K3 or K4:
        i. Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion (K3)

        OR

        ii. Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete (K4)

    AND

    b. Physical ability, including adequate cardiovascular and pulmonary reserve, for ambulation

    AND

    c. Adequate cognitive ability to master use and care requirements for the technology

2. A microprocessor-controlled ankle-foot system is **not covered** in individuals who do not meet the criteria in D 1.

POLICY GUIDELINES

A. Amputees are 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. A 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 two or more of these activities would be needed to show benefit.

B. Benefits are not provided for repair or replacement of prosthetic devices due to misuse, malicious damage or gross neglect, or to replace lost or stolen items.

C. Benefits are not provided for implantable prosthetic components and limbs, exoskeleton prosthetic devices or cosmetic components and coverings for prosthetic devices

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:
   1. Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear
   2. Inability to tolerate the weight of the prosthesis
   3. Medicare level K0-no ability or potential to ambulate or transfer (See Coding section for full Medicare Functional Classification Levels (MFCL) definition)
   4. Medicare level K1-limited ability to transfer or ambulate on level ground at fixed cadence (See Coding section for full MFCL definition)
   5. 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 (See Coding section for full MFCL definition)
   6. Inability to use swing and stance features of the knee unit
   7. Poor balance or ataxia that limits ambulation
   8. Significant hip flexion contracture (>20°)
   9. Significant deformity of remaining limb that would impair the ability to stride
   10. Limited cardiovascular and/or pulmonary reserve or profound weakness
   11. Limited cognitive ability to understand gait sequencing or care requirements
   12. Long distance or competitive running
   13. Falls outside of recommended weight or height guidelines of the manufacturer
   14. Specific environmental factors-such as excessive moisture or dust, or inability to charge the prosthesis

15. Extremely rural conditions where maintenance ability is limited.

B. Indications for the use of the microprocessor knee should include the following:
   1. Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence
   2. Adequate strength and balance in stride to activate the knee unit
   3. Should not exceed the weight or height restrictions of the device
   4. Adequate cognitive ability to master technology and gait requirements of the device
   5. Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower-extremity amputees are candidates if they meet functional criteria as listed
   6. The individual is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue
   7. 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
   8. Medicare level K3-unlimited community ambulator (See Coding section for full MFCL definition)
   9. Medicare level K4-active adult, athlete who needs to function as a K3 level in daily activities (See Coding section for full MFCL definition)
   10. Potential to lessen back pain by providing more secure stance control, using less muscle control to keep the knee stable
   11. Potential to unload and decrease stress on remaining limb
   12. Potential to return to an active lifestyle.

C. Physical and Functional Fitting Criteria for New Amputees:
   1. New amputees may be considered if they meet certain criteria as outlined above
   2. Premorbid and current functional assessment important determinant
   3. Requires stable wound and ability to fit the socket
   4. Immediate postoperative fit is possible
   5. Must have potential to return to an active lifestyle

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.

RATIONALE

This evidence review was created 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 (2007, 2008)[16,17,]	Lab and home	U.S.	15	Functional level K3 or K4	MPK acclimation of 10-39 wk	Own NMPK	10 d
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	

Study	Study Location	Country	N	Participants	MPK	NMPK	Home Monitoring
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 activities requiring balance		• Subjective benefit on PEQ • No preference for C-Leg over C-Leg compact	No difference in objectively measured activity level

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
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	Oxygen consumption reduced for Rheo but not C-Leg	Preferred MPK	

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
	decrease in hip work			
K2 to K4 ambulators				
Carse et al (2021)[19,]		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.[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 . 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.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
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.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping (eff. 04/01/2025)
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.
L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source.

Medicare Functional Classification Levels (MFCL)	
K0	Lower extremity prosthesis functional level 0 - does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility
K1	Lower extremity prosthesis functional level 1 - has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. typical of the limited and unlimited household ambulator
K2	Lower extremity prosthesis functional level 2 - has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. typical of the limited community ambulator

Medicare Functional Classification Levels (MFCL)	
K3	Lower extremity prosthesis functional level 3 - has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion
K4	Lower extremity prosthesis functional level 4 - has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete

REVISIONS	
01-01-2021	Policy published 11-03-2020. Policy effective 01-01-2021.
04-01-2021	Added HCPCS code K1014
05-04-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Renamed "modifier" section to "Medicare Functional Classification Levels (MFCL)"
	Updated References Section
04-25-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 codes
	Updated References Section
01-01-2024	Updated Coding Section ▪ Added L5615 (eff. 01-01-2024) ▪ Removed deleted code K1014 (eff. 01-01-2024)
04-23-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
04-23-2025	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Added L5827 (eff. 04/01/2025)
	Updated References Section

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