Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 81

Powered and Microprocessor-Controlled Knee and Ankle-Foot Prostheses and Microprocessor-Controlled Knee-Ankle-Foot Orthoses

Effective: December 1, 2024

Next Review: September 2025
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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Microprocessor-controlled prostheses and orthoses use feedback from sensors to adjust joint movement on a real-time as-needed basis and powered prostheses are designed to replace muscle activity in the affected limb.

MEDICAL POLICY CRITERIA

I. Microprocessor-controlled knee may be considered **medically necessary** in amputees when all of the following criteria are met (A. – E.):

   A. At least one of the following criteria are met:

      1. Demonstrated need for ambulation at variable rates or for long distances such that the patient would benefit from a device that may reduce energy consumption. (Use of the limb only in the home and/or for basic community ambulation does not establish medical necessity of the computerized limb over standard limb applications); or

      2. Demonstrated daily activities or job tasks that do not permit full focus of concentration on knee control and stability, including but not limited to

ambulation on uneven terrain, curbs, ramps, regular use on stairs or repetitive lifting and/or carrying. (Use of the limb for limited stair climbing in the home or employment environment does not establish medical necessity of the computerized limb over standard prosthetic application).

B. All of the following criteria must be met to demonstrate adequate physical ability:

1. Adequate cardiovascular and pulmonary reserve for ambulation at faster than normal walking speed; and
2. Adequate stride strength and balance to activate the knee unit; and
3. Classified as one of the following Medicare Functional Levels:

a. Select Level K2—Patients capable of limited community ambulation, but only if improved stability in stance permits increased independence, decreased risk of falls, and potential to advance to a less restrictive walking device. The microprocessor is required to enable fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator; or

b. Level K3—Patients who have 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; or

c. Level K4—Patients who have 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.

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

D. Patients with amputation from hemi-pelvectomy through knee-disarticulation level including bilateral lower extremity; and

E. All of the following criteria must also be met:

1. Stable or absent wound; and
2. The request is for either a microprocessor-controlled knee or a non-microprocessor-controlled mechanical prosthesis but not both for a single knee; and
3. Adequate socket fitting with the potential to return to active lifestyle.

II. The replacement of all or part of an existing microprocessor-controlled knee is considered **medically necessary** when either of the following are met:

A. The existing microprocessor-controlled knee is malfunctioning, cannot be repaired, and is no longer under warranty; or

B. The current prosthetic can no longer meet the patient’s medical needs due to a significant change in the patient’s physiological condition.

III. Replacement of all or part of an existing microprocessor-controlled knee is considered **not medically necessary** when Criterion II. is not met.

IV. A microprocessor-controlled knee is considered **not medically necessary** when Criterion I. is not met or when any of the following apply:

A. Medicare Functional Levels K0, K1, and the subset of K2 patients capable of limited community ambulation who do not have the cardiovascular reserve, strength, and balance to improve stability in stance to permit increased independence, decreased risk of falls and potential to advance to a less restrictive walking device

B. When the primary benefit is to allow the patient to perform leisure or recreational activities

C. Inability to tolerate the weight of the prosthesis

D. Significant hip flexion contracture (over 20 degrees)

E. Patient falls outside of recommended weight or height guidelines of manufacturer

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

VI. A microprocessor-controlled ankle-foot *prosthesis* or knee-ankle-foot *orthosis* is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of need at variable rates or for long distance ambulation from a device that reduces energy consumption
- Documentation of specific ADLS including job tasks that call do not permit full focus of concentration on knee control and stability
- Documentation of adequate ability to ambulate faster than normal walking speed including cardiovascular/pulmonary reserve, stride length, balance, Medicare Functional Level, and cognitive ability
- Type of amputation
- Wound status if applicable
- If a replacement is requested, documentation that the device is malfunctioning, cannot be repaired, and is no longer under warranty OR documentation of a significant change in the patient's physiological condition that makes the current prosthetic no longer able to meet the patient's medical needs

CROSS REFERENCES

1. Definitive Lower Limb Prostheses, Durable Medical Equipment, Policy No. 18
2. Myoelectric Prosthetic and Orthotic Components for the Upper Limb, DME, Policy No. 80
3. Powered Exoskeleton for Ambulation, DME, Policy No. 89

BACKGROUND

MICROPROCESSOR-CONTROLLED PROSTHETIC KNEES

Microprocessor-controlled prosthetic knees have been developed, including the Intelligent Prosthesis (IP) (Blatchford, England), the Adaptive (Endolite, England), the Rheo Knee® (Össur, Iceland), the C-Leg®, Genium™ Bionic Prosthetic System, and the X2 and X3 prostheses (Otto Bock Orthopedic Industry, Minneapolis, MN), 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. For example, the prosthetist can specify several different optimal adjustments that the computer later selects and applies according to the pace of ambulation. In addition, these devices (with the exception of the IP) use microprocessor control in both the swing and stance phases of gait. (The C-Leg Compact provides only stance control). By improving stance control, they 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. The C-Leg was cleared for marketing in 1999 through the 510(k) process of the U.S. Food and Drug Administration (FDA; K991590). Next-generation devices such as the Genium Bionic Prosthetic system and the X2 and X3 prostheses utilize 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, for example, in water, sand, and mud. The X2 and X3 were developed by Otto Bock as part of the Military Amputee Research Program.

MICROPROCESSOR-CONTROLLED ANKLE-FOOT PROSTHESES

Microprocessor-controlled ankle-foot prostheses are being developed for transtibial amputees. These include the Proprio Foot® (Össur), the iPED (developed by Martin Bionics and licensed to College Park Industries), and the Elan Foot (Endolite). With sensors in the feet that determine the direction and speed of the foot's movement, a microprocessor controls the flexion angle of the ankle, allowing the foot to lift during the swing phase and potentially adjust to changes in force, speed, and terrain during the step phase. The intent of the technology is 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 and considered class I devices that are exempt from 510(k) marketing clearance. Information on the Össur website indicates 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). The Meridium and Empower are microprocessor ankle-feet available from Otto Bock, and the Kinnex is a microprocessor ankle-foot available from Freedom Innovations.

POWERED PROSTHESES

In development are lower-limb prostheses that also replace muscle activity in order 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. The Power Knee™ (Össur), which is designed to replace muscle activity of the quadriceps, uses artificial proprioception with sensors similar to the Proprio Foot in order to anticipate and respond with the appropriate movement required for the next step.

REGULATORY STATUS

Microprocessor-controlled prostheses are categorized as class I, exempt devices. Manufacturers must register prostheses with the restorative devices branch of FDA and keep a record of any complaints but do not have to undergo a full FDA review. FDA product codes include ISW and KFX.

EVIDENCE SUMMARY

Evaluating the effects of the increased sophistication of powered knee, powered ankle-foot, and microprocessor-controlled ankle-foot prostheses requires comparison with body-powered prostheses, passive prostheses, or no prosthesis. The most informative data are prospective comparative studies with objective measures that directly address function, safety, and health-related quality of life.

The evidence review below does not address microprocessor-controlled knees, which have been shown to improve function measures and decrease the cognitive burden associated with monitoring the prosthesis.

MICROPROCESSOR-CONTROLLED ANKLE-FOOT PROSTHESES

Systematic Reviews

A 2004 Cochrane review of ankle-foot prostheses (updated in 2008 with search dates through June 2006) concluded that there is insufficient evidence from high quality comparative studies to determine the overall superiority of any individual type of prosthetic ankle-foot mechanism.[1] The review included 26 cross-over studies with 3 to 16 participants in each study (n=245). Only one study was considered to be of high methodological quality while the remainders were considered of moderate quality. The vast majority of clinical studies on human walking have used standardized gait assessment protocols (e.g., treadmills) with limited “ecological validity”. The authors recommended that for future research, functional outcomes should 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.

Randomized Controlled Trials

Colas-Ribas (2022) conducted a cross-over study in 45 patients with ankle prosthesis at two centers in France.[2] Participants had a prosthetic foot for more than three months and were able to walk outdoors. After randomization, each foot (Proprio Foot or non-microprocessor) was worn for a total of 34 days which included two weeks of adaptation and 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=0.005) as were mental scores (72.0 vs. 66.2; p=0.006).

Gailey (2012) published a randomized, within-subject crossover study that compared self-reported and objective performance outcomes for four types of prosthetic feet, including the SACH (solid ankle cushion heel), SAFE (stationary attachment flexible endoskeletal), Talux mechanical foot, and the Proprio Foot microprocessor-controlled ankle prosthesis.[3] Ten patients with transtibial amputation were tested with their own prosthesis and then, in random order, each of the other prostheses after training and a two week acclimation period. No differences between prostheses were detected for the following measures:

- Prosthesis Evaluation Questionnaire (PEQ) (self-reported subjective rating of ease of use, social and emotional issues, and function over different surfaces)
- Locomotor Capabilities Index (self-reported subjective rating of capability to perform certain activities such as walking in various environments on various surfaces, sitting, standing, bending)
- Six-minute walk test (objective distance measurement)
- Steps per day
- Hours of daily activity

In 2014, the same investigators reported the effects of these prosthetic feet on ramp ambulation in 10 unilateral transtibial amputees.[4] Higher symmetry was reported with the Talux mechanical foot and the Proprio Foot during ramp descent, while no significant difference was found between the prostheses during ramp ascent.

Due to the limited sample sizes in these studies, conclusions cannot be reached about the comparisons between the various types of foot prostheses.

Nonrandomized Comparative Studies

Riveras (2020) reported on minimum toe clearance and tripping probability in 13 transtibial amputees using three prosthetic ankle-foot designs.[5] The participants tested a non-articulating ankle (NAA), an articulating hydraulic ankle (AHA), and an articulating hydraulic ankle with microprocessor (AHA-MP). Statistically significant differences were found for minimum toe clearance for ramp ascending ($p \leq 0.001$) and descending ($p=0.003$), with larger median values in the prosthetic limb when using the AHA-MP. The coefficient of variation was also significantly lower on the prosthetic limb for both types of articulating hydraulic ankle compared to the non-articulating ankle during ramp descent ($p=0.014$). The lowest tripping probability was reported for the AHA-MP.

Two comparative trials of the microprocessor-controlled ankle from the same investigators investigated the Proprio Foot. Its use was evaluated in 16 transtibial amputees during stair ascent and descent[6] or while walking up and down a ramp[7]. These studies were limited to the effect of flexion angles (flexion versus neutral angle). Healthy controls were also used for comparison. The outcomes of these studies were mixed. For example, the adapted mode (ankle flexion) resulted in more normal gait analysis results during ramp ascent but not during descent; however, some patients reported feeling safer with the adaptive mode ankle than with the Proprio Foot.

Thomas-Pohl (2021) compared three different types of ankle-foot prostheses, including the Proprio Foot, in a within-subject crossover study.[8] The primary outcome was to evaluate the ability of these prostheses to adapt to ground inclination. Six patients tested each of the three devices; each data acquisition was preceded with a two-week acclimation period and was

followed by a three-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.

Other small studies have reported on these devices, including a study on ankle flexion using individuals as their own comparison group.[9] A within-subject study of six patients reported no benefit of an active Proprio Foot compared with the same prosthesis turned off with level walking or with slope ascent or descent.[10] An additional study reported a lower energy cost of floor walking with the Proprio Foot compared with a dynamic carbon fiber foot in 10 transtibial amputees.[11]

Section Summary

These studies do not permit conclusions about the clinical benefits and risks of the microprocessor-controlled foot compared with mechanical prostheses due to methodological limitations. These limitations included, among others, the small sample size, which limits the ability to rule out chance as an explanation of the study findings.

POWERED KNEE AND/OR ANKLE-FOOT PROSTHESES

Cacciola (2022) conducted a survey of 57 individuals who were current or (n=41) or former (n=16) users of a powered ankle-foot. All survey respondents were male with an average age of 53.5 years and an average of 13.1 years since amputation.[12] 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 (one vs. two; p=0.001), amputated side knee pain (one vs. two; p=0.001), and low-back pain (one vs. three; p<0.001). Limitations of this study include the use of recall data for pain and pain-related function since individuals tend to overestimate past pain, and other factors that may impact musculoskeletal pain, such as prosthetic alignment or concurrent medical treatments, were not accounted for in the study comparisons.

Kim (2021) reported results of a randomized trial of twelve participants that compared the BiOM powered ankle prosthesis with the participants' prescribed, unpowered prostheses.[13] Seven participants were randomly allocated to the powered prosthesis first group and five to the unpowered prosthesis first. Ten participants completed the study. No significant differences were identified in metabolic costs (p=0.585), daily step count (p=0.995), walking speed in-lab (p=0.145) and in daily life (p=0.226), or perception of mobility between prostheses (p≥0.058).

Ferris compared the BiOM powered ankle-foot prosthesis with an energy-storing and –returning (ESR) foot in 11 transtibial amputees. These results were also compared with 11 matched controls with intact limbs.[14] Compared with the ESR foot, the powered ankle-foot increased walking speed, but there were no significant differences in physical performance measure or conditions on the PEQ. Compared with the intact limb, the powered ankle-foot had increased step length and greater ankle peak power but had reduced range of motion. There appeared to be an increase in compensatory strategies at proximal joints with the powered prosthesis; the authors noted that normalization of gait kinematics and kinetics may not be

possible with a uniarticular device. Seven patients preferred the PowerFoot BiOM and four preferred the ESR prosthesis.

In another small study of seven amputees and seven intact controls, Herr (2012) reported gross metabolic cost and preferred walking speed to be more similar to non-amputee controls with the powered foot than with the ESR prosthesis.[15]

Mancinelli (2011) compared the PowerFoot BiOM with a passive-elastic foot in five transtibial amputees.[16] At the time of this study 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). This study did not report the impact of these measurements on patient function.

Section Summary

The current evidence is insufficient to permit conclusions about the benefits of powered lower extremity prostheses compared with other prostheses. These small studies mainly report on the feasibility of various prototypes. Larger, higher quality studies are needed to determine the impact of these devices on functional outcomes with greater certainty.

MICROPROCESSOR-CONTROLLED ORTHOSES

Randomized Controlled Trials

Ruetz (2023) published a multi-center, crossover RCT among individuals with lower limb paralysis who were previous users of knee-ankle-foot orthoses.[17] Participants were randomized to either start the study with their traditional (KAFO) or the C-brace. Participants used orthoses at-home for three months, and treatment crossover occurred after a one-month rest period. The intention-to-treat analysis included 102 participants. The primary outcome, Berg Balance Scale score, improved by 3.3 ± 6.3 points ($p<0.0001$), and significantly fewer participants had Berg Balance Scale scores less than 40, indicative of decreased fall risk (16 vs. 36, p=0.018). Mean falls reduced from 4.0 ± 16.8 to 1.1 ± 3.3 (p=0.002). This study had a high attrition rate of 30%. Limitations of this study include lack of a parallel control group and high medical heterogeneity, which limit generalizability.

A randomized crossover trial of a microprocessor swing- and stance-controlled knee-ankle-foot orthosis was reported by Deems-Dluhy in 2021.[18] A total of 18 community-dwelling adults were assigned to receive a C-brace orthosis and a stance-control-orthosis in a randomized order. The C-brace controls with a microprocessor-controlled knee throughout stance and swing phases of gait. All participants received six sessions of training over a one-month period. Statistically significant differences were reported between post-microprocessor orthosis and post-stance-control orthosis in the six-minute walk test, with longer times post-microprocessor orthosis. Higher quality of life scores were reported in the Modified Falls Efficacy Scale, Orthotic and Prosthetic User's Survey (OPUS) (p=0.02) and physical health domain of the World Health Organization Quality of Life (WHOQOL-BREF) (p=0.037) after using the microprocessor-controlled orthosis. There were also fewer participant-reported falls when wearing the microprocessor-controlled orthosis versus a stance-control-orthosis or locked knee-ankle-foot orthosis.

Nonrandomized Comparative Studies

Pröbsting (2017) reported results of a questionnaire filled out by 13 patients at baseline (regarding their current locked knee ankle foot orthosis or stance control orthosis) and following use of a microprocessor stance and swing control orthosis.[19] The patients completed the Orthosis Evaluation Questionnaire, a new self-reported outcome measure created by modifying the Prosthesis Evaluation Questionnaire for use in lower limb orthotics and the Activities of Daily Living Questionnaire. There were statistically significant differences in the total score and the domains of ambulation (p=0.001), paretic limb health (p=0.04), sounds (p =0.02), and well-being (p=0.01), with superior results reported for the microprocessor orthosis.

Section Summary

The current evidence is insufficient to permit conclusions about the benefits of microprocessor-controlled lower extremity orthoses compared with other orthoses. These limitations include, among others, the small sample size. Larger, higher quality studies are needed to determine the impact of these devices on functional outcomes with greater certainty.

PRACTICE GUIDELINE SUMMARY

A 2019 clinical practice guideline from the Department of Veterans Affairs and the Department of Defense (VA/DoD) included the following recommendation with a weak strength of evidence:[20]

> 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.

The VAs' Prosthetic and Sensory Aids Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program to coordinate the development of clinical practice recommendations for prosthetic prescriptive practices. The following are guidelines from the Veterans Health Administration Prosthetic Clinical Management program:[21]

A. Contraindications for use of the microprocessor knee should include:
    - 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 K 0—no ability or potential to ambulate or transfer.
    - Medicare Level K 1—limited ability to transfer or ambulate on level ground at fixed cadence.
    - Medicare Level K 2—limited community ambulator that 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 (over 20 degrees).
    - Significant deformity of remaining limb that would impair 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 manufacturer.
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis.
- Extremely rural conditions where maintenance ability is limited.

B. Indications for use of the microprocessor knee should include:
    - Adequate cardiovascular and pulmonary reserve to ambulate at variable cadence.
    - Adequate strength and balance in stride to activate the knee unit.
    - Should not exceed the weight or height restrictions of the device.
    - Adequate cognitive ability to master technology and gait requirements of device.
    - Hemi-pelvectomy through knee-disarticulation level of amputation, including bilateral; lower extremity amputees are candidates if they meet functional criteria as listed
    - Patient is an active walker and requires a device that reduces energy consumption to permit longer distances with less fatigue.
    - Daily activities or job tasks that do not permit full focus of concentration on knee control and stability—such as uneven terrain, ramps, curbs, stairs, repetitive lifting, and/or carrying.
    - Medicare Level K 2—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 patient has cardiovascular reserve, strength, and balance to use the prosthesis. The microprocessor enables fine-tuning and adjustment of the hydraulic mechanism to accommodate the unique motor skills and demands of the functional level K2 ambulator.
    - Medicare Level K 3—unlimited community ambulator.
    - Medicare Level K 4—active adult, athlete who has the need to function as a K 3 level in daily activities.
    - Potential to lessen back pain by providing more secure stance control, using less muscle control to keep knee stable.
    - Potential to unload and decrease stress on remaining limb.
    - Potential to return to an active lifestyle.

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

SUMMARY

Research has shown that microprocessor-controlled knees improve function for some amputees and decrease the cognitive burden associated with monitoring the prosthesis. Those considered most likely to benefit from these prostheses have both the potential and need for frequent movement at a variable pace, uneven ground, or on stairs. Therefore, a

microprocessor-controlled knee may be considered medically necessary when policy criteria are met.

In certain situations, a microprocessor-controlled knee may no longer be able to perform its basic function due to damage or wear or because of a change in the patient's physiological condition. When this occurs, replacement of the device may be medically appropriate. Therefore, replacement of all or part of a microprocessor-controlled knee may be considered medically necessary when device replacement Criteria are met.

When a microprocessor-controlled knee is in its warranty period or can be repaired or adapted adequately to meet the patient's medical needs, replacement of the device is not medically appropriate. Therefore, replacement of all or part of a microprocessor-controlled knee is considered not medically necessary when device replacement Criteria are not met.

There is not enough research to show if or how well microprocessor-controlled knees improve health outcomes when criteria are not met. Therefore, microprocessor-controlled knees are not medically necessary when policy criteria are not met.

There is not enough research to show that there are improved health outcomes for microprocessor-controlled ankle-foot prostheses compared with conventional prostheses. Therefore, microprocessor-controlled ankle-foot prostheses are considered investigational.

There is not enough research to evaluate the health benefits and risks of powered lower limb prostheses. Therefore, powered knee and/or powered ankle-foot prostheses are considered investigational.

There is not enough research to show that microprocessor-controlled knee-ankle-foot orthoses improve health outcomes compared with conventional orthoses. Therefore, microprocessor-controlled knee-ankle-foot orthoses are considered investigational.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	~~K1014~~	~~Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control~~ (Deleted 01/01/2024)
	L2006	Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated
	L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
	L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
	L5857	;swing phase only, includes electronic sensor(s), any type
	L5858	;stance phase only, includes electronic sensor(s), any type
	L5859	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered
	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, include power source
	L5999	Lower extremity prosthesis, not otherwise specified

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