Medical Policy

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Microprocessor-Controlled Prostheses and Orthoses for the Lower Limb

Description/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 individual's underlying activity level. For example, the requirements of a prosthetic knee in an elderly, largely homebound individual will differ from those of a younger, active person. Key elements of a prosthetic knee design involve providing stability during both the stance and swing phase of the gait. Prosthetic knees vary in their ability to alter the cadence of the gait, or the ability to walk on rough or uneven surfaces. In contrast to more simple prostheses, which are designed to function optimally at one walking cadence, fluid and hydraulic-controlled devices are designed to allow amputees to vary their walking speed by matching the movement of the shin portion of the prosthesis to the movement of the upper leg. For example, the rate at which the knee flexes after "toe-off" and then extends before heel strike depends in part on the mechanical characteristics of the prosthetic knee joint. If the resistance to flexion and extension of the joint does not vary with gait speed, the prosthetic knee extends too quickly or too slowly relative to the heel strike if the cadence is altered. When properly controlled, hydraulic or pneumatic swing-phase controls allow the prosthetist to set a pace adjusted to the individual amputee, from very slow to a race-walking pace. Hydraulic prostheses are heavier than other options and require gait training; for these reasons, these prostheses are prescribed for athletic or fit individuals. Other design features include multiple centers of rotation, referred to as "polycentric knees." The mechanical complexity of these devices allows engineers to optimize selected stance and swing-phase features.

Lower Extremity Orthotics

An orthosis (brace) is a rigid or semi-rigid device that is used for the purpose of supporting a weak or deformed lower extremity or restricting or eliminating motion in a diseased or injured lower extremity. An orthosis can be either pre-fabricated or custom-fabricated.

The C-brace™ (Ottobock) is a microprocessor stance and swing control knee-ankle-foot orthosis (KAFO) that is custom made for each individual user. Per the manufacturer, “the C-brace consists of individually fabricated thigh, calf and foot components. An ankle joint, unilateral or bilateral fitting, or an individual spring element connects the foot and calf components. The sensor system continuously measures the flexion of the knee joint and its angular acceleration.” The C-brace enables the user’s walking phase and hydraulic resistances to be detected and controls the flexion and extension of the knee joint. It is intended to reportedly increase mobility in individuals with leg paresis and allows for more natural movement on stairs, inclines, and rough terrain. A rechargeable lithium-ion battery powers the microprocessor, which is then controlled by the user via a mobile app.

The FDA describes the Sensor Walk™(Ottobock) as “a microprocessor-controlled knee-ankle-foot orthosis (KAFO) designed to help wearers achieve a safer, more physiologically correct gait. It does this by unlocking the knee joint when the wearer is ready for swing phase and locking it again for stability during stance phase.” The system includes an onboard microprocessor, a clutch spring knee joint, foot pressure sensors, a knee angle sensor, a battery (which lasts for 12 hours), and a battery charger. It is designed for community ambulators who exhibit knee instability in the sagittal plane while bearing weight during the stance phase of their gait cycle.

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.

Medical Policy Statement

A microprocessor-controlled knee (hydraulic actuator) may be considered **established** when individuals meet the below criteria

A powered knee (motor actuator) is considered experimental/investigational.

A microprocessor-controlled Knee-ankle-foot (KAF) device (e.g., Ottobock C-Brace™ Orthotronic Mobility System, Ottobock the Sensor Walk™ stance control KAFO) is considered experimental/investigational.

Inclusionary and Exclusionary Guidelines

Inclusions:
The microprocessor-controlled knee (hydraulic actuator) 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 individual 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.

SELECTION AND IDENTIFICATION

Amputees should be evaluated by an independent, qualified professional to determine the most appropriate prosthetic components and control mechanism. A trial period may be indicated to evaluate the tolerability and efficacy of the prosthesis in a real-life setting. Decisions about the potential benefits of microprocessor knees involve multiple factors including activity levels and the individual's physical and cognitive ability. An individual's need for daily ambulation of at least 400 continuous yards, daily and frequent ambulation at variable cadence or on uneven terrain (e.g., gravel, grass, curbs), and daily and frequent use of ramps and/or stairs (especially stair descent) should be considered as part of the decision. Typically, the daily and frequent need of 2 or more of these activities would be needed to show benefit.

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.

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.
- 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 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.

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.
- Must have potential to return to an active lifestyle.

Exclusions:

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.

* The above guidelines come from the Veterans Health Administration Prosthetic Clinical Management Program Clinical Practice Recommendations for Microprocessor Knees (Berry, 2000).

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

L5615 L5856 L5857 L5858 L5973

Other codes (investigational, not medically necessary, etc.):

L2006 K1007

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

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 individuals 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 one 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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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 **PICOS** were used to select literature to inform this review.

Populations

The relevant population(s) of interest are individuals with transfemoral or tibial amputation.

Interventions

The therapy being considered are prosthesis with 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 Food and Drug Administration (FDA) through the 510(k) process (K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses use additional environmental input (e.g., gyroscope and accelerometer) and more sophisticated processing that is intended to create more natural movement. One improvement in function is step-over-step stair and ramp ascent. They also allow the user to walk and run forward and backward. The X3 is a more rugged version of the X2 that can be used in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

Comparators

The relevant comparator is prosthesis with a conventional knee.

Outcomes

Relevant outcomes for microprocessor-controlled lower-limb prostheses may include the individual'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.

Review of Evidence

The Veterans Administration Technology Assessment Program (2000) issued a report on computerized lower-limb prosthesis.[2] This report offered the following observations and conclusions:

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

Systematic Reviews

Thibaut et al (2022) conducted a systematic review including studies of microprocessor prosthetic knees in patients with lower limb amputation.[3] The authors identified 18 studies (7 RCTs [later determined 5 RCTs were the same study reporting different outcomes], 6 cross-sectional studies, and 5 follow-up studies). All RCTs were cross-over studies. Overall the authors found better functional status and mobility with microprocessor prosthetic knees, but it remains unclear whether there are differences among various models of microprocessor prosthetic knees.

In a systematic review and meta-analysis of microprocessor prosthetic knees in limited community ambulators, Hahn et al (2022) identified 13 studies (N=2366; n=704 limited community ambulators).[4] In limited community ambulators, microprocessor prosthetic knees had improved outcomes in terms of falls, fear of falling, risk of falling, and mobility grade when compared with non-microprocessor prosthetic knees.

Nonrandomized Trials

The primary literature consists of small (sample range, 7-28 patients) within-subject comparisons of microprocessor-controlled with non-microprocessor controlled prostheses in transfemoral amputees. These studies are described in Tables 1 and 2, divided by the Medicare Functional Level (MFL). MFL K2 describes a limited community ambulatory who is able to traverse low barriers such as curbs and walk with a fixed cadence. MFL K3 describes a community ambulatory who is able to traverse most barriers at variable cadence and may have activities beyond basic locomotion, and MFL 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 MFL K2 amputees. The C-Leg, which provides both stance and swing control, has been tested in MFL K3 and K4 amputees, in addition to MFL 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 (see Table 1). The other studies used an alternating or randomized order, with more than one test session for each type of prosthesis. Most studies compared performance in laboratory activities and about half also included a period of home use.

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

Study	Study Location	Country	N	Participants	MPK	NMPK	Home Monitoring
K2 Ambulators							
Theevenet al (2011, 2012)	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)	Level and ramp walking	U.S.	10	Functional level K2	C-Leg compact 3-mo acclimation	OWN NMPK	
K2 to K3 Ambulators							

VA (2006)	Lab and Home	U.S.	8	Functional level K2 to K3	C-Leg	Hydraulic	1 wk
Hafner and Smith (2009)	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)	Ramp		21	Independent community ambulator	C-leg with 3-mo Acclimation	Own NMPK	
Howard et Al (2018)	4-wk laboratory Sessions for each phase (AB- A or BA-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)	A-B-A-B design in lab and city sidewalk	U.S.	17	Proficient community ambulator		Own Mechanical	
Kaufman et al (2018)	Free living Environment	U.S.	50 48K2	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)	Lab and home	U.S.	15	Functional level K3 or K4	MPK acclimation of 10-39 wk	Own NMPK	10 d
Johansson (2005)	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)	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 ambulators there was a reduction in falls demonstrated by the change from baseline while using MPK and an increase in falls with reversion to NMPK.

- 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 MFL 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 vs a Non-Microprocessor Knee

Study	Performance	Gait Efficiency	Preference (Self-Report or PEQ)	Activity at Home
K2 Ambulators				
Theevenet al (2011, 2012)	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
Burnfield et al (2012)	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)		Marginally improved	7 of 8 participants preferred the MPK	No difference
Hafner and Smith (2009)	Improved mobility and speed			Decrease in self-reported stumbles and falls
Highsmith et al (2013)	Improved hill descent time (6.0 s vs 7.7 s) and HAI			
Howard et al. (2018)	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)	Improved for descent of stairs and hills only		Subjective improvement with MPK	
Kaufman et al (2018)	Reduction in falls			Subjective improvement in PEQ satisfaction with MPK
K3 to K4 Ambulators				
Kaufman et al (2007, 2008)	More natural gait	No significant Difference	Preferred MPK	Increased
Johansson (2005)	More natural gait and decrease in hip work	Oxygen consumption reduced for Rheo but not C-Leg	Preferred MPK	
Carse et al (2021)		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; 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-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 level K2 ambulators suggests that a prosthesis with stance control only can improve activities that require balance and improve walking in this population. Only 1 biomechanical study of the next-generation Genium prosthesis was identified. One small study found little difference in performance between the Rheo Knee II and the user's own non-microprocessor-controlled knee.

Powered-Knee Prostheses for Individuals with Transfemoral Amputation

Clinical Context and Therapy Purpose
The purpose of powered-knee prostheses in 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(s) of interest are individuals with transfemoral amputation.

Interventions
The therapies being considered are powered-knee prostheses.
The Power Knee™ (Össur), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot to anticipate and respond with the appropriate movement required for the next step.

Comparators
The relevant comparator is prosthesis with a conventional knee.

Outcomes

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

Review of Evidence
No literature was identified 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(s) of interest are individuals with tibial amputation.

Interventions
The therapies being considered are microprocessor-controlled ankle-foot protheses. Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), Freedom Kinnex 2.0 (Proteor), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot's movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. This technology is designed to make ambulation more efficient and prevent falls in patients ranging from the young, active amputee to the elderly, diabetic patient. The Proprio Foot® and Elan Foot are microprocessor-controlled foot prostheses that are commercially available at this time and are considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates the use of the Proprio Foot® for low- to moderate-impact for transtibial amputees who are classified as level K3 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence).

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

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

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

(e.g., treadmills) with limited “ecological validity,” and recommended that for future research, functional outcomes be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changes in walking speed.

Proprio Foot

Gait analysis with the Proprio Foot was evaluated in 16 transtibial K3-K4 amputees during stair and ramp ascent and descent.[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 plantar flexed ankle (adaptive mode) during ramp descent. Another small within-subject study (2014; n=6) found no benefit of an active Proprio Foot compared with the same prosthesis turned off with level walking or with slope ascent or descent.[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 -returning (ESR) 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(s) of interest are individuals 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.

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

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

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 ESR 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 ESR 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 ESR. Compared with controls with intact limbs, the PowerFoot had reduced range of motion but provided greater ankle peak power.

In another similar, small pre-post study (7 amputees, 7 controls), Herr and Grabowski (2012) found gross metabolic cost and preferred walking speed to be more similar to nonamputee controls with the PowerFoot BiOM than with the patient's own ESR.[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=0.06).

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.

Microprocessor-Controlled Knee-Ankle-Foot Orthosis

Clinical Context and Therapy Purpose

The purpose of the microprocessor-controlled C-Brace™ (Ottobock) and Sensor Walk™(Ottobock) orthosis to allow users to flex their leg under load and to navigate slopes, walk on uneven terrain, or descend stairs step-over-step.

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

Populations
The relevant population(s) of interest are individuals with paraplegia, paralysis or neurological disorders.

Interventions
The therapies being considered are microprocessor-controlled ankle-foot orthosis.

Comparators
The relevant comparator is an orthosis with a conventional ankle/foot.

Outcomes
Relevant outcomes may include the individual's perceptions of subjective improvement attributable to the orthosis 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 orthosis.

Review of Evidence
Schmalz et al (2016) investigated the new technical functions of the C-Brace orthosis, based on some biomechanical parameters.[34] The study enrolled six patients. The C-Brace orthosis was compared with conventional leg orthoses (four stance control orthoses, two locked knee-ankle-foot orthoses) using biomechanical parameters of level walking, descending ramps and descending stairs. With the C-Brace, a nearly natural stance phase knee flexion was measured during level walking (mean value 11° ± 5.6°). The maximum swing phase knee flexion angle of the C-Brace approached the normal value of 65° more closely than the stance control orthoses (66° ± 8.5° vs 74° ± 6.4°). No significant differences in the joint moments were found between the C-Brace and stance control orthosis conditions. In contrast to the conventional orthoses, all patients were able to ambulate ramps and stairs using a step-over-step technique with C-Brace (flexion angle 64.6° ± 8.2° and 70.5° ± 12.4°). More studies are required to demonstrate the benefits of the C-Brace in comparison with conventional orthotic mechanisms.

Probsting et al (2017) evaluated the potential benefits of a microprocessor stance and swing control orthosis compared to stance control orthoses and locked knee ankle foot orthoses in activities of daily living.[35] Thirteen patients with various lower limb paresis completed a baseline survey for their current orthotic device (locked knee ankle foot orthosis or stance control orthosis) and a follow-up for the microprocessor stance and swing control orthosis with the Orthosis Evaluation Questionnaire, a new self-reported outcome measure devised by modifying the Prosthesis Evaluation Questionnaire for use in lower limb orthotics and the Activities of Daily Living Questionnaire. The Orthosis Evaluation Questionnaire results demonstrated some improvements by microprocessor stance and swing control orthosis use in the total score and the domains of ambulation (p = .001), paretic limb health (p = .04), sounds (p = .02), and well-being (p = .01). Activities of Daily Living Questionnaire results also showed some improvements with the microprocessor stance and swing control orthosis with regard to perceived safety and difficulty of activities of daily living.

Section Summary: Microprocessor-Controlled Knee-Ankle-Foot Orthosis

A couple of small studies have been reported with microprocessor-controlled KAFO. The evidence to date is insufficient to support an improvement in functional outcomes.

Summary of Evidence

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

For individuals who have a transfemoral amputation who receive a prosthesis with a powered knee, the evidence includes limited data. Relevant outcomes are functional outcomes, health status measures, and quality of life. The limited evidence available to date does not support an improvement in functional outcomes using a powered knee prostheses with standard prostheses. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

For individuals who require a lower limb orthoses, only a couple of small studies have been reported with microprocessor-controlled KAFOs. The evidence to date is insufficient to support an improvement in functional outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be

given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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

In 2019, the Veterans Affairs/Department of Defense Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation made the following recommendations:[30]

"We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces. (From Table 3. Clinical practice guideline evidence–based recommendations and evidence strength)."

Ongoing and Unpublished Clinical Trials

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

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
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)	100 107	Dec 2026
NCT05267639	Clinical outcomes with passive MPKs vs. powered prosthetic knees	12	Apr 2025
Unpublished			
NCT05407545	Evaluation of a Motorised Prosthetic Knee	10	Aug 2023
NCT04112901	Activity, Mobility, Social Functioning, Mental Health and Quality of Life Outcomes in Limited Mobility Transfemoral and Knee Disarticulation Amputees Using Microprocessor-Controlled Knees or Non-Microprocessor Controlled Knees in the United Kingdom: A Cohort Study	330	May 2020

NCT: national clinical trial

Government Regulations

National:

Medicare Benefit Policy Manual, chapter 15—Covered Medical and Other Health Services, section 120-Prosthetic Devices (Rev.12497, 02/08/24)

The Benefits Improvement and Protection Act of 2000 amended §1834(h)(1) of the Act by adding a provision (1834 (h)(1)(G)(i)) that requires Medicare payment to be made for the

replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary.

Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

1. A change in the physiological condition of the patient;

2. An irreparable change in the condition of the device, or in a part of the device; or

3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

This provision is effective for items replaced on or after April 1, 2001. It supersedes any rule that that provided a 5-year or other replacement rule with regard to prosthetic devices.

Local:

LCD: L33787, Lower Limb Prostheses, effective 01/01/2024.

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

A lower limb prosthesis is covered when the beneficiary:

1. Will reach or maintain a defined functional state within a reasonable period of time; and
2. Is motivated to ambulate.

FUNCTIONAL LEVELS:
A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

1. The beneficiary's past history (including prior prosthetic use if applicable); and
2. The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
3. The beneficiary's desire to ambulate.

Clinical assessments of beneficiary rehabilitation potential must be based on the following classification levels:

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.

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.

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.

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.

Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the beneficiary's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

GENERAL:
If a prosthesis is denied as not reasonable and necessary, related additions will also be denied as not reasonable and necessary.

When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which will be denied as not reasonable and necessary. When a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are covered in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which will be denied as not reasonable and necessary.

When an above knee initial prosthesis (L5505) or an above knee preparatory (L5560-L5580, L5590-L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, and L5710-L5780, L5790-L5795 which will be denied as not reasonable and necessary. When an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which will be denied as not reasonable and necessary.

In the following sections, the determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered in an individual case if additional documentation is included which justifies the medical necessity. Prostheses will be denied as not reasonable and necessary if the beneficiary's potential functional level is 0.

FEET:
A determination of the type of foot for the prosthesis will be made by the treating physician and/or the prosthetist based upon the functional needs of the beneficiary. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for coverage based upon functional classification.

An external keel SACH foot (L5970) or single axis ankle/foot (L5974) is covered for beneficiaries whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for beneficiaries whose functional level is 2 or above.

A microprocessor controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered for beneficiaries whose functional level is 3 or above.

The microprocessor foot or ankle system addition with power assist which includes any type of motor (L5969) is not covered because there is insufficient information to demonstrate that the item meets the Medicare standard to be considered reasonable and necessary as per PIM Chapter 13. Claims for L5969 will be denied as not reasonable and necessary.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot. This information must be retained in the physician's or prosthetist's files.

A user-adjustable heel height feature (L5990) will be denied as not reasonable and necessary.

KNEES:
A determination of the type of knee for the prosthesis will be made by the treating physician and/or the prosthetist based upon the functional needs of the beneficiary. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are

considered for coverage based upon functional classification.

A high activity knee control frame (L5930) is covered for beneficiaries whose functional level is 4.

A fluid, pneumatic, or electronic/microprocessor knee (L5610, L5613, L5614, L5722-L5780, L5814, L5822-L5840, L5848, L5856, L5857, L5858) is covered for beneficiaries whose functional level is 3 or above.

L5859 (ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)) is only covered when the beneficiary meets all of the criteria below:

1. Has a microprocessor (swing and stance phase type (L5856)) controlled (electronic) knee
2. K3 functional level only
3. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone
4. Is able to make use of a product that requires daily charging
5. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

If these coverage criteria for the knee component are not met, L5859 will be denied as not reasonable and necessary.

Other knee systems (L5611, L5616, L5710-L5718, L5810-L5812, L5816, L5818) are covered for beneficiaries whose functional level is 1 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of knee. This information must be retained in the physician's or prosthetist's files.

ANKLES:
An axial rotation unit (L5982-L5986) is covered for beneficiaries whose functional level is 2 or above.

HIPS:
A pneumatic or hydraulic polycentric hip joint (L5961) is covered for beneficiaries whose functional level is 3 or above.

SOCKETS:
More than 2 test (diagnostic) sockets (L5618-L5628) for an individual prosthesis are not reasonable and necessary unless there is documentation in the medical record which justifies the need. Exception: A test socket is not reasonable and necessary for an immediate prosthesis (L5400-L5460).

No more than two of the same socket inserts (L5654-L5665, L5673, L5679, L5681, L5683) are allowed per individual prosthesis at the same time.

Socket replacements are considered reasonable and necessary if there is adequate documentation of functional and/or physiological need. It is recognized that there are situations where the explanation includes but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Myoelectric Prosthetic and Orthotic Components for the Upper Limb

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/20	6/16/20		Joint policy established
9/1/21	6/15/21		Routine policy maintenance, added reference #27. Added K1007 as E/I. No change in policy status.
9/1/22	6/21/22		Routine policy maintenance, added references #16 and 23. No change in policy status.
9/1/23	6/13/23		Updated rationale section, added references 3,4,20,28 and 33. No change in policy status. Vendor managed: Northwood (ds)
9/1/24	6/18/24		Changes to MPS and inclusion/exclusion section. Added PICO for C-brace. Added code L5615 as established. No change in policy status. Vendor managed: Northwood (ds)

Next Review Date: 2nd Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MICROPROCESSOR-CONTROLLED PROSTHESES AND ORTHOSES FOR THE LOWER LIMB

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered per policy
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.